

<Patient title> <Patient forename> <Patient surname>

<Patient address 1>

<Patient address 2>

<Patient city>

<Patient post code>

<date>

Dear <Patient title> <Patient surname>,

Invitation to an outpatient appointment to discuss a research study

Our hospital [**hospital name**] is taking part in a research study called PROHIBIT-ICH. We want to assess the feasibility, safety and effectiveness of intensive Blood Pressure (BP) treatment compared to standard care. Our records indicate that you may be eligible for this as you are over the age of 30 and have had a brain haemorrhage. Further details are available in the summary attached and also in the enclosed Patient Information Sheet. We would like to invite you to consider taking part in this study.

We have enclosed a short form for you to complete to respond to this letter. If you are interested in hearing more about the PROHIBIT-ICH study, we will arrange an outpatient appointment to review your health and treatment and to discuss whether you could participate. We will provide you with more information at the appointment.

Please let us know if you are interested, or not, by following the instructions attached by email, telephone or post.

Yours sincerely,

Signature of PI

[Hospital site address]

[Hospital site Telephone number]

<p>Background to research</p>	<ul style="list-style-type: none"> • About 1 in 10 strokes are due to a bleed into the brain from a ruptured (burst) artery, called intracerebral haemorrhage (ICH). • In some cases, ICH is caused by injury or surgery, in others it happens suddenly without warning (“spontaneous”). • Spontaneous ICH is sometimes the result of high blood pressure (BP) which, over time, causes damage to the small blood vessels supplying the brain, making them more likely to rupture. • The main cause of spontaneous ICH is called “small vessel disease” (SVD), which may be related to poor BP control. • BP lowering is the most promising preventive strategy, but adherence and BP control in clinical practice remain poor. • There is an urgent need to improve ICH secondary prevention through improved long term BP control
<p>Aims of the research</p>	<ul style="list-style-type: none"> • The trial will investigate whether intensive lowering of blood pressure (BP) using telemetric home monitoring in survivors of intracerebral haemorrhage (ICH) is feasible, safe and effective in reducing brain injury. • If successful we hope this study will be a precursor for a larger trial. • Telemetric home monitoring is a promising strategy to facilitate home BP monitoring after stroke, which should improve adherence and optimize medication to better control BP. • Telemetry allows patients with hypertension to monitor their own BP and automatically send the information to a secure website, available to

	<p>their clinicians to monitor and adjust their treatment.</p> <ul style="list-style-type: none"> • The intervention should allow survivors of ICH to know, understand, and manage their own BP to prevent strokes and cognitive impairment, and improve outcomes.
<p>Design and methods used</p>	<ul style="list-style-type: none"> • Eligible patients will be identified by the research practitioner or member of research/clinical teams, from acute stroke units or high dependency units at participating hospitals, outpatient clinics (stroke, neurology, geriatric, neurosurgical), primary care centres and from site databases • Staff will provide the patient, their legal representative, or their nearest relative with information leaflets about this trial • After consent is given, trial staff will take some details from the participants and carry out some tests, BP test and where possible an MRI scan • Participants will be randomly allocated to either intensive BP treatment guided by telemetric home monitoring or standard care in adult ICH survivors • We will follow-up these two groups of participants to assess whether BP lowering using this home monitoring is feasible, safe and effective in reducing brain injury. • There will be 2 follow ups: one at 3 months and one at 12 months • A sample of blood will also be collected to find out if there are any genetic variations associated with ICH or SVD.
<p>Participants</p>	<ul style="list-style-type: none"> • Participants invited will be over the age of 30 and have had a spontaneous ICH, most likely due to SVD, confirmed on a brain scan

Dissemination

- The results of the study will be reported to the funder of the study and published in scientific journals. Following completion and publication, these results will be posted on a study website for participants to view.

Please reply to this invitation, using one of the methods below:



Email us at ****@**

Or



Telephone us on: ***** *****

Or



Provide your details below, tick the relevant box, and return this slip in the enclosed envelope.

Print your name	
Date of birth	
Your address, including post code	
Phone number (and best time to call)	

Tick one box:

I would like to know more about PROHIBIT-ICH. Please contact me.

I realise that this is not a commitment to taking part in the study.

I do not wish to be considered for PROHIBIT-ICH. We will assume that you do not want to take part in the study and we will make no further contact if we do not hear from you. However, you are still welcome to tick the 'No' box above and provide feedback if you wish.