[Short Communication]

A Survey of the General Population's Attitude towards Clinical Trial Participation in Emergency Situations: What Decision Would You Like to Make?

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ABSTRACT

Background Obtaining informed consent（IC）from study participants is essential for conducting clinical trials. However, in disorders with a narrow window of opportunity for treatment, such as acute cerebral stroke, obtaining proper IC at the right time is difficult. Thus, depending on the patient's condition, a family member may become the patient's legal representative. We investigated whether individuals would want to participate in a clinical trial even if they were in a situation where they could not make the decision themselves due to a medical emergency and explored the reasons for their choice.

Methods A questionnaire survey was conducted during March 3-6, 2023. Participants were members of the general population aged≥20 years. Medical professionals and their families and people with prior experience of decision-making during a medical emergency were excluded. The participants were asked whether they would participate in a clinical trial and their reasons. Subsequently, text mining of the reasons was conducted. IC was obtained for publication.

Results Three hundred individuals participated in the survey. Regarding participation in a clinical trial should they experience a medical emergency, 46（15%）, 109（37%）, 84（28%）, 36（12%）, and 25（8%）responded "Definitely want to participate", "Don't mind participating", "Can't decide to participate", "Prefer not to participate" and "Definitely don't want to participate", respectively.

Conclusions The level of understanding and image of clinical trials vary greatly among the general population, and this subject must be addressed suitably to build trust and obtain proper IC.

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KEY WORDS　Clinical trial, Decision making, Emergency situations, Informed consent

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緊急事態時の臨床試験参加に対する一般市民の態度に関する調査：
あなたは，どのような意思決定をしたいですか？

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INTRODUCTION

Obtaining informed consent（IC）from study participants is essential for conducting clinical trials[1),2)]. However, in disorders with a narrow window of opportunity for treatment, such as acute cerebral stroke, obtaining proper IC at the right time is difficult[3),4)]. Thus, depending on the patient's condition, a family member may become the patient's legal representative[5),6)]. We had previously conducted a survey among the general population regarding the decisions they would make as surrogates when asked to consent to a family member's participation in a clinical trial during a medical emergency. The findings indicated that insufficient knowledge and information about clinical trials, along with the lack of prior discussions about the family member's wishes, made the decision-making process challenging[7)]. Hence, we investigated whether individuals would want their families to decide on their participation in a clinical trial should they experience a medical emergency and explored the reasons for their choice.

METHODS

This survey was conducted online from March 3 to 6 2023 by Cross Marketing Group Inc., a major online survey company in Japan（https://www.cm-group.co.jp/company/profile/）. Participants, randomly selected from the company's pool, were members of the general population aged≥20 years excluding medical professionals and their families and people with prior experience of decision-making during a medical emergency（such as cerebral hemorrhage or myocardial infarction）.

The participants were asked whether they would participate in the clinical trial in a hypothetical situation（**Table 1**）. They had to choose from the following multiple choices,"Definitely want to participate","Don't mind participating","Can't decide to participate","Prefer not to participate","Definitely don't want to participate" and write their reasons in the free descriptions space.

Text mining was used to analyze the reasons behind their choices using the User Local AI text-mining tool（https://textmining.userlocal.jp/）, which calculates the frequency of extracted words and importance score. This score reflects how "important" each word is, typically calculated using statistical processing through the Term Frequency- Inverse Document Frequency method. Words that only appear frequently in the specific documents being analyzed（feature words）will have higher scores.

ETHICAL CONSIDERATION

We displayed the summary in a browser window and asked the participants to click the start button if they agreed to participate in the survey. The survey did not obtain their personal information, and the results were published with consent. Our survey falls outside the scope of the Japanese government's Ethical Guidelines for Life Science and Medical Research Involving Human Subjects and there are no national guidelines in Japan for social and behavioral research. Therefore, we conducted this survey following the Ethical Principles of the declaration of Helsinki.

RESULTS

Data was collected from 300 participants（Male: 188, Female: 112）. Regarding participation in a clinical trial should they experience a medical emergency, 46（15%）, 109（37%）, 84（28%）, 36（12%）, and 25（8%）responded "Definitely want to participate","Don't mind participating","Can't decide to participate","Prefer not to participate" and "Definitely don't want to participate", respectively（**Fig. 1**）.

An analysis of the reasons showed that for those who chose "Definitely want to participate", the most frequent word was "possibility", and the most featured word was "Useful"（**Fig. 2-1**）. For those who chose "Don't mind participating", the most frequent word was "possibility", and the most featured word was "Treatment method"（**Fig. 2-2**）. For those who chose "Can't decide to participate", the most frequent and most featured word was "Don't know"（**Fig. 2-3**）. And for those who chose "Prefer not to participate", the most frequent words were "Experimental guinea pig","Don't know" and "Treatment". Additionally, the most featured words were"Experimental guinea pig" and "Don't know"（**Fig. 2-4**）. Who chose "Definitely don't want to participate", the most frequent word and the most featured word was "Experimental guinea pig"（**Fig. 2-5**）. In **Fig. 2b**）, words with higher scores have a larger font size and the word positioning has no special meaning.

Table 1　Hypothetical Situation

You suddenly get a headache, lose the ability to move your right leg, and collapse. You have slurred speech and cannot speak well. You are taken by ambulance to a university hospital and diagnosed with a cerebral hemorrhage. Since you are unconscious, treatment must begin as soon as possible. There is currently no established effective treatment for cerebral hemorrhage. The university hospital to which you were taken is conducting a clinical trial to develop a new treatment, and your doctor has suggested that you participate in the clinical trial.

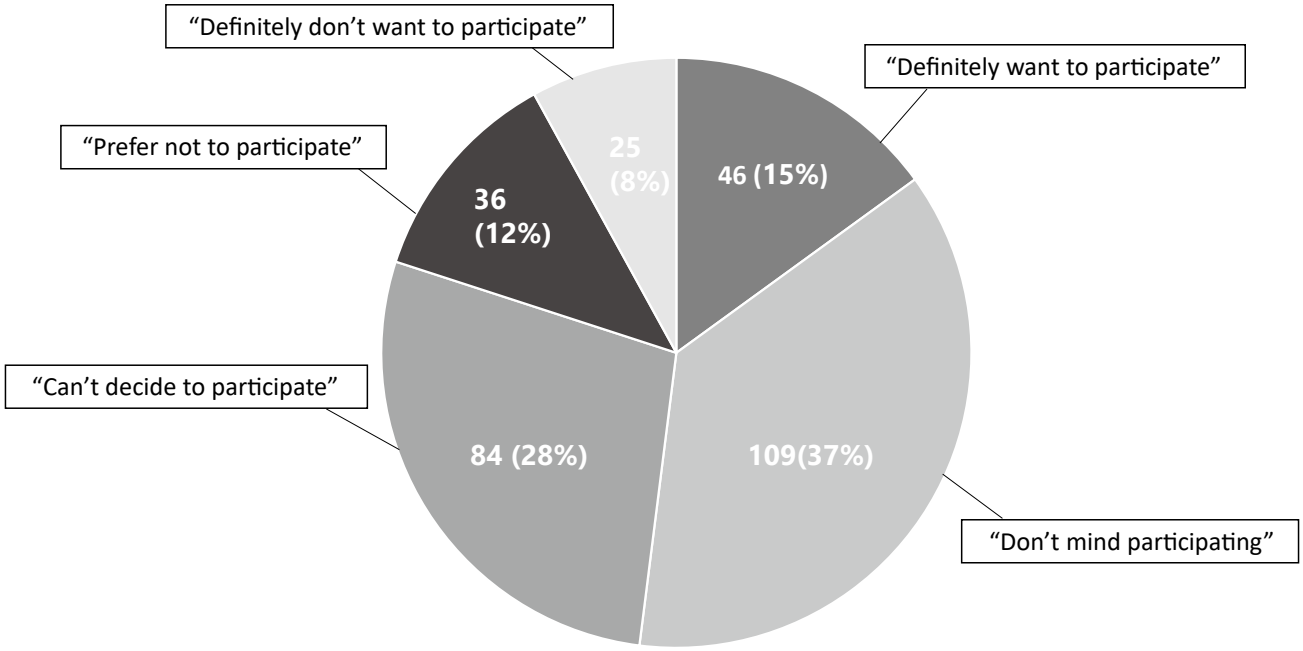


Fig. 1　Number and percentage of respondents（*N*=300）

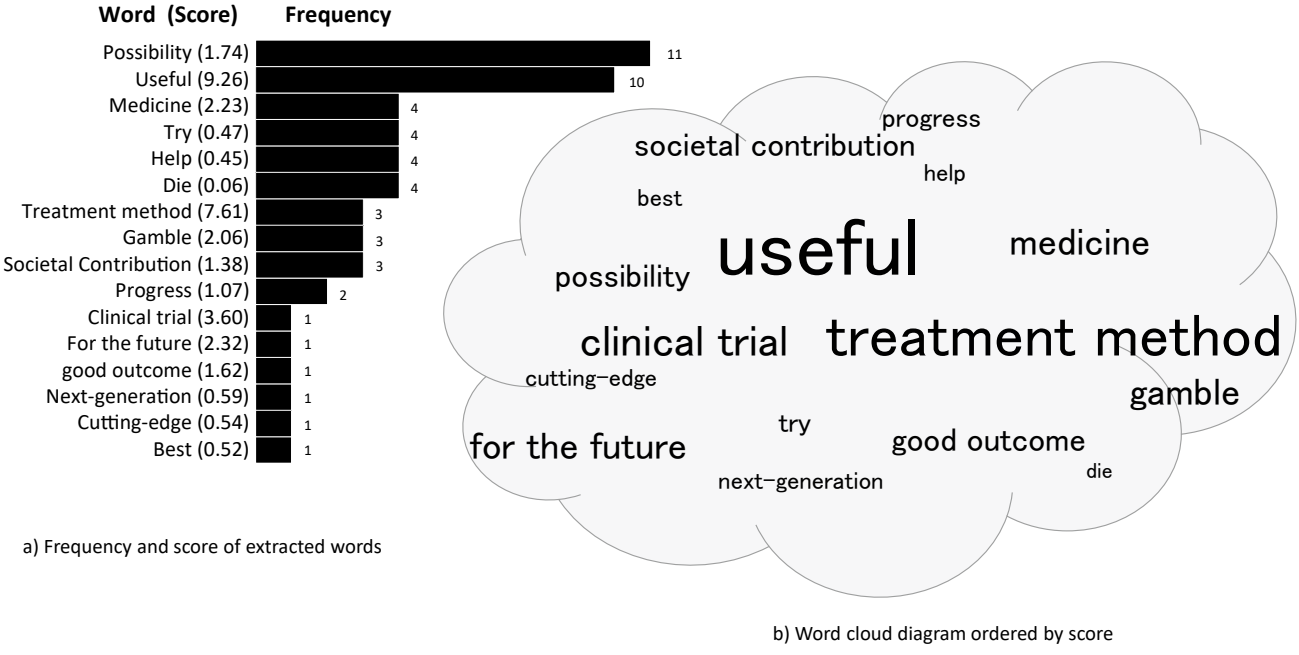
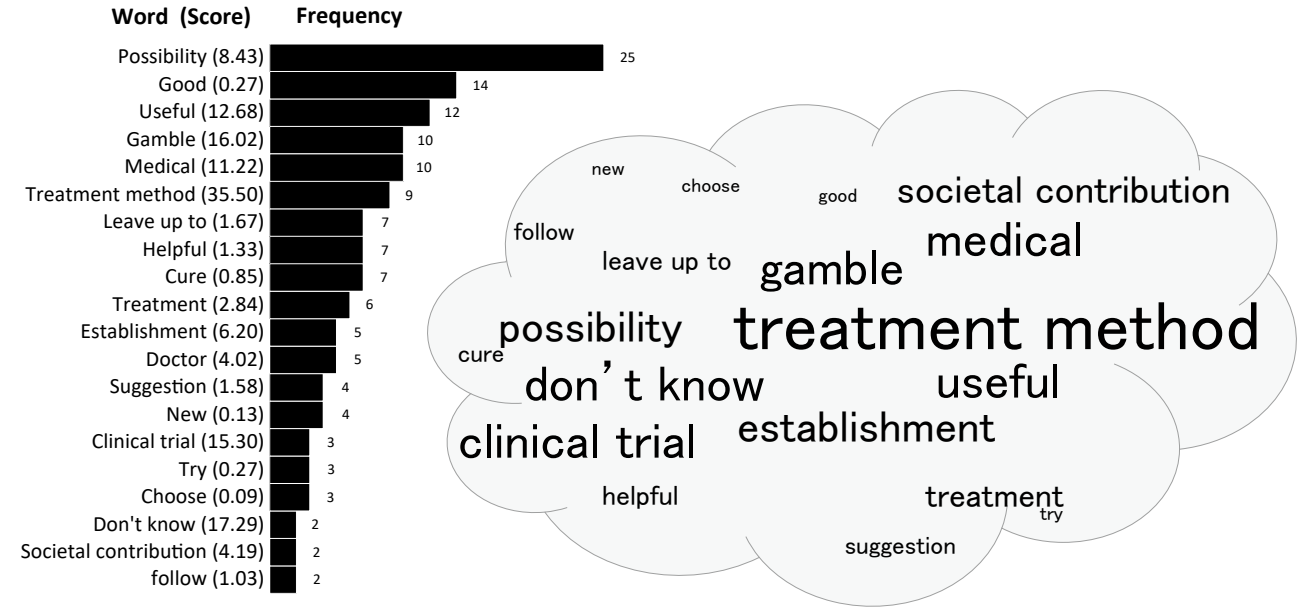


Fig. 2-1　"Definitely want to participate"（*N*=46）



a) Frequency and score of extracted words　　b) Word cloud diagram ordered by score

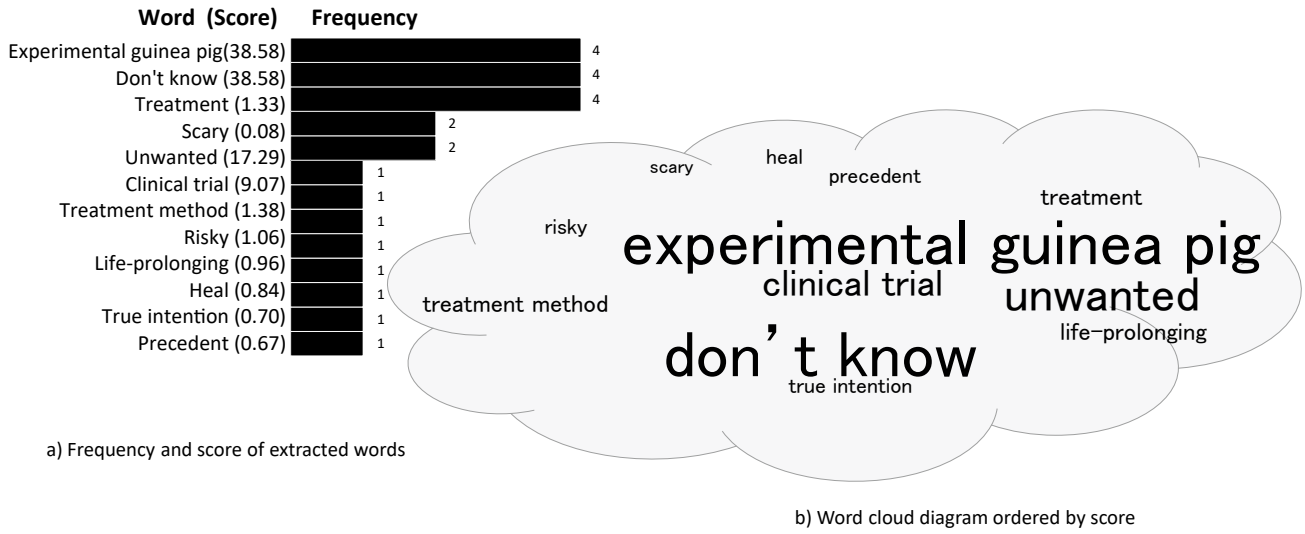
Fig. 2–2　"Don't mind participating"（*N*=109）

a) Frequency and score of extracted words　　b) Word cloud diagram ordered by score

Fig. 2–3　"Can't decide to participate"（*N*=84）

DISCUSSION

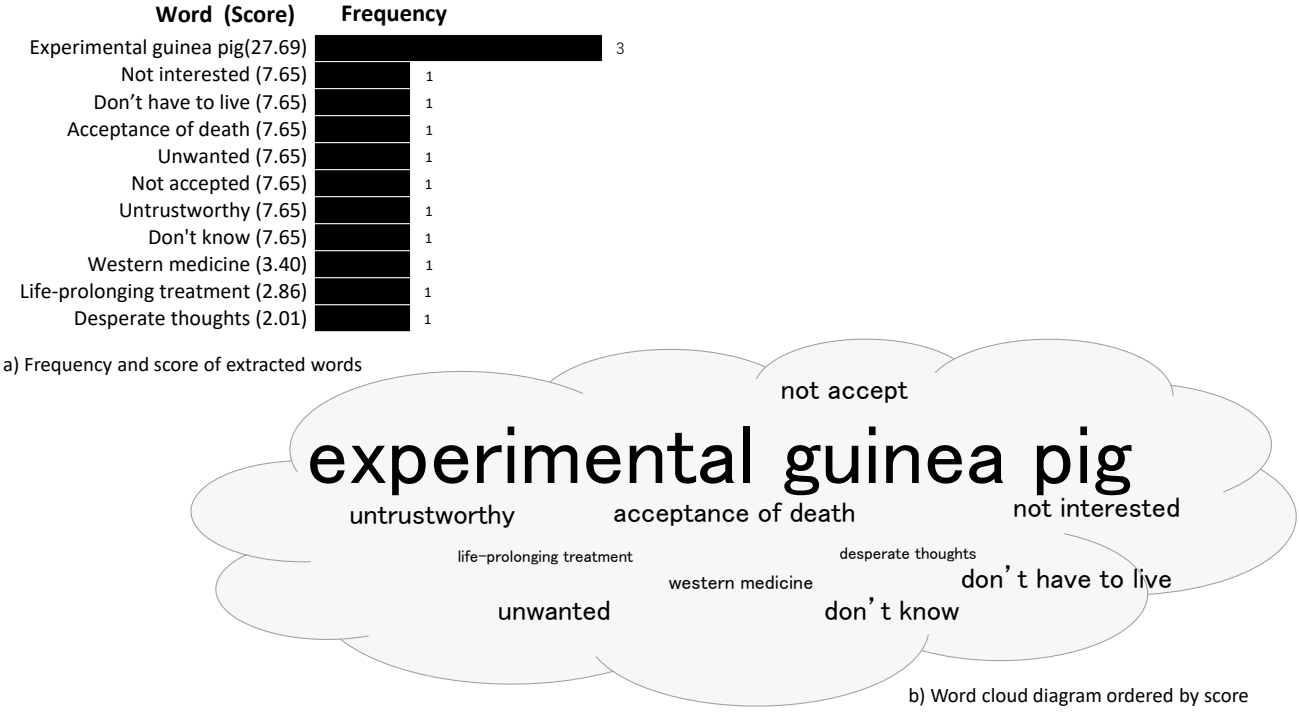
Our results showed that the level of understanding and perception of clinical trials vary greatly among the general population. Those who chose "Definitely want to participate" and "Don't mind participating" perceived clinical trials as a treatment method and hoped for the possibility of recovery. It is a natural human emotion to hope for recovery and view participation in a clinical trial as a form of treatment when no other treatment option is available. However, without fully understanding the risks and making an informed decision based on adequate explanation, there is a concern that this could lead to therapeutic misconceptions[8]. Particularly in emergency situations, where decisions must be made under time constraints and without sufficient leeway, greater caution and consideration



a) Frequency and score of extracted words

b) Word cloud diagram ordered by score

Fig. 2-4　"Prefer not to participate"（*N*=36）



a) Frequency and score of extracted words

b) Word cloud diagram ordered by score

Fig. 2-5　"Definitely don't want to participate"（*N*=25）

are required.

In our previous survey on decision-making as surrogates when asked to consent to a family member's participation in a clinical trial during a medical emergency, the most frequently selected response was "Can't decide to participate"[7]. Similarly, in this survey, which explored participants' preferences for joining a trial themselves, many selected "Can't decide to participate（28%）", with the primary reason being a lack of knowledge about clinical trials. To address the general public's lack of understanding about clinical trials, it is essential to provide education through various means, such as workshops, seminars, informational brochures, videos, and community meetings. Providing education from an early stage, particularly during junior high school, is deemed crucial for fostering foundational understanding.

Furthermore, to ensure that family members follow the patient's wishes in emergency situations where the patient is unable to express them, as was the case in this study, it is important to encourage Advance Care Planning among the general population. It is recommended that individuals discuss their wishes with their family before the need arises, specifying their preferred treatments if they are no longer able to express their own intentions.

And lastly, those who chose "Prefer not to participate" and "Definitely don't want to participate", had a negative image of clinical trials, associating participation with being experimental guinea pigs due to a lack of trust in medical professionals. To build trust in medical professionals, we must ensure clear communication about clinical trials, clearly explain the purpose, process, risks, and benefits of clinical trials.

A limitation of this study is that, while we extracted frequently occurring and characteristic terms from the given reasons for participation and non-participation in clinical research, other terms might emerge in groups with a small number of respondents. Moreover, the context and relationships between the terms were not analyzed.

CONCLUSIONS

Since the level of understanding and image of clinical trials vary greatly among the general population, it is necessary to address these issues appropriately to build trust and obtain proper IC. Since it has been reported that experience in participating in clinical research affects IC, we plan to conduct further research focusing on individuals with experience in clinical trials regarding decision-making during emergencies[9]. Such research could promote a correct understanding of clinical trials among the population.

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