CHIEF SCIENTIST OFFICE

CODE: HIPS/22/36

RESEARCH PROJECT BRIEFING

PLatform study for INTracerebral Haemorrhage (PLINTH): a feasibility study

AIMS

Determine the feasibility of recruiting an inclusive, diverse and representative sample of people with incident stroke due to intracerebral haemorrhage (ICH) to a future PLINTH involving multiple randomised controlled trials addressing management uncertainties after ICH.

KEY FINDINGS

- We screened 320 people with incident (new) ICH in NHS Lothian and NHS Lanarkshire between 01 Oct 2023 to 30 Jun 2025, of whom 200 (63%) were eligible to take part, of whom 197 (62%) were approached, of whom 169 (53%) gave verbal consent, of whom 165 (52%) gave written consent, of whom 140 (44%) were willing to take part in a future PLINTH.
- Showing a short video with simple information about the study before asking for verbal consent was acceptable to participants: 165 of 169 (98%) who gave verbal consent later gave written consent after considering the supplementary patient information leaflet.

- Almost all (98%) participants who gave verbal consent had two or more aspects of their care in which different options could be investigated in randomised trials in a future PLINTH.

WHAT DID THE STUDY INVOLVE?

We invited people with incident ICH to participate in our PLINTH feasibility study if:

- They had onset of their stroke symptoms between 1 Oct 2023 to 30 Jun 2025
- They were resident in the Lothian or Lanarkshire regions of Scotland
- They had one or more management uncertainties about their care
- The patient or legal representative could be approached to take part

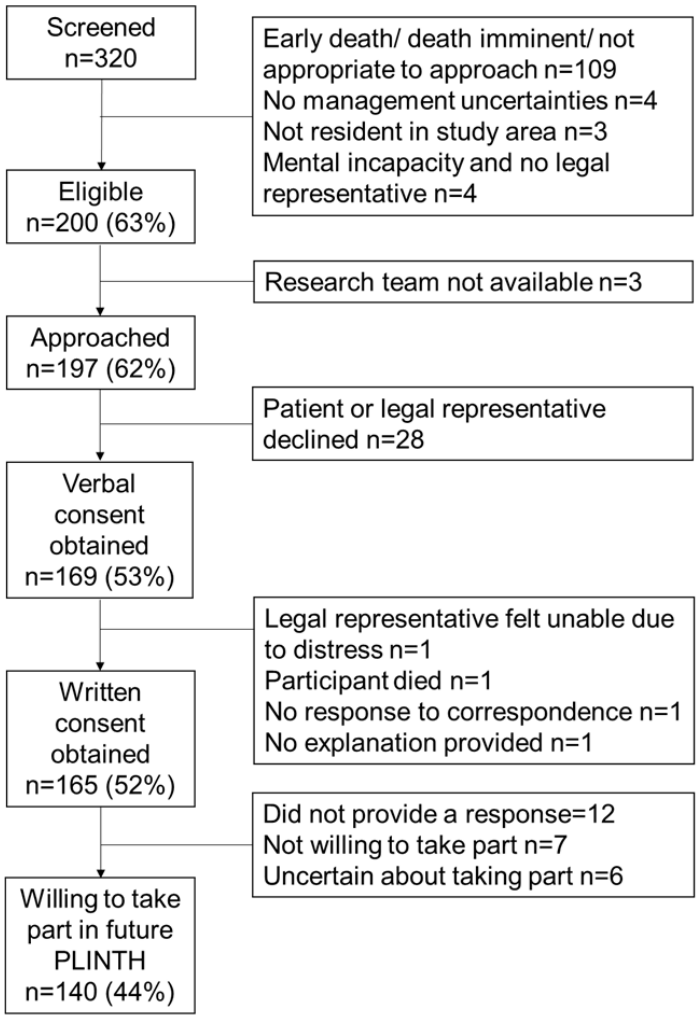
We showed eligible people with ICH a short video with information about our study and sought their verbal consent to take part.

We followed this with supplemental patient information delivered as part of a tailored information-giving session. We outlined information about their diagnosis and care, including uncertainties that might be addressed by a future PLINTH. We sought their written consent to take part in two semi-structured interviews and for use of their routinely collected health data.

We interviewed participants at 3 and 14 days after their ICH to ask their views about our approach to consent, their priorities for future research and their willingness to participate in a future PLINTH.

WHAT WERE THE RESULTS AND WHAT DO THEY MEAN?

The proportion of people with ICH who were screened, approached, consented is shown in the Figure.



140 or 320 (44%) people with ICH met the criteria for our primary outcome of having:

- one or more management uncertainties related to their care *and*
- consented to participate in our PLINTH feasibility study *and*
- agreed to consider participating in a future PLINTH

165 of 169 (98%) who gave verbal consent later gave written consent

Our results show that:

Recruiting a diverse population of people with ICH to a future PLINTH is possible (we included people with varying degrees of stroke severity and other health problems, from a range of socioeconomic backgrounds, with equal numbers of male and female participants).

A simple, proportionate and staged approach to consent involving a short video before seeking verbal consent, followed by sharing detailed tailored information before seeking written consent was effective and acceptable to people with ICH.

WHAT IMPACT COULD THE FINDINGS HAVE?

Our findings have direct impact on future clinical trials of treatments to improve outcome for people with ICH by providing estimates of participation to inform simulation studies that aim to inform the design and methodology of a future PLINTH involving multiple randomised comparisons.

Our finding that people with ICH, who often lack capacity to consent to research in emergency, find a staged approach to consent acceptable, challenges the current legal framework that precludes participation in some research designs before full written consent.

HOW WILL THE OUTCOMES BE DISSEMINATED?

We presented our results at the UK Stroke Forum in Aberdeen, November 2025. We will publish the findings in peer-reviewed stroke journals and via social media, with PPI input.

CONCLUSION

The frequency and characteristics of patients, and the acceptability of a staged consent process in this feasibility study will influence the design of a future PLINTH including multiple randomised trials.

RESEARCH TEAM & CONTACT

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Additional Information
This project was completed on 30th March 2026 with funding of £298,985 received from the CSO