Examining the host trial's impact on SWAT delivery

Caroline Rick1, Brittany Hare2, Joseph Dib2, Christopher Cheung2, Kennedy Cadman2, Solomon Adegbola2, Chaamanti Menon2, Lee J Haywood2, Iris Mhlanga2, Lisa Woodhouse2, Tiffany Hamilton2, Trish Hepburn1, Alan Montgomery1, Philip M Bath2, Nikola Sprigg2, and Andy Willis3 on behalf of TICH-3 investigators

1 Nottingham Clinical Trials Unit, & 2 Nottingham Stroke Trials Unit, University of Nottingham, UK; 3 School of Public Health, University College Cork, IE

Aim

To explore the impact the host trial's design has on a SWAT intervention delivery.

Background

Embedding SWATs in clinical trials is an inexpensive, efficient way to test methodological questions in multiple settings, to determine whether they are effective and generalisable.

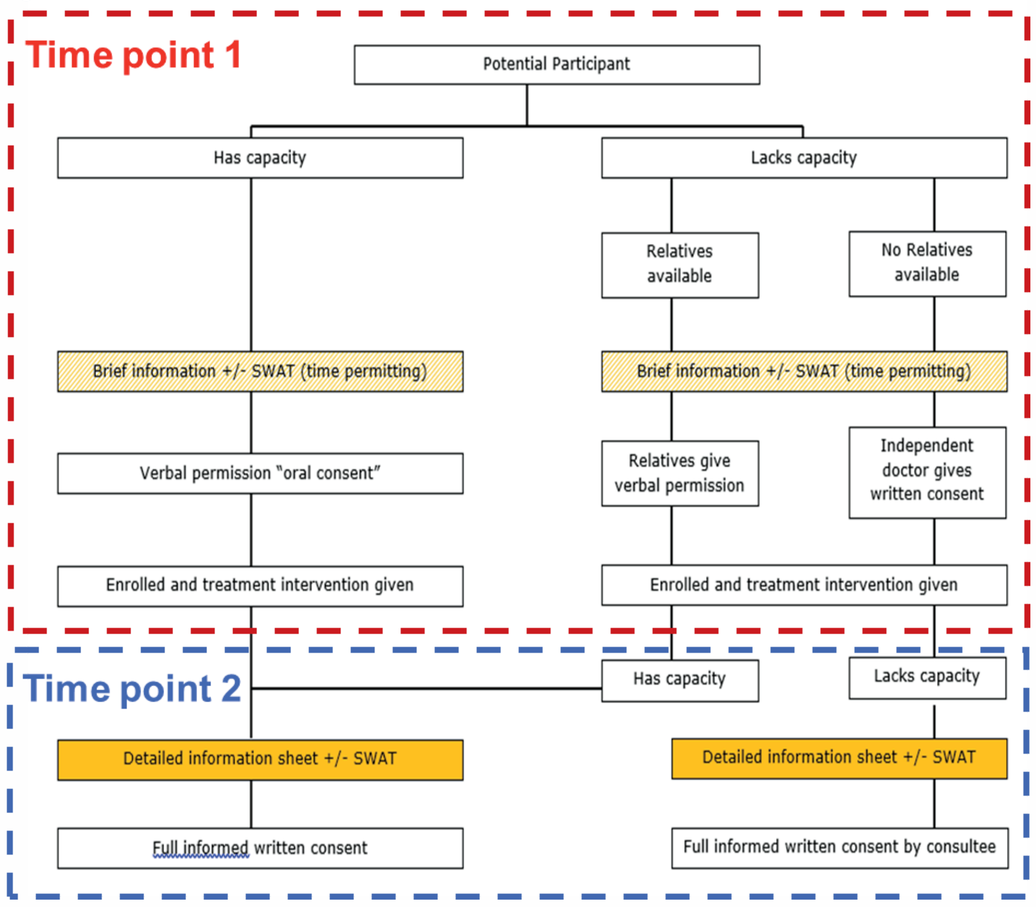
The methodology necessitates that the SWAT does not adversely impact the host trial and that the trial does not affect the ability to test the SWAT intervention.

SWAT 156 (Belfast SWATstore registry) was developed for the TICH-3 trial (NIHR129917) to test whether a culturally-sensitive animated information video, translated into 5 commonly spoken languages as well as English, delivered with the standard patient information sheets (PIS) is more effective than PIS alone in the recruitment and retention of: (1). Participants overall and (2). Non-English speaking participants.

TICH-3 tests whether Tranexamic acid reduces death and disability after intracerebral haemorrhage with emergency verbal consent (<4.5hrs) and deferred written consent as soon as possible post-intervention.

Methods

Figure 1. Participant flow.



The SWAT was cluster randomised by site to ensure sites work to a single protocol, the videos are accessed via a site-specific link/QR code to the trial website, and the database records the number of times the videos are accessed by site and language.

It was tested at 2 timepoints: t1 - under emergency conditions (within 4.5hrs of haemorrhagic Stroke) and t2 - follow on written consent after treatment had been administered when there were fewer time pressures.

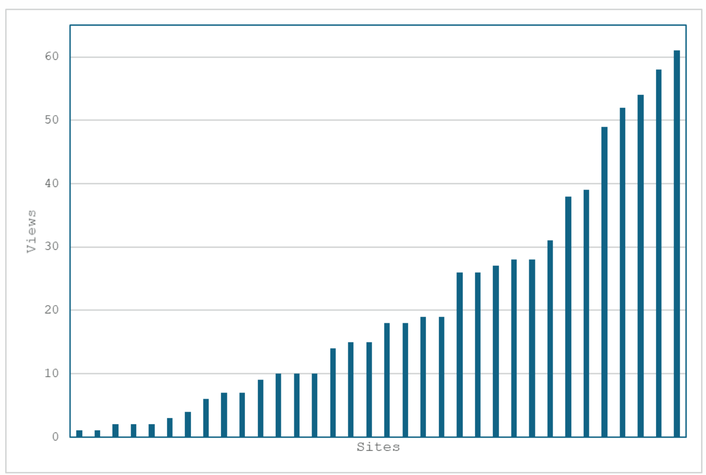
Results

Table 1. Total number of views by potential participants.

Total Views	745
Views in Bengali	33
Views in English	592
Views in Polish	47
Views in Punjabi	29
Views in Urdu	31
Views in Welsh	13

- 81.2% Views in English or Welsh (79.5% and 1.6% respectively).

Figure 2. SWAT Intervention Compliance.



- 35 of the 38 sites (92.1%) randomised to the SWAT intervention have viewed the video at least once.
- Of the 34 sites accessing the video for more than 2 months, 23 have used the video at least 10 times, and 13 have accessed it at least 20 times.

Limitations

The overarching need for the SWAT to not adversely impact the TICH-3 trial, has impacted our ability to reliably test the SWAT intervention:

1.The denominator is unknown – Given the emergency conditions of the initial consent (within 4.5 hours of haemorrhagic stroke occurring) and thus the stripped down processes; sites were not required to record how many potential participants were approached about the trial or offered the SWAT intervention.

2.To not impact the potential participant flow through the clinical pathway nor the host trial, the SWAT usage was recorded by tallying the number of times a video was viewed at a given site and which language was chosen by an automated link to the trial website. This required the potential participant or their relative connecting their phone to the website via the hospital Wi-Fi. This was particularly challenging in the stroke admissions units where there is often no or extremely limited access to Wi-Fi. Such technical glitches often deterred sites from mentioning the video to potential participants.

3.Compliance with the intervention is sub-optimal – with only 38.2% of sites having potential participants viewed the video more than 20 times and 39.5% (including those who have never used it) of sites having less than 10 views, the intervention is not being delivered as planned.

Conclusion/Discussion

- Pooling or meta-analysing SWAT data for complicated SWAT interventions across a range of host trials, without considering the impact of the context, is likely to lead to underestimations of the effectiveness of the intervention; given the impact of the overarching trial on SWAT intervention compliance.
- Complex SWATs need to include funding for additional work to separate the effects of the SWAT from those of the context in which they are being tested.

SUPPORTED BY NIHR | National Institute for Health and Care Research

This project is funded by the NIHR Health Technology Assessment Programme (NIHR129917). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.