The ExStroke Pilot Trial: Rationale, design, and baseline data of a randomized multicenter trial comparing physical training versus usual care after an ischemic stroke

Lars-Henrik Krarup a,b,*, Christian Gluud b, Thomas Truelsen a, Anders Pedersen a, Marianne Lindahl a, Lotte Hansen a, Sascha Michelsen a, Grethe Andersen c, Xianrong Zeng d, Janika Körv e, Adam Oskedra f, Gudrun Boysen a
ExStroke Pilot Trial Group
a Department of Neurology, Bispebjerg Hospital, Copenhagen University Hospital, Denmark
b Copenhagen Trial Unit, Center for Clinical Intervention Research, Rigshospitalet, Copenhagen University Hospital, Denmark
c Department of Neurology, Aarhus University Hospital, Denmark
d Department of Neurology, Sichuan Provincial People's Hospital, Chengdu, China
e Department of Neurology and Neurosurgery, University of Tartu, Estonia
f 2nd Department of Neurology, Institute of Psychiatry and Neurology, Warsaw, Poland

Received 25 May 2007; accepted 25 September 2007

Abstract

Introduction: A high level of physical activity is associated with a decreased risk of first stroke and physical activity modifies recognized stroke risk factors and is recommended for stroke survivors. Available research shows that stroke patients can increase their level of physical performance over a short period. When the intervention period is over, physical performance often declines towards baseline level. Currently, there is no evidence on the association between physical activity and the risk of recurrent stroke. The ExStroke Pilot Trial is a randomized clinical trial with the aim of increasing stroke patients' level of physical activity and secondarily to associate the level of physical activity to the risk of recurrent stroke, myocardial infarction, and all-cause mortality in the two groups. We describe the rationale, design, and baseline data of the ExStroke Pilot Trial.

Methods: Patients with ischemic stroke above 39 years were randomized to intervention or control group. The intervention group will, over a 2-year period, receive information on and verbal instruction to exercise by a physiotherapist or a physician. The control group will receive the department's usual care. Physical activity is assessed in both groups seven times during follow-up using the Physical Activity Scale for the Elderly (PASE) questionnaire, which quantifies the amount of physical activity done in the last seven days prior to interview. The PASE score constitutes the primary outcome measure. The secondary outcome is the time from randomization to recurrent stroke, myocardial infarction, or all-cause mortality. Further outcome measures include: time from randomization to recurrent stroke, myocardial infarction, and vascular death; recurrent stroke; modified Rankin Scale: quality of life; occurrence of falls and fractures.

* Corresponding author. Bispebjerg University Hospital, Department of Neurology, Bispebjerg Bakke 23, DK-2400 Copenhagen NV, Denmark.
Tel.: +45 35 31 27 54; fax: +45 35 31 61 12.
E-mail address: lh.krarup@gmail.com (L.-H. Krarup).

1551-7144/$ - see front matter © 2007 Elsevier Inc. All rights reserved.
doi:10.1016/j.cct.2007.09.008