SERVED Memory: Feasibility study of Screening & Enhanced Risk management for Vascular Event related Decline in Memory

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Country

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Title of project or programme

SERVED Memory: Feasibility study of Screening & Enhanced Risk management for Vascular Event related Decline in Memory

Source of funding information

RfPB Competition 18 - East of England

Total sum awarded (Euro)

€ 339,454

Start date of award

01/09/2015

Total duration of award in years

2.5

Keywords
Research Abstract
Background

Dementia after a cerebrovascular event is common; up to a third of patients show signs of dementia as early as 3 months post event. Furthermore, mild cognitive deficits are detectable in a significant proportion of patients presenting with stroke/TIA and this appears to be related to

the number of vascular risk factors. Controlling individual risk factors (e.g. blood pressure) may be beneficial in reducing the risk of subsequent dementia. However, to date no definitive trial evidence exists that enhanced, target driven multiple risk factor control in stroke/TIA patients who are at risk of cognitive decline would be clinically effective, cost effective, and safe.

Aims

The proposed project aims to evaluate the feasibility of conducting a randomised controlled trial (RCT) in an NHS setting on patients following stroke and TIA who are at risk of further cognitive decline. We aim to target risk factors more intensively through closer monitoring and enhanced control of vascular risk factors (VRF) compared to usual care. A secondary aim is to examine the link between the extent of risk factor control and subsequent cognition in this patient population.

Plan of investigations

We will offer a simple and validated cognitive screening test (Montreal Cognitive Assessment (MoCA)) to all stroke and TIA patients with life expectancy >1 year. Those with mild-moderate cognitive impairment (MoCA 20-25) will be invited to take part in the feasibility trial. Those who have normal cognition and those who are eligible but not interested in the feasibility trial will be invited to a parallel observational study.

Participants of the feasibility trial will be randomly assigned to control group (treatment as usual i.e. annual targets set for general population) and intervention (enhanced risk factor management) group. The intervention will comprise individualised targets and closer monitoring (at 3, 6, and 9 months) of risk factors including blood pressure, cholesterol level, atrial fibrillation and diabetes. In both groups, further cognitive testing will be carried out again at 6 months. Final follow up with repeat cognitive testing will be carried out at 1 yr in all groups.

We will assess (1) the feasibility of opportunistic routine memory testing at clinic/hospital attendance;(2) feasibility of randomising (willingness to participate by patients) those who have cognitive impairment into routine risk factor management and enhanced risk factor management with individualised targets for controllable risk factors;(3) willingness of clinicians to recruit and manage closely;(4) acceptability and logistics of process involved by patients and carer/family, GPs and staff e.g. following up more frequently than usual (recruitment rates and logistics);(5) potential clinical benefit and the potential cost-effectiveness in order to estimate the sample size for a future definitive multi-centre multiple intensive risk factor intervention; and (6) adverse events with enhanced risk factor control.

Combining the control arm of the trial with the observational group will provide further information on the relationship between the number of risk factors, their level of control and cognition after stroke/TIA with routine management to help us to better understand the magnitude of effect of the intervention.

Potential benefits

Cognition is not assessed routinely in the NHS in this high risk patient population. The World Alzheimer Report (2010) emphasised the benefits of early diagnosis and intervention. If the feasibility trial shows promising results a definitive trial can be rolled out across the NHS through established NIHR Research Networks. If the definitive trial is positive, cases of vascular dementia can be delayed or prevented with enormous potential benefit for both patients and NHS services. Additionally, by enhanced risk factor management, the co-morbidity burden to NHS will be reduced e.g. preventing further stroke and subsequent disability/further memory decline.

Further information available at:

Types:
Investments < €500k

Member States:
United Kingdom

Diseases:
N/A

Years:
2016

Database Categories:
N/A

Database Tags:
N/A