SWAT 232: Use of telephone follow-up with text or WhatsApp message summary versus telephone follow-up alone to trial participants to improve trial retention.

Objective of this SWAT
To test the effectiveness of follow-up telephone calls with summary text or WhatsApp messages versus follow-up telephone calls alone, to be delivered to trial participants with poststroke cognitive impairment between completion of a cognitive rehabilitation intervention assessment and 4-month post-intervention follow-up assessment.

Additional SWAT Details
Primary Study Area: Retention
Secondary Study Area: Qualitative
Who does the SWAT intervention target: Participants
Estimated resources needed to conduct the SWAT: Low
Estimated cost of the SWAT (£): 12,600

Findings from Implementation of this SWAT
Reference(s) to publications of these findings:
Primary Outcome Findings:
Cost:

Background
Clinical trials can provide evidence about which interventions work. However, recruiting and then retaining sufficient trial participants is necessary to avoid delays in trial completion, and to ensure confidence in trial results. Retention or loss to-follow-up, in particular, remains an ongoing challenge, and is one of the top 3 priorities for methodological research into clinical trials (1). A 2017 UK study found, for example, that the median loss-to-follow up in a sample of 151 trials was 11% (2). A Cochrane Methodology Review identified 81 eligible trials of strategies to improve retention in randomised trials, however the evidence was limited. Most eligible studies focused on the return of postal or electronic questionnaires and associated strategies to incentivise this (3). The review highlighted the lack of research into methods to improve retention in trials, confirming that many questions and uncertainties remain (4).

This Study Within a Trial (SWAT) will generate evidence on the effectiveness of regular telephone calls accompanied by summary text or WhatsApp messages as a communication strategy for improving retention, versus follow-up telephone calls alone. There is some, albeit limited, evidence that telephone follow-up has a positive impact on retention (5). The inclusion of a written text or WhatsApp summary in the communication, in addition to a telephone call, may assist trial participants where cognitive impairment is an issue. To date, there is no widely used rehabilitation intervention for cognitive impairment post-stroke, despite it being a very common post-stroke outcome. The relative absence of randomised trials on cognitive rehabilitation interventions post-stroke in turn means that there is an absence of data on issues and challenges of retention to post-stroke cognitive rehabilitation interventions. This compounds the pre-existing evidence gap on strategies to improve retention in trials.

This SWAT will be undertaken in a pilot cognitive rehabilitation RCT with consecutive stroke patients who have mild to moderate cognitive impairment following stroke (StrokeCog). It will be undertaken during a key period in the pilot RCT, between the immediate post-intervention assessment session and the 4-month post-intervention cognitive assessment for the intervention group, and during the matching time period for the control group. Patients will be further randomised to the SWAT intervention within the intervention group (N=32) and the control group (N=32).

This is a prioritised area for research, identified by the stakeholders for which this matters most, including patients and members of the public. This SWAT will provide evidence to inform one of the top twenty priority trial methodology research questions arising from the PRioRiTy II study,

which aimed to identify and prioritise important unanswered trial retention questions for research (4). The prioritised question is 6: How could technology be best used in trial follow-up processes?

Host Trial Population: Adults
Host Trial Condition Area: Stroke

Interventions and Comparators
Intervention 1: Intervention Arm:
Two follow-up telephone calls with a supporting summary text or WhatsApp message. The first communication intervention will be delivered one month after the immediate post-intervention assessment and the second will be delivered one month before the final 4-month post-intervention follow-up assessment.
Intervention 2: Comparator Arm:
Two follow-up telephones call delivered one month after the immediate postintervention assessment and the second delivered one month before the final 4-month post-intervention follow-up assessment. There will be no follow-up text or WhatsApp messages in the comparator arm.

Method for Allocating to Intervention or Comparator: Randomisation

Outcome Measures
Primary Outcomes: Retention in the host trial at the 4-month final post-intervention assessment, measured by numbers of participants retained to the StrokeCog trial in the SWAT intervention and comparator groups.
Secondary Outcomes: Cost of SWAT intervention per participant retained, measured by calculating costs of telephone and text/WhatsApp, and the cost of staff time spent administering the intervention.

Analysis Plans
The primary analysis will involve:
a. Quantitative analysis of the difference in retention rate between those receiving the telephone plus follow-up text or WhatsApp message, and those receiving the telephone intervention alone. These comparisons will be conducted using chi-square analysis.

b. Qualitative analysis of SWAT participant perceptions of the acceptability and effectiveness of an additional telephone with or without text or WhatsApp follow-up. A process evaluation will be conducted as part of the main pilot trial. Two or three additional questions will be added to the process evaluation to ask specifically about the SWAT intervention, asking patients for their views of the experience of contacts from the team in the interval between completion of the intervention and final follow-up assessment, or the matching time period for the control group.

Analysis of the proportion of patients withdrawing from the host trial before the 4-month post-intervention assessment will be presented as numbers and percentages. Comparisons between the SWAT intervention and control groups will be conducted using chi-square analysis.
Secondary analysis will assess the difference in cost per participant retained between those receiving the telephone follow-up plus text or WhatsApp summary, and those receiving telephone calls alone, to include assessment of telephone and text/WhatsApp costs, and the cost of staff time spent administering the intervention.

Possible Problems in Implementing This SWAT
Possible problems include difficulty in recruiting and retaining patients over the course of intervention delivery to the point of recruiting into the SWAT. This might diminish the effect of the intervention being assessed in this SWAT. The StrokeCog-R intervention has included steps to minimise this risk, such as follow-up communication with randomised patients in the acute-phase awaiting cognitive assessment; follow-up communication with patients in both the intervention arm and control arm during the StrokeCog intervention period to support ongoing engagement.

References Cited in This Outline

1. Tudur Smith C, Hickey H, Clarke M, et al. The trials methodological research agenda: results from a priority setting exercise. Trials. 2014;15(1):32. doi:10.1186/1745-6215-15-32.
2. Walters SJ, Bonacho Dos Anjos Henriques-Cadby I, Bortolami O, et al. Recruitment and retention of participants in randomised controlled trials: a review of trials funded and published by the United Kingdom Health Technology Assessment Programme. BMJ Open. 2017;7(3):e015276. doi: 10.1136/bmjopen-2016-015276.
3. Gillies K, Kearney A, Keenan C, et al. Strategies to improve retention in randomised trials. Cochrane Database of Systematic Reviews. 2021;(3):MR000032. doi: 10.1002/14651858.MR000032.pub3.
4. Brunsdon D, Biesty L, Brocklehurst P, et al. What are the most important unanswered research questions in trial retention? A James Lind Alliance Priority Setting Partnership: the PRioRiTy II (Prioritising Retention in Randomised Trials) study. Trials. 2019;20(1):593. doi: 10.1186/s13063-019-3687-7.
5. Johnson NA, Kypri K, Latter J, et al. Effect of telephone follow-up on retention and balance in an alcohol intervention trial. Preventive Medicine Reports 2015;2:746-9.

References to This SWAT

Source of This SWAT

People to show as the source of this idea: Professor Anne Hickey, Dr. Carlos Bruen, Dr. Catherine Moran
Contact email address: ahickey@rcsi.ie
Date of idea: 06/07/2020
Revisions made by:
Date of revisions: