

Methodology of the Stroke Self-Management Rehabilitation Trial: An International, Multisite Pilot Trial

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Rationale: Stroke is a major cause of long-term adult disability with many survivors living in the community relying on family members for on-going support. However, reports of inadequate understanding of rehabilitation techniques are common. A self-management DVD-based observational learning tool may help improve functional outcomes for survivors of stroke and reduce caregivers' burden. *Aims:* This article describes the methodology of the stroke self-management rehabilitation trial. The overall aim of this pilot trial is to assess the feasibility and preliminary efficacy of a DVD-based intervention for improving functional outcomes of survivors of stroke 2 months postrandomization to inform the design of a full-scale randomized clinical trial. *Design:* Recruitment of a minimum of 20 survivors of stroke and their informal caregivers (where available) in each of the participating centers will occur across multiple international sites. After baseline assessments, participants will be randomly assigned to an intervention or standard care group. The intervention comprises a structured DVD observation and practice schedule over 8 weeks. All participants will complete follow-up assessments. *Study outcomes:* The outcome measures will include a global shift in the Rankin Scale scores and dichotomized scores, changes in quality of life, general health, depression, and caregiver burden at 2 months postrandomization. A qualitative analysis of the effects of the intervention will also be undertaken. *Discussion:* The results of the pilot study will provide knowledge of whether observational learning techniques delivered via DVD can

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effectively improve recovery after stroke and reduce caregiver burden. **Key Words:** Stroke—rehabilitation—clinical trials—methodology—protocols—treatment.
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Introduction

Stroke is a leading cause of long-term disability, with recent projections forecasting a worldwide rise to 200 million disability-adjusted life years lost per annum by

2030.¹ After acute hospitalization, at least 45% of stroke survivors return home usually relying on family members for any further care and support.²⁻⁴ Caregivers often report insufficient knowledge or skills to care for

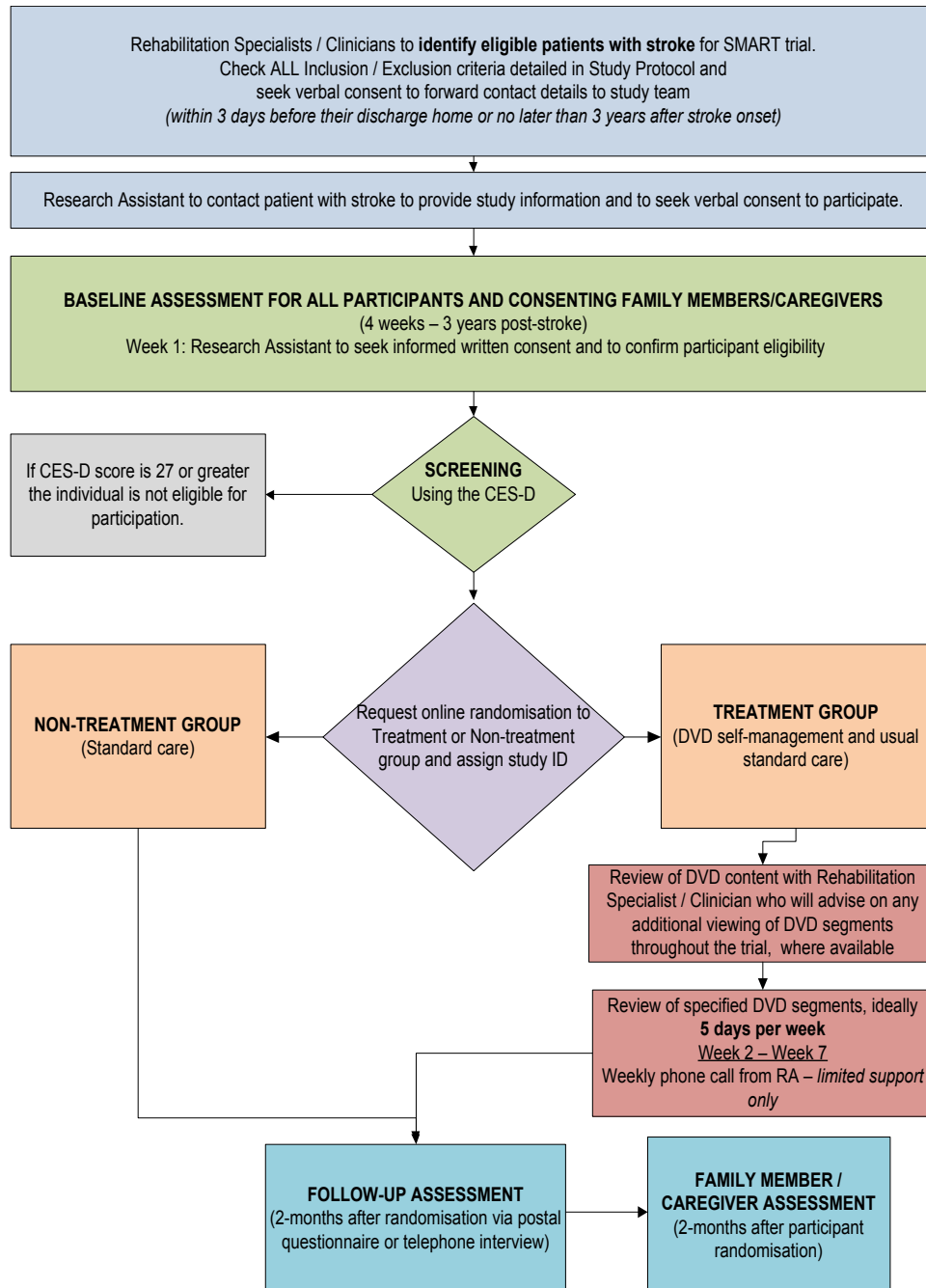


Figure 1. Standard trial design. Abbreviation: CES-D, Center for Epidemiological Studies—Depression.¹³

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