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Brief Communication

Advance Consent for Participation in Acute Stroke Trials: A Focus Group Study with People with Lived Experience of Stroke

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ABSTRACT: Advance consent could address many of the limitations traditional consenting methods pose to participation in acute stroke trials. We conducted a series of five focus groups with people with lived experience of stroke. Using an inductive thematic approach, two themes were developed: factors in favour of, and against, advance consent. Participants supported the idea of advance consent and highlighted trust, transparent communication and sufficient time as major factors that would positively affect their decision to provide advance consent. The results will be used to finalise a model of advance consent suitable for testing the feasibility in stroke prevention clinics.

RÉSUMÉ: Consentement préalable à la participation à des essais cliniques sur l'AVC en phase aiguë : une étude de groupe avec des personnes ayant été victimes d'un AVC. Le consentement préalable pourrait remédier à bon nombre des limites que les méthodes traditionnelles de consentement imposent à la participation à des essais cliniques sur les AVC en phase aiguë. À cet égard, nous avons organisé une série de cinq groupes de discussion avec des personnes ayant été victimes d'un AVC. En utilisant une approche thématique inductive, deux thèmes ont été développés : les facteurs en faveur et contre le consentement préalable. Dans l'ensemble, les participants ont appuyé l'idée du consentement préalable et ont souligné que la confiance, le fait de communiquer en toute transparence et des délais suffisants étaient des facteurs majeurs qui pourraient influencer positivement leur décision de fournir un consentement préalable. Ces résultats seront utilisés pour finaliser un modèle de consentement préalable dont la faisabilité sera testée dans les cliniques de prévention des AVC.

Keywords: Advance consent; focus groups; people with lived experience of stroke; research ethics

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In the setting of acute stroke research, standard informed consent is difficult to obtain because most patients no longer have the ability to give their own consent, and decision-making must occur very quickly.[1] We are exploring the concept of advance consent, in which people at risk of stroke can consent to participate in a clinical trial should they become eligible in the future. In order to inform the model of advance consent we intend to test in a real-world feasibility study, we conducted a series of focus groups designed to explore the perspectives of people with lived experience of stroke around advance consent.

We recruited 15 people from the Stroke Prevention Clinic at The Ottawa Hospital: 12 patients who had experienced stroke and 3 carers/surrogate decision-makers.

A focus group guide was developed by the research team in collaboration with patient engagement experts and was trialled with the research team and with non-clinicians (Appendix I). It consisted of open-ended questions geared towards allowing participants to share their experiences and perspectives without constraints. Interviews were conducted in English.

We conducted five semi-structured focus group sessions over Microsoft Teams in 2023, all led by a study coordinator with experience in conducting focus groups. Thirteen of 15 participants (7 men and 6 women) completed the focus groups. The study was terminated after the fifth focus group when no new information was obtained from the participants, reflecting thematic saturation.[2] The focus groups lasted for an average of 65 minutes (range 47–77 minutes). Using an inductive thematic approach, two themes were developed from the data: factors in favour of and against advance consent.

In favour of advance consent, participants acknowledged the value of giving consent before participation in a clinical trial. They identified the importance of knowing the risks or benefits associated with a trial before agreeing to be enrolled. Participants acknowledged the complexities associated with giving consent

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during an emergency condition such as stroke. Some participants acknowledged that placing such a decision on a loved one could be a burden, especially if they had not previously discussed wishes about research participation. Participants reported that a major factor that would make them more likely to provide advance consent to participate in an acute stroke trial was a good relationship with their treating physician. A few participants expressed that they would be more likely to give advance consent to a study coordinator or member of the research team who approached them with more information and was willing to sit with them and answer their questions. They favoured advance consent over other consenting methods, such as deferred consent, because of the ability to receive and process relevant information and make an informed decision about clinical trial participation. Some participants reported that being able to withdraw their advance consent if they no longer felt comfortable with being enrolled in an acute stroke trial would increase their likelihood to provide advance consent in the first place.

However, some participants felt that, like any other medical decision, a member of their family or a power of attorney should be consulted and be responsible for providing consent on their behalf. Other participants expressed a preference for their doctors to make these decisions independently. All participants expressed that they would be less likely to provide advance consent if a trial presented to them had too many risks. Some participants also stated that they would be less likely to give advance consent if the process took too long and they were presented with more than two acute stroke trials to consider. Some respondents acknowledged reticence about anticipating a future stroke, citing cultural beliefs that talking about a future event might make it occur.

Participants were asked about the idea of blanket or broad advance consent, independent of any specific trial protocol. While some participants were open to this idea, others expressed reluctance to give advance consent if the consent was not for a specific trial. Participants were concerned about the potential for abuse of broad consent and said that this approach defeated the purpose of advance consent, which was to keep the patient as informed as possible about any clinical trials in which they could potentially participate.

In this series of focus groups, participants were generally supportive of the notion of advance consent for participation in acute stroke trials. They highlighted the importance of trust, transparent communication and the ability to withdraw their consent as major factors that would positively affect their decision to provide advance consent. Additionally, consistent with the results of published studies on this topic, including interviews with stroke physicians[3] and research ethics personnel,[4] participants expressed concern about the burden of information if multiple trials were being considered at the same time and were uncomfortable with the idea of blanket or broad consent. The results from this focus group study will be used to finalise a model of advance consent suitable for testing the feasibility of obtaining advance consent in stroke prevention clinics and consequently enrolling patients with advance consent into acute stroke clinical trials.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/cjn.2024.302.

Authors' contributions. All authors made significant contributions to this manuscript. UU, BD, SN and MS contributed to the development of the focus group guide. UU and MS identified and contacted potential participants. UU facilitated the focus groups. UU, RS, BD and MS analysed the focus group transcripts. UU wrote the initial draft of the manuscript. All authors reviewed and revised the manuscript.

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Competing interests. None.

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