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Study protocol for a randomized controlled trial on the effectiveness of Advance Care Planning (ACP) in general practice

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Background

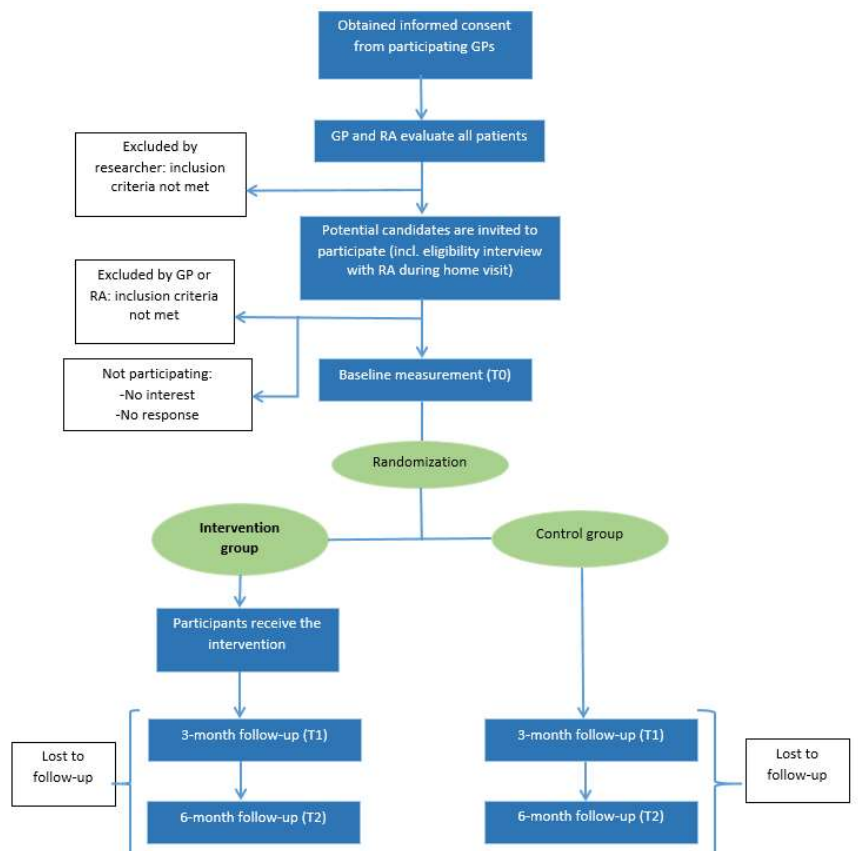
General practice is an optimal setting for ensuring timely initiation of ACP discussions. A multi-component ACP intervention developed for the general practice setting, aimed at patients with chronic life-limiting illnesses (life expectancy up to 24 months) and their general practitioner, has been pilot tested. The aim of this study is to evaluate the effectiveness of this intervention and to evaluate its implementation by means of a process evaluation.

Methods/Design: A cluster-randomized controlled trial (RCT) (randomization at the practitioner level, n=20 practitioners per condition, n=80 patients per condition), to compare the structured ACP communication intervention to usual care.

Primary endpoint: Patient's readiness to engage in ACP (ACP Engagement Survey, 4-item). Other patient outcomes: health-related quality of life, symptoms of anxiety or depression, appointment of a surrogate decision-maker.

Practitioner outcomes: ACP self-efficacy (ACP-SE), ACP knowledge and attitudes, and documentation of ACP discussions in the patient electronic medical file.

Following the RE-AIM framework, structured diaries for trainers and general practitioners, as well as qualitative interviews with general practitioners, patients and family caregivers are among the measures used for the process evaluation.



Discussion

After this Phase III RCT, we will be able to present a well-tested and evaluated ACP intervention that can be implemented in general practice. The results of the process evaluation will provide insight needed to allow adaptation of the intervention for a greater variety of national and international contexts.

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