

SWAT 142: Use of a video animation to improve participant understanding, engagement and compliance with an intervention in a cluster randomised trial of stroke survivors

Objective of this SWAT

This SWAT aims to examine whether the addition of a video animation to the Get Set Go intervention increases participant and staff understanding, engagement and compliance with the intervention and whether this translates into a reduction in sedentary behaviour.

Study area: Intervention engagement

Sample type: Participants

Estimated funding level needed: Unfunded

Background

The RECREATE WS5 trial is a multicentre cluster randomised trial designed to evaluate the clinical and cost effectiveness of the Get Set Go intervention (ISRCTN82280581). The intervention will be delivered by NHS stroke services across the UK. NHS stroke services randomised to the intervention group will be trained to deliver the intervention, whilst those randomised to the control group will continue to deliver usual practice. This embedded SWAT will examine whether a video animation enhances engagement, understanding and compliance with the intervention and improves participant outcomes.

As part of their study to improve fidelity to a complex intervention following stroke, Bragstad et al. hypothesised that participant responsiveness and strategies to facilitate implementation could increase compliance to the intervention and thus improve outcomes (1). A feasibility study in Malaysia found positive responses to video narratives as part of stroke care, indicating that stroke survivors can find video-based interventions useful (2). Studies have also considered that intervention delivery may be hindered by busy settings, such as stroke wards (3).

We hypothesise that a video animation could increase participant understanding of the intervention, resulting in improved engagement and compliance with the Get Set Go intervention. It should help participants to feel that the intervention is targeted towards people like them. Being able to watch the video at home will allow them to re-watch the video and process the information in a comfortable setting, rather than receiving the information only at discharge when a lot of additional information is provided.

Interventions and comparators

Intervention 1: Intervention: RECREATE Get Set Go intervention plus video animation

Intervention 2: Control: RECREATE Get Set Go intervention only

Index Type: Participant Information, Video animation

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Mean daily sedentary time as measured by the activPAL (activity monitor) at 6 months.

Secondary: Secondary outcomes will be time spent in sedentary behaviour derived from the activPAL (activity monitor) data at 12 months and NEADL outcome score at 6 months.

In addition, compliance to the intervention and acceptability of the video will be measured via the 12-week assessment form which asks intervention participants about their engagement with the intervention. These might include, for example, how frequently they viewed the video and if they had problems accessing it. We will also explore the use of website analytics, which will be completely anonymous and provide information on site level access only. Stroke survivor and staff opinion on the animation, its usefulness and their engagement with the video will be a component of the process evaluation, which is examining intervention engagement generally.

Analysis plans

All patients recruited within a stroke service will be analysed according to the randomised allocation for that stroke service. All analyses and data summaries will be carried out using the intention to treat (ITT) population. The ITT population is defined as all patients registered for active follow-up regardless of non-compliance with the Get Set Go intervention or the video animation. Statistical significance will be assessed at the 5% level. Final analyses will take place when all participants complete follow-up at 24 months, after the database has been cleaned and locked.

Continuous variables will be summarised by mean, standard deviation (SD), median, minimum, and maximum, as well as interquartile range, if appropriate. Categorical variables will be summarised by frequencies and percentages. Summary statistics will be presented for each time point by allocation.

Because of the small number of clusters, analyses on the sedentary behaviour and NEADL outcomes will use a two-stage approach for an adjusted analysis of cluster-level summaries (4). Continuous distributions will be transformed where residuals are non-normal.

Compliance to the intervention will be measured at the 12-week assessment only and will be analysed using descriptive summary statistics by allocation. This will include information on viewing the animation and its usefulness. Participant opinion on the animation, its usefulness and their engagement with the video will be assessed in semi-structured interviews as part of the process evaluation.

Possible problems in implementing this SWAT

Participants may not have the resources to access the animation online. To address this, the animation will be made available in alternative formats (e.g. USB stick or CD/DVD) if the online format is not acceptable.

There may be variation between stroke services but we have tried to address this using stratification in the cluster randomisation process.

References

1. Bragstad LK, Bronken BA, Sveen U, et al. Implementation fidelity in a complex intervention promoting psychosocial well-being following stroke: an explanatory sequential mixed methods study. *BMC Medical Research Methodology* 2019;19(1):59.
2. Appalasamy JR, Joseph JP, Ramaiah SS, et al. Video Narratives Intervention Among Stroke Survivors: Feasibility and Acceptability Study of a Randomized Controlled Trial. *JMIR aging* 2020; 3(2):e17182.
3. McInnes E, Dale S, Craig LE, et al. Process Evaluation of the T3 Trial: A Nurse-Initiated Intervention to Improve Stroke Care in the Emergency Department. *International Journal of Stroke* 2018;13(2 suppl 1):197.
4. Hayes RJ, Moulton LH. *Cluster randomised trials*. CRC press: 2017.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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