SWAT 50: Comparison of the small modified Rankin Scale questionnaire with face-to-face modified Rankin Scale

Objective of this SWAT
To study the agreement between the Swedish small modified Rankin Scale questionnaire and a face-to-face modified Rankin Scale at 6 months post stroke.

Study area: Outcomes, Follow-up, Data Quality
Sample type: Patients, Participants
Estimated funding level needed: Very Low

Background
The modified Rankin Scale (mRS) is the most common outcome measure in stroke trials.[1] Many large trials have used mRS by telephone interview and postal questionnaire but the mRS has suboptimal reliability[2] and there is limited evidence about its reliability when used over the telephone.[3] The simplified modified Rankin questionnaire (smRSq) was developed to improve the mRS, with the aim of keeping the assessments simple and short, while preserving the construct and validity of the original mRS.[4-6] The smRSq consists of five questions that address the key function on each mRS, and has been found to have reasonable validity.
EFFECTS (www.effects.se; NCT02683213) is a Swedish academic-initiated, investigator-led multicentre, parallel group, randomised, placebo-controlled trial of fluoxetine for stroke recovery. The trial's primary objective is to investigate whether routine administration of fluoxetine (20mg daily) in the 6 months after an acute stroke improves the patient's functional outcome. The primary outcome in EFFECTS is the mRS measured with the smRSq. This SWAT will test the agreement between the Swedish translation of the smRSq and face-to-face investigation of the mRS at 6 months post stroke, filling a gap because agreement between smRSq and mRS has been validated in English but not in Swedish.[4-6]

Interventions and comparators
Intervention 1: The smRSq is sent to all patients in EFFECTS by the Trial Manager Assistant (TMA) at 6 and 12 months after randomisation. If the patient does not answer, the TMA telephones them as a reminder to return the questionnaire. If the patient finds it difficultl in answer for themself, TMA helps them fill in the form over the telephone. This smRSq is used to calculate a mRS score.
Intervention 2: In EFFECTS, patients re-visit their local center at 6 months and, for this SWAT, the mRS will be complete face-to-face and be compared to the postal or telephone smRSq. The study personnel who perform the face-to-face mRS will be blinded to the results of the smRSq.

Index Type: Method of Follow-up

Method for allocating to intervention or comparator
Non-Random

Outcome measures
Primary: Agreement between smRSq (postal or telephone) and mRS face-to-face at 6 months.
Secondary:

Analysis plans
The primary aim of the SWAT is to evaluate whether the mRs-score measured by the smRSq differs from the mRS-score measured by a clinician. A disparity of one step or more in the mRs-score would be a clinically significant difference. However, the number of patients in this SWAT will depend on the number needed for EFFECTS, and it is likely that 60 patients will be included in the analysis after enrolling up to 65 patients.
Statistical comparisons will test differences between dependent observations by using pair-wise Student's t-test for correlated means and the Student's t-test for uncorrelated means after validation for normal distribution with the Shapiro Wilk test. The Pearson correlation coefficient will be used to test independence between variables. Descriptive statistics will be used to characterize the data. The weighted and not weighted Kappa values will also be calculated.

Possible problems in implementing this SWAT

Delays if the necessary training of face-to-face training in mRS are not performed.

References

1. van Swieten JC, Koudstaal PJ, Visser MC, et al. Interobserver agreement for the assessment of handicap in stroke patients. Stroke 1988; 19: 604-7.
2. Quinn TJ, Dawson J, Walters MR, Lees KR. Reliability of the modified Rankin Scale: a systematic review. Stroke 2009; 40: 3393–5.
3. Janssen PM, Visser NA, Dorhout Mees SM, et al. Comparison of telephone and face-to-face assessment of the modified Rankin Scale. Cerebrovascular Disease 2010; 29: 137–9.
4. Bruno A, Shah N, Lin C, et al. Improving modified Rankin scale assessment with a simplified questionnaire. Stroke 2010; 41: 1048-50.
5.Bruno A, Akinwuntan AE, Lin C, et al. Simplified Modified Rankin Scale Questionnaire: Reproducibility Over the Telephone and Validation With Quality of Life. Stroke 2011; 42: 2276-9.
6. Dennis M, Mead G, Doubal F, Graham C. Determining the modified Rankin score after stroke by postal and telephone questionnaires. Stroke 2012; 43: 851-3.

Publications or presentations of this SWAT design

The SWAT has ethical approval as an amendment 6 of the host trial (2017-03-28 Dnr: 2017/638-32).

Examples of the implementation of this SWAT

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