SWAT 156: Impact of an animated video translated into four commonly spoken languages on recruitment into the TICH-3 trial

Objective of this SWAT
To determine whether the use of an animated video translated into four languages that are commonly spoken in the black, Asian and minority ethnic (BAME) communities in the United Kingdom (UK) alongside standard participant information sheets (PIS) improves recruitment and retention into the TICH-3 trial, and whether it specifically improves recruitment and retention of individuals from BAME communities.

Study area: Recruitment, Retention
Sample type: Patients, Carer/Parent
Estimated funding level needed: Very Low

Background
Currently, members of BAME communities in the UK are under-represented in research in general and specifically in research in stroke.(1) In trials in emergency settings, this is often seen in differential deferred consent and follow-up return rates. A great deal of effort is often expended in recruiting participants to trials. Ensuring that as many of these participants as possible are recruited, retained and provide outcome data can greatly improve research efficiency and minimise the risk of bias resulting from incomplete data. In the TICH-3 trial of tranexamic acid for hyper acute spontaneous intracerebral haemorrhage (ISRCTN97695350), we will use a consent waiver, with consent for continuation and follow up taken when the participant is able to do so. Outcome data are collected at 180 days after randomisation through postal or telephone questionnaires. It is hypothesised that improving communication and understanding of the trial rationale, events to date and the importance of their input and the extent of the commitment involved with people from BAME communities may increase rates of consent to follow up and increase response rates to follow-up questionnaires. Data from the TICH-2 trial (ISRCTN93732214) in a similar participant population using emergency consent procedures, demonstrated a difference in follow up return rate at 3 months of people from BAME communities compared to non-BAME communities (96.5% vs 98.7%; p=0.004).

Previous trials and clinical practice have used translations of documents including animated videos, but none have been tested in a SWAT-setting to determine the impact on recruitment and retention into Trials.(2,3) Using data from the TICH 2 trial (4), we will match population demographics at UK sites for this SWAT in the TICH-3 trial and randomise sites to either the intervention or control.

This SWAT will investigate the effects of an animated video about the TICH-3 trial that will be dubbed into four key languages as well as in English, which will be used alongside the standard PIS. Given their age and recent stroke, the intervention may improve understanding of all participants (not just those in BAME groups), and the SWAT will include all UK participants rather than just the sub-set from BAME communities.

Interventions and comparators
Intervention 1: Animated video co-created with a PPI (patient and public involvement) group from the centre for BAME health at University of Leicester and translated into four key languages as well as English together with standard PIS.
Intervention 2: Standard PIS without the animated video.

Index Type: Method of Recruitment, Method of Follow-up

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Follow up completion rates in the SWAT intervention and control groups.
Secondary: Proportion of participants providing consent for follow up in the TICH-3 trial for the 1) UK study population as a whole and 2) by BAME versus non-BAME subgroups.

Analysis plans
Analyses will include descriptive statistics and between-group comparisons for each strategy using multivariate regression models. One interim analysis is planned 36 months after the start of the TICH-3 trial. We predict 1100 participants will have been enrolled in the UK by that time, and 850 will have reached the 180 day follow-up timepoint. If there is strong evidence of an effect on follow-up completion at 180 days of either control or intervention, the strategy showing the greatest return rate would then be implemented for all future participants. Otherwise, the SWAT will continue until the end of the TICH-3 trial.

Possible problems in implementing this SWAT
We do not envision problems implementing this SWAT given that most of the sites took part in the TICH-2 trial, so the demographics of the populations they serve are known. There may by problems ensuring that all participants at sites randomised to the SWAT intervention are given access to the animated video in an appropriate language, but we will ensure that the importance of consistently offering the animated video to all participants in the SWAT intervention group is stressed during the site initiation visit (SIV) and ongoing training events.

References
1. Boden-Albala B, et al., Examining Barriers and Practices to Recruitment and Retention in Stroke Clinical Trials. Stroke 2015;46(8):2232-7.
2. Cowan EA, et al. Spanish and English video-assisted informed consent for intravenous contrast administration in the emergency department: a randomized controlled trial. Annals of Emergency Medicine 2007;49:22130.
3. Wald DS, et al. Animation-supported consent for urgent angiography and angioplasty: a service improvement initiative. Heart 2020;106:1747-51.
4. Sprigg N, et al. Tranexamic acid for hyperacute primary IntraCerebral Haemorrhage (TICH-2): an international randomised, placebo-controlled, phase 3 superiority trial. Lancet 2018;391:2107-15.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Date of idea: 30/JUL/2019
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Date of revisions: