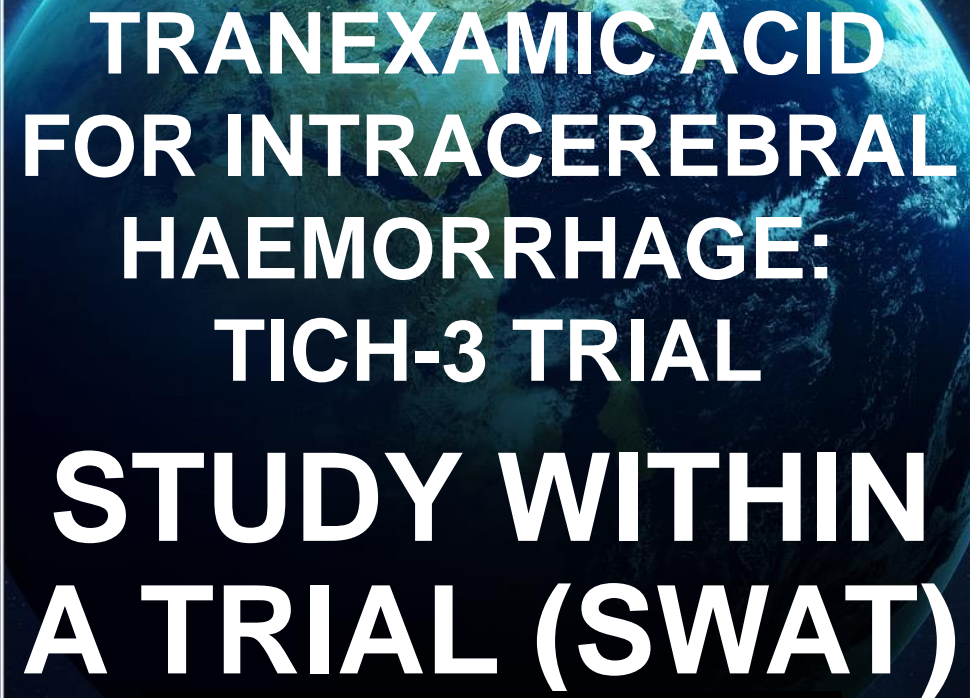
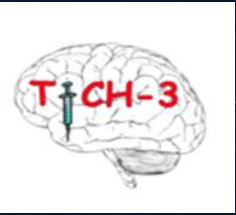




University of  
Nottingham

UK | CHINA | MALAYSIA

A large, glowing blue and green Earth seen from space, centered in the background.

**TRANEXAMIC ACID  
FOR INTRACEREBRAL  
HAEMORRHAGE:  
TICH-3 TRIAL  
STUDY WITHIN  
A TRIAL (SWAT)**

Professor Nikola Sprigg

On behalf TICH-3 Trial Team

Final v1.3 24/04/2024

**SWAT TRAINING IS ONLY FOR UK  
SITES THAT HAVE BEEN  
RANDOMISED INTO ENHANCED  
CONSENT PROCESS (ANIMATED  
VIDEO)**



# SWAT Sub-study



**Aim:** To reduce inequalities in enrolling participants from minority communities.

**Population:** All individuals recruited to the TICH-3 trial in the UK.

**Intervention:** Animated participant video

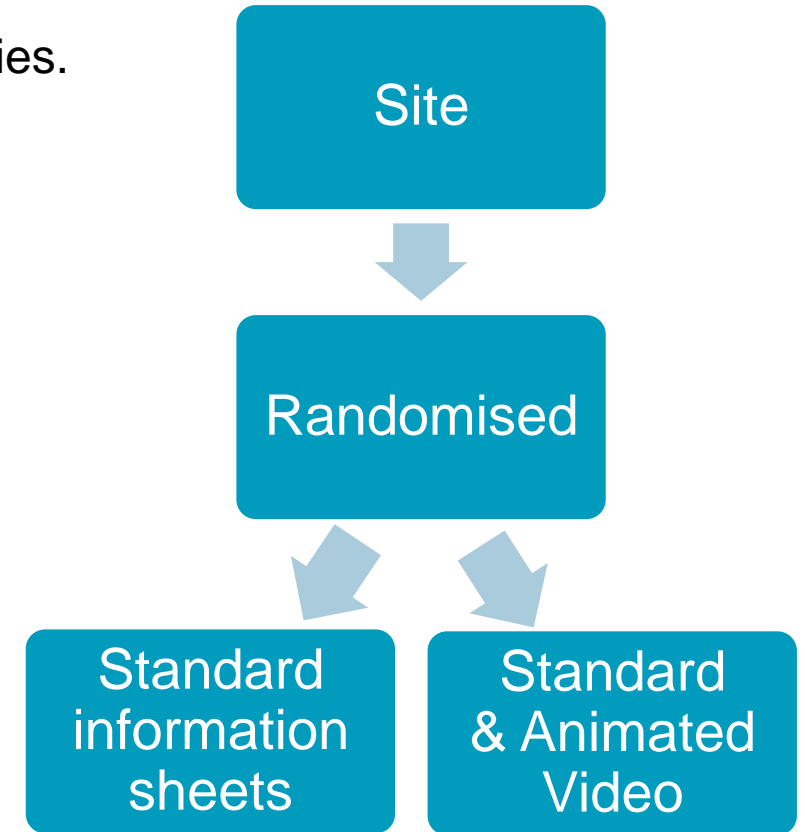
**Control:** Standard information sheets

**Outcome measures:**

1. Proportion providing consent for follow up:
  - i. In the TICH-3 UK study population as a whole
  - ii. By ethnic minority groups versus non-ethnic minority groups
  - iii. Follow up completion rates in the control and intervention groups.

**Design:** Cluster randomisation at site level

Sites will be informed of their randomisation prior to initiation and Sites will be given training on how to use the video if randomised to animated video



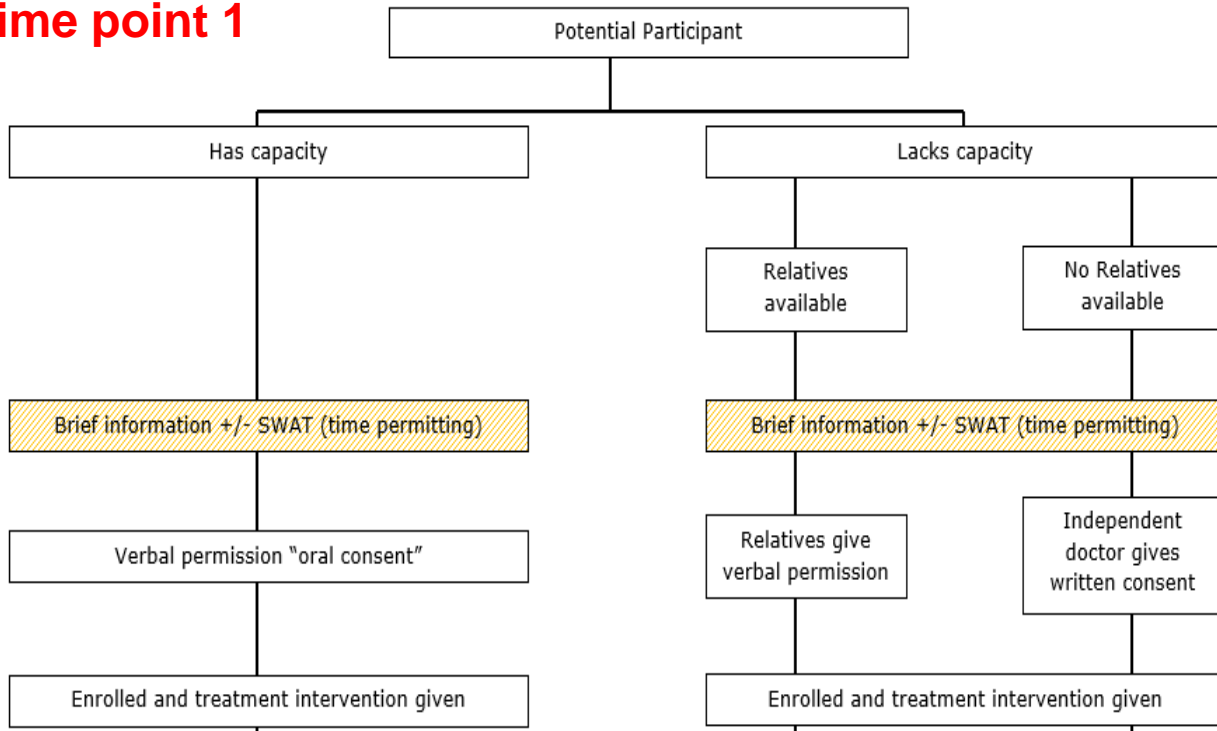
**Note:** Animated video will be used **in addition** to the standard consent process and information sheets. Given the age and recent stroke, the intervention **may improve understanding of all participants** not just those in ethnic minority group, we will therefore **include all UK participants** rather than the sub-set from ethnic minority groups in the SWAT.



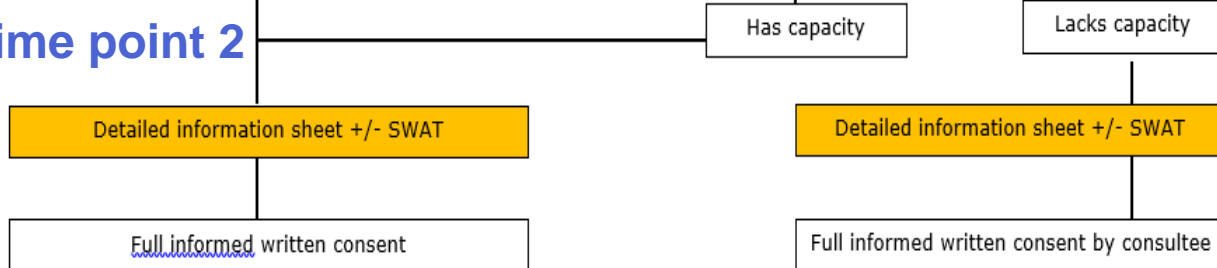
# SWAT Consent Process



## Time point 1



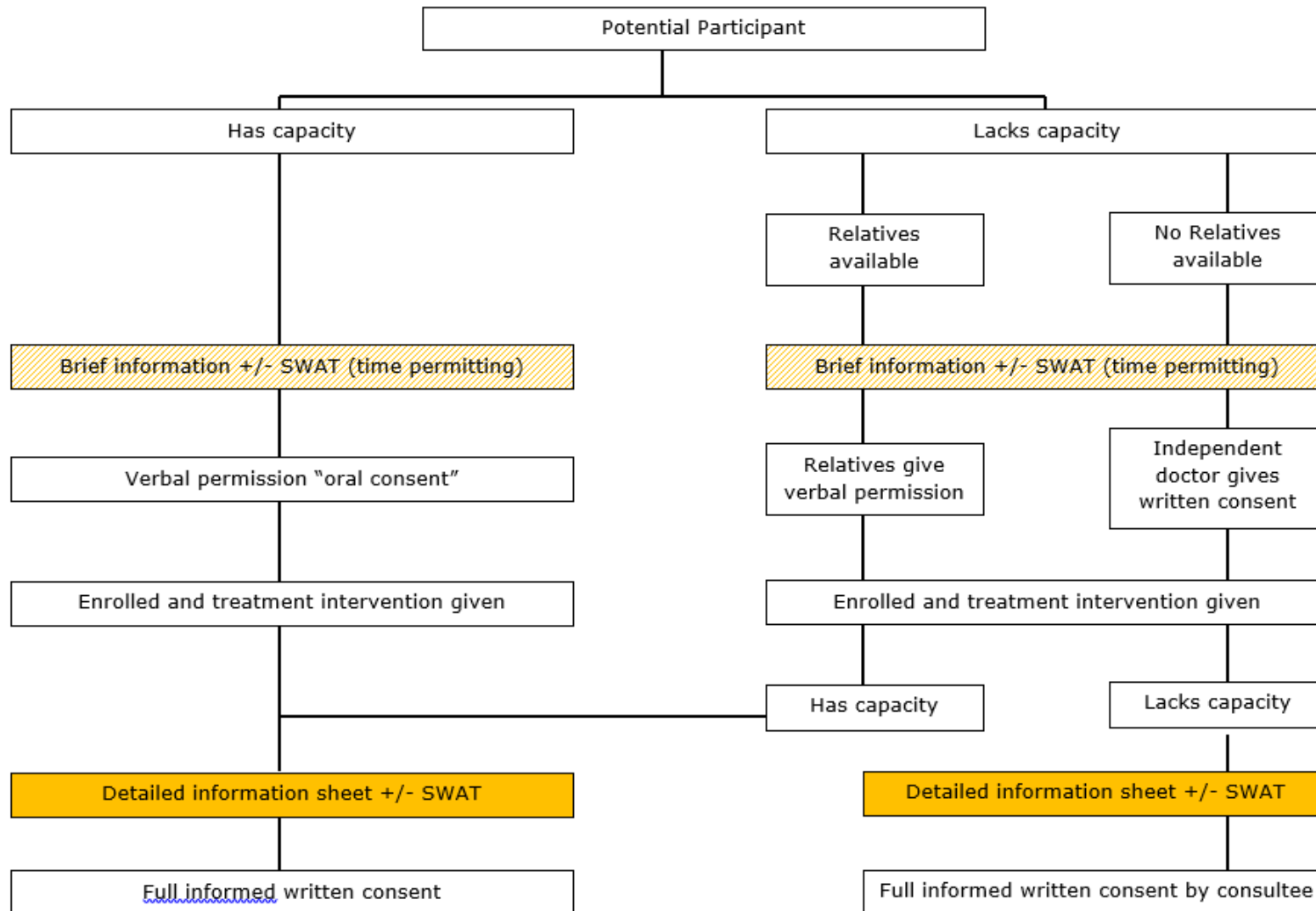
## Time point 2



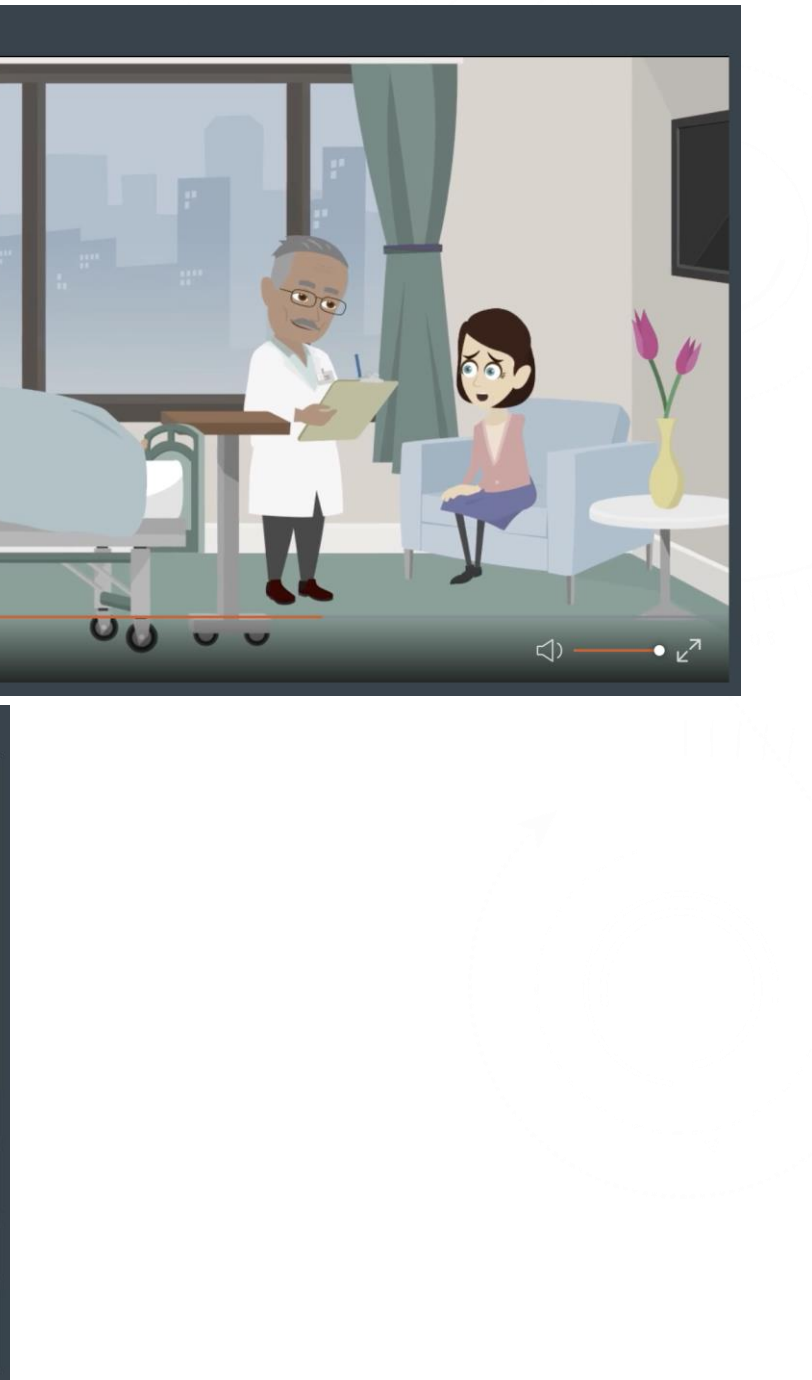
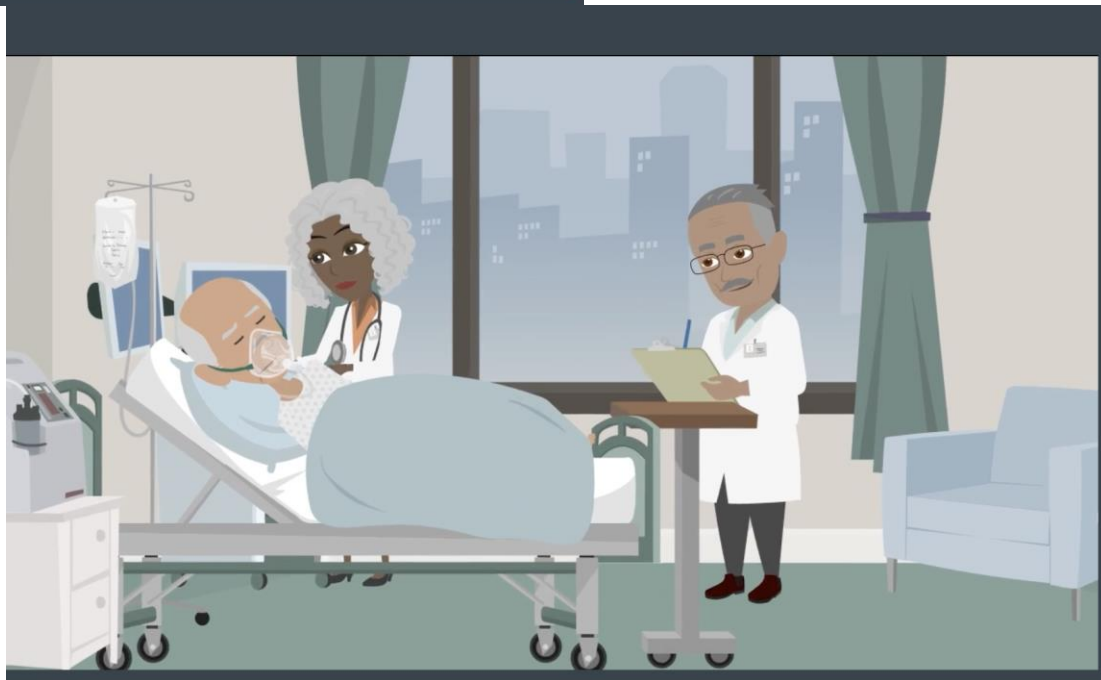
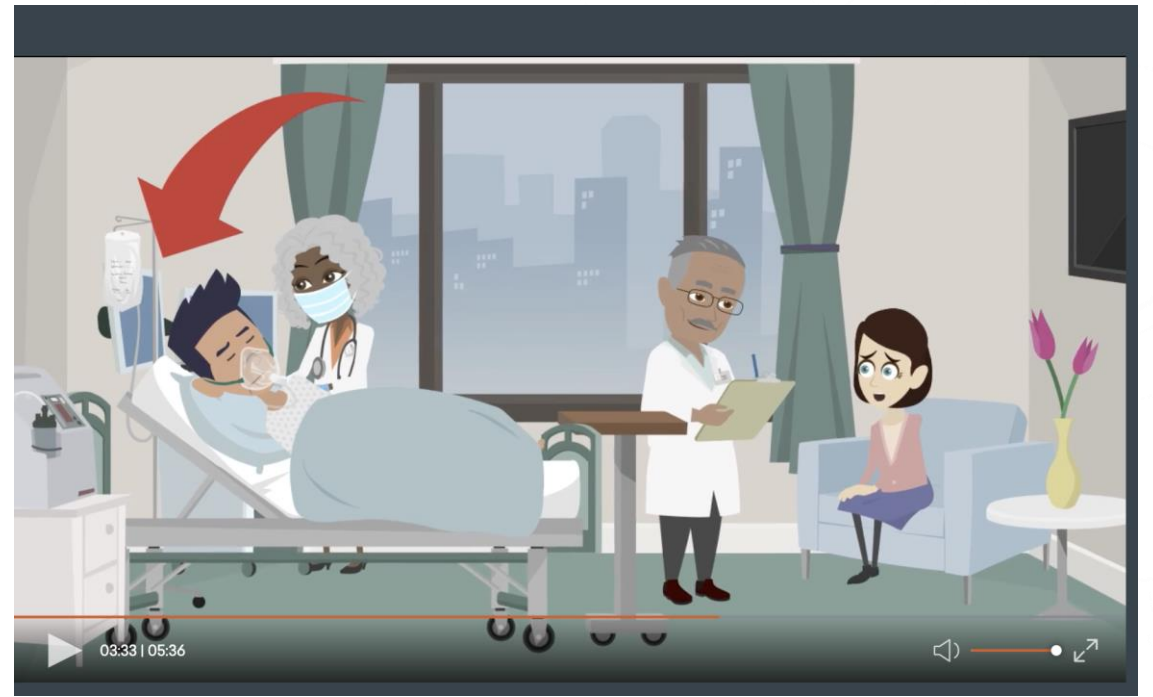
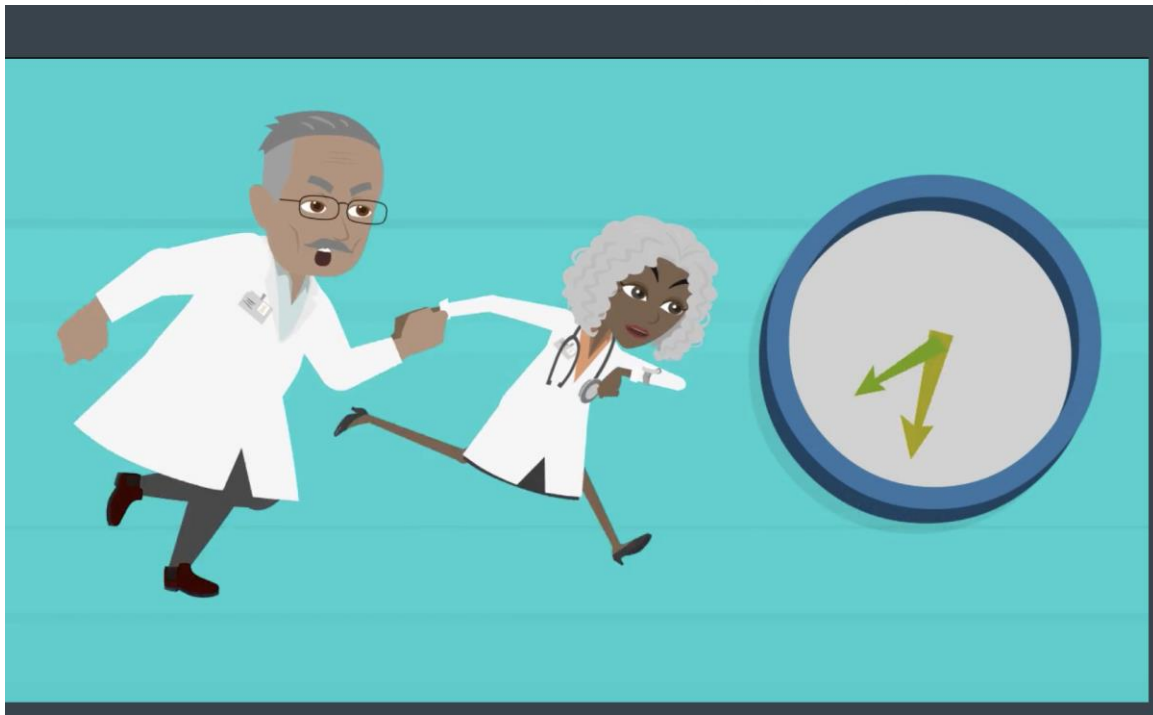
- We anticipate that the SWAT animated video will be mostly used for obtaining follow on written consent, time point 2.
- If time allows, the SWAT animated video can be used when obtaining oral enrolment consent, time point 1.



# SWAT Consent Process Flowchart



- All participants give follow on written consent.
- Sites randomised to the enhanced process will have access to the website with the video in 5 languages.
- enrolment eCRF and day 7 eCRF will capture if the video was used.
- The database will also record when the video is accessed.





# Translated versions of SWAT videos:



- 5 languages available in addition to English -
  - Bengali, Polish, Punjabi and Urdu
  - Welsh – translated video available on TICH-3 website August 2024
- For foreign languages - video has text in English but the audio has been translated into the above languages
- Please use the video for ALL patients – irrespective of language/ethnicity - the intervention **may improve understanding of all participants** not just those in minority ethnicity groups, we will therefore **include all UK participants** in the SWAT.




# Obtaining site specific access to videos



## TICH-3 log-in only required first time to obtain link

1. Login into to TICH-3 and click on consent video section in contents list  
(Anyone with a TICH-3 investigator account at your site will have access to the link)
2. Get site specific link to consent videos
3. Bookmark this link – it can be used in future without logging in
4. The site specific link can be shared with colleagues at your site – or relatives of patients at your site, no log in is required

- [Participant list](#)
- [Data reports](#)
- [Treatment pack list](#)
- [Recruitment alerts](#)
- [Site delegation log](#)
- [SWAT consent videos](#)
- [View your training certificate](#)



### TICH-3 consent videos

Welcome to TICH-3, which is a clinical trial trying to reduce the number of people who die or who are left disabled after stroke caused bleeding in the brain (intracerebral haemorrhage).

Please select the most suitable language for the patient or their family/friends

- [English](#)
- [Welsh](#) Cymraeg y Gymraeg
- [Polish](#) polski polszczyzna
- [Bengali](#) Bangla বাংলা
- [Punjabi](#) Panjabi پنجابی ਪੰਜਾਬੀ
- [Urdu](#) اُردو





# Sites randomised to enhanced consent will be given access to the video links



## TICH-3 consent videos

Welcome to TICH-3, which is a clinical trial trying to reduce the number of people who die or who are left disabled after stroke caused bleeding in the brain (intracerebral haemorrhage).

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- [Punjabi](#) Panjabi پنجابی ਪੰਜਾਬੀ
- [Urdu](#) اُردُو

- Clicking on the link takes you to the appropriate language video
- You do not need to be logged into TICH-3 or have a TICH-3 investigator account to watch the video
- You can share the link with relatives to watch remotely
- Please DO NOT share video link with staff/investigators at another site



# Sites randomised to enhanced consent will be given access to video links



## TICH-3 consent videos

Welcome to TICH-3, which is a clinical trial trying to reduce the number of people who die or who are left disabled after stroke caused bleeding in the brain (intracerebral haemorrhage).

**English** [Polish](#) (polski polszczyzna) [Bengali](#) (Bangla) [Punjabi](#) (Panjabi) [Urdu](#)

- The video starts by clicking on the 'play' symbol below (▶).
- There is a voiceover, so please make sure that sound is enabled on your computer.
- You can enlarge the picture to full screen by clicking the  icon in the bottom-right corner of the video image (recommended) and also by using the link underneath to open it in a new tab.

If you have trouble watching the video, please try switching to the video hosted by YouTube, using the link underneath. Check that your computer can play YouTube videos and that access is not being blocked by internet safety settings.



Having trouble playing this video?  
[Switch to the alternate copy](#)  
of this video hosted by **YouTube**.

- The video can be viewed on most web browsers and smart phones
- Alternatively, the video can be viewed by a link to you-tube

Having trouble playing this video?  
[Switch to the alternate copy](#)  
of this video hosted by **YouTube**.

- Please DO NOT share video link with staff/investigators at another site



# QR codes to videos by language



- You told us....

We don't have devices for showing the video


- We did...

Printable QR codes – show this document to participant/relatives to view the video on their own devices

The template pictured can be obtained on the TICH-3 documents page <https://stroke.nottingham.ac.uk/tich-3/docs/> under heading SWAT substudy.

Then please insert the QR for each language you can get the QR code once logged into the TICH-3 website.

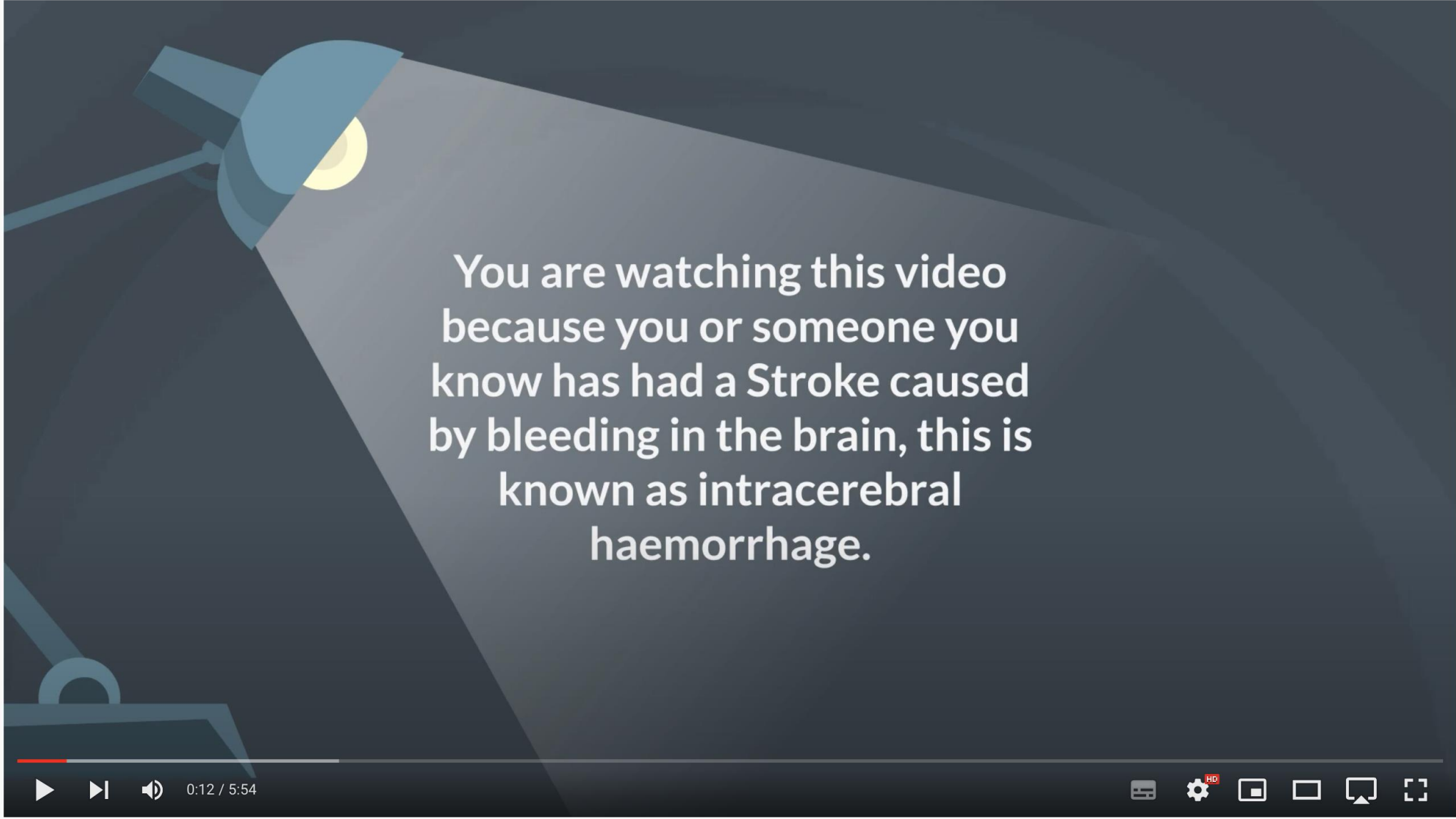
*[Form to be printed on local headed paper]*

 **TICH-3 Consent Video Access**

Welcome to TICH-3, please scan the QR code below using your mobile phone to access a short 6-minute video in your preferred language that will explain the TICH-3 trial.

[INSERT SITE SPECIFIC QR CODE FOR ENGLISH CONSENT VIDEO]	<b>English</b>
[INSERT SITE SPECIFIC QR CODE FOR POLISH CONSENT VIDEO]	<b>Polish</b>
[INSERT SITE SPECIFIC QR CODE FOR BENGALI CONSENT VIDEO]	<b>Bengali</b>
[INSERT SITE SPECIFIC QR CODE FOR PUNJABI CONSENT VIDEO]	<b>Punjabi</b>
[INSERT SITE SPECIFIC QR CODE FOR URDU CONSENT VIDEO]	<b>Urdu</b>
[INSERT SITE SPECIFIC QR CODE FOR URDU CONSENT VIDEO]	<b>Welsh</b>

TICH-3 Consent Video Access Links – site specific template Final v1.1 08.08.2024



TICH-3 - for English language speakers

🔒 Unlisted

3 views • 26 Apr 2022

👍 0    💬 DISLIKE    ➦ SHARE    ⚙️ SAVE    ...



# Record use of SWAT video on enrolment eCRF



## Section C: SWAT video

Only UK sites randomised to the SWAT active group should answer this section. If you are entering data for any other site, please answer 'Not applicable'.

C1	Was the participant/relative shown the animated consent video?	<input type="checkbox"/> Yes - before enrolment <input type="checkbox"/> Yes - after enrolment <input type="checkbox"/> Yes - both before/after enrolment  <input type="checkbox"/> No
C2	If yes, which language was used?	<input type="checkbox"/> English <input type="checkbox"/> Polish <input type="checkbox"/> Urdu <input type="checkbox"/> Bengali <input type="checkbox"/> Punjabi
C3	If yes, who watched the video?	<input type="checkbox"/> Participant <input type="checkbox"/> Relative <input type="checkbox"/> Both

The questions on the enrolment eCRF are establishing if the animated video was used for enrolment consent.



# Record use of SWAT video on day 7 eCRF



## Section I: SWAT video

- Only UK sites randomised to the SWAT active group should answer this section. If you are entering data for any other site, please answer 'Not applicable'.
- Please record data here only when the video was shown after the day of enrolment. Data on video views on the day of enrolment should be recorded on the enrolment CRF.

I1	Was the participant/relative shown the animated consent video?	<input type="checkbox"/> Yes - before written consent <input type="checkbox"/> Yes - after written consent <input type="checkbox"/> Yes - both before/after written consent  <input type="checkbox"/> No
I2	If yes, which language was used?	<input type="checkbox"/> English <input type="checkbox"/> Polish <input type="checkbox"/> Urdu <input type="checkbox"/> Bengali <input type="checkbox"/> Punjabi
I3	If yes, who watched the video?	<input type="checkbox"/> Participant <input type="checkbox"/> Relative <input type="checkbox"/> Both

The questions on the day 7 eCRF are establishing if the animated video was used for follow on written consent.



# Summary- Enhanced consent video



- The SWAT video should be used for ALL eligible participants irrespective of language/ethnicity
- Only UK sites randomised into the enhanced consent process (animated video) will have access to the videos
- A site investigator at your site only needs to log in once to obtain the site specific link, this can then be shared with the team and book marked with no further log in requirements to watch the video
- Please DO NOT share the link with any other sites
- Contact the coordinating center if you need any assistance

# CONTACT INFORMATION





# University of Nottingham Trial Team



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## Trial Coordinating Centre contact information:



+44(0)115 823 1782

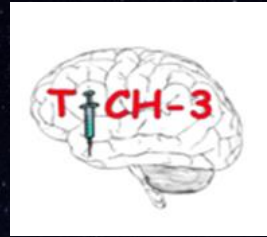


TICH-3@nottingham.ac.uk



University of  
Nottingham

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**THANK YOU!**

**Any questions?**

# OTHER INFORMATION



# Ethical approval for SWAT



- SA\_02\_22

SWAT video completed and transcript uploaded for ethical approval. Day 180 form typo amended.

Submitted – 21/02/2022

Approved – REC and HRA 31/03/2022

We now have full ethical approval to use the animated SWAT videos.



# Audit list of updates to training presentations



## Previous versions

### Version 1.1 25/05/2022

- Changed wording BAME to ethnic minority groups

### Version 1.2 11/12/2023

- Added slide for QR code template
- Updated University of Nottingham Trial Team

### Version 1.3 24/04/2024

- Added slide Record use of SWAT video on enrolment eCRF
- Updated slide Record use of SWAT video on day 7 eCRF

## This version

### Version 1.4 08/08/2024

- Added that video translated into 5 languages not 4 – addition Welsh from August 2024
- Updated screenshot of access to videos on TICH-3 website
- Updated screenshot of QR code template document
- Moved ethical approval slide to section at end for ‘other information’