GODIF

SOP for obtaining the long-term outcomes for the GODIF trial

These are the three outcomes that should be obtained at 1-year follow-up: Mortality, cognitive function, and Health-Related Quality of Life (HRQoL).

Retention strategies

- When obtaining patient consent, please ensure that the patients are informed about the 1-year contact
- Similarly, inform the relatives about the 1-year follow-up when obtaining their consent
- If the patients cannot be reached at 1-year follow-up, aim to contact the patient daily during the following 4 weeks until 1-year follow-up is obtained
- If the patient is assumed to be at work, then try to make contact during the late afternoon
- If the patient chooses to answer by e-mail (or post) the time for obtaining answers is extended by another 4 weeks, with a reminder 2 weeks after the e-mail/letter has been posted. Remark that cognitive function can only be assessed by telephone.

We cannot contact any participants who rejected to be contacted or were withdrawn with the demand of no further data registration.

Procedure at 1-year follow-up:

1. Assure patient is alive
2. Contact the patient first weekday 1 year after randomisaiton
3. Ask the patient to sit in an undisturbed room **without a clock or calendar**.
4. 1st obtain MoCA 5 min
5. 2nd obtain EQ-5D-5L + EQ-VAS
6. Not obtainable -> register cause in eCRF

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Paper questionnaires are used for the telephone interview. The papers can be used while interviewing the patients. Afterwards, the answers must be entered into the GODIF e-CRF or you can enter the answers directly in the e-CRF. The paper questionnaires are not to be filed but discarded according to local regulations for paper with patient data. Please read the instructions for both questionnaires beforehand, to obtain as objective answers as possible.

Cognitive function is assessed with a 4-item questionnaire. The official MoCA 5 min is a shorter version than the full MoCA. The MoCA 5 min only takes 5 minutes, and you will need the instructions (short guide) together with the questionnaire. MoCA requires certification to conduct the cognitive function assessment, which covers the full MoCA. MoCA 5 min can only be assessed by telephone or face to face and not by mail.

HRQoL is assessed with EQ-5D-5L. It is a 5-item questionnaire together with a VAS scale score and takes 5 minutes. We recommend conducting the interview by phone, but it is also possible to answer the questionnaire by mail. If the patient is too frail or cognitively impaired to consistently complete EQ-5D-5L, try to obtain the patients HRQoL from relatives (there is a specific questionnaire for relatives). The relative assesses the HRQoL from the relative's point of view. Please contact us if you need questionnaires for sending in the mail or to the relatives.

MoCA certification: This is done here: https://www.mocatest.org/training-certification/ and takes 1 hour. The full MoCA instructions are very helpful. The training and certificates are free for academic researchers or publicly operated healthcare institutions. You need to apply, and they will require proof of your status. They normally accept a copy of your paycheck as documentation for your position. Please send the coordinating centre a copy of the certificate. If you cannot get the certification for free – please contact the coordination centre.

Charges: case money contains coverage of long-term follow-up. If there is a central person conducting all follow-ups in a country, we kindly ask you to solve this internally.

Coordinating centre: godif.@cric.nu