MAESTRO: the effects of a multidisciplinary care programme for elderly persons with stroke who are admitted to a nursing home for rehabilitation and return home after discharge.

Published: 08-09-2010
Last updated: 01-05-2024

Primairy objective: The primary objective of this study is to get insight in the effect of the multidisciplinary integrated care programme on self-help, social participation and experienced quality of life of elderly stroke patients. And the effect...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON38341

Source
ToetsingOnline

Brief title
Multidisciplinary Aftercare for Elderly persons with Stroke (MAESTRO)

Condition

- Neurological disorders NEC

Synonym
Cerebrovascular accident, Stroke

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: aftercare, quality of life, social participation, Stroke

Outcome measures

Primary outcome

Primairy outcome measures of the patients:

- ability to live independently will be measured with the dutch version of the

Frenchay Activity Index, the MODI-FAI .

- functional status will be measured with the Katz-15 questionnaire.

- perceived quality of life (disease specific) will be measured with the Stroke

Specific Quality of Life Measure.

- social participation will be measured with the *Impact on participation en

autonomy (IPA)*.

Pimairy outocme measuresof the informal caregivers:

- objective care burden will be measured with the Erasmus iBMG meetinstrument.

- perceived care burden will be measured with the Self-Rated Burden Vas en

Carer Quality of life questionnaire

Secondary outcome

Secondary outcome measures of the patients:

- perceived health will be measured with the RAND-36.

- perceived quality of life (general) will be measured with the RAND-36, a

grade for the current life (Cantril*s Self Anchoring Ladder)

- psychological wellbeing will be measured with the RAND-36.

- social functioning will be measured with the RAND-36

Secondary outcome measures of the informal caregivers:

- percieved quality of life wll be measured with the RAND-36 and a grade for

the current life (Cantril*s Self Anchoring Ladder).

- perceived health will be measured with the RAND-36.

Study description

Background summary

Stroke is one of the major causes of loss of independence, decreased quality of life and mortality among elderly people. Each year, about 41,000 people in the Netherlands suffer a stroke and the associated functional impairments. The incidence of stroke strongly increases with age. Among persons aged 65 to 69, the incidence of stroke is 5.1 per 1000 people, rising to 37.7 per 1000 among those aged 95 years or over. Due to the multidimensional problems related to stroke, care for stroke patients is complex, even more so for elderly stroke patients because of multimorbidity. The Dutch health council recently recommended that special attention be paid to older people with multimorbidity. Furthermore, the Dutch associations for stroke patients (Samen Verder) and people with non-congenital brain damage (Cerebraal)) also draw attention to an important problem in the care for this group of senior citizens: the lack of adequate aftercare after rehabilitation in a nursing home. Of those experiencing stroke about 85% is admitted to hospital. After discharge from hospital, 8% is admitted to a rehabilitation centre, and 15% to a nursing home for rehabilitation. The group of patients admitted to a nursing home is older, frailer and have more complex care needs compared to the younger, more vital patients referred to a rehabilitation centre. Both groups receive rehabilitation treatment for a certain period in order to be able to function (largely) independently again. Compared to younger stroke patients who continue rehabilitation at home through a tailor-made day care programme after discharge from the rehabilitation centre, care for elderly patients discharged from

nursing homes is far less tailored to their specific individual situations and needs, while their health problems are substantially more complex. Elderly stroke patients usually receive primary healthcare after discharge from nursing homes. Cooperation between the various primary care professionals, however, is often limited, with the multidimensional health problems that in the subacute phase led to admission to a nursing home for multidisciplinary treatment being continued by individually working healthcare professionals. In general, however, these primary care professionals have insufficient experience with the required integrated treatment, care and support of older stroke patients with complex care needs. This lack of tailor-made, specialized aftercare following rehabilitation in nursing homes results in this patient group being insufficiently able to cope with the remaining physical, cognitive and/or psychosocial impairments in their home environment. This prevents them from performing normal day-to-day activities, fulfilling social roles and maintaining the achieved functional level. Besides having negative consequences for these patients, these problems may also increase the burden of care for their informal caregivers. In recent years, many studies have focused on improving the quality and coordination of care
for stroke patients. The results of these studies have led to considerable improvements in the continuity of care for stroke patients in the acute and subacute stages. Currently, in the Netherlands, about 70 stroke chains of care have been implemented in regular care, and many hospitals, nursing homes and rehabilitation centres now house specialised stroke units. But aftercare for stroke patients still receives insufficient attention.
Although the introduction of care coordinators in Dutch primary care has led to an improvement in the logistic coordination of care, this is still insufficient in view of the target group*s complex care needs, which prevents them from reaching and remaining optimal levels of functioning.

Study objective

Primairy objective:
The primary objective of this study is to get insight in the effect of the multidisciplinary integrated care programme on self-help, social participation and experienced quality of life of elderly stroke patients. And the effect on the reduction of burden of care of carers.

Secondary objective(s):
The secundary objective of this study is to get insight in the effect on the adjustment of stroke care between health care professionals ans the health care consumption and its related costs.

Study design

The study design is a multicentre randomised controlled trial (RCT). Study participants will be randomly allocated in the intervention or control group.

The participants in the intervention group will receive the new multidisciplinary integrated care programme. The control group will receive care as usual. The study duration will be 36 months. The inclusion period will be 18 months and the intervention will have the duration between 2 and 6 months (depending of the patients issues). There will be a follow-up period of 12 months. The study will be conducted in four nursing homes in the South of the Netherlands.

Intervention

The transmural integrated care programme consists of three care modules;
1) working on recovery and learning to deal with impairments
2) self-management after stroke
3) education programme for patients and carers

The main goal of the programme is to give optimal support and treatment to as well the patients as the carers. This will be provided in the nursing home and at the patients home. The main objectives of the programme are improving self-help, social participation and quality of life of the patients. An other important objective is to reduce the burden of care of the carer. The programme has a duration of minimum 2 and maximum 6 months. The first care module will take place in the nursing home and the second care module at the patients' home. The part of the programme which wille take place in the nursng home will have a duration of minimum 1 and maximum 2 months. Th part of the intervention at the patients'homes will have a duration (depending of the exact problem) of minimum 1 and maximum 4 months. The exact duration will be variabel and depending of the health status and further demands of the patient and the carer.

Study burden and risks

We expect that the study will only form a minor burden for the participants. Both patients and their informal caregivers receive three measurement during a periode of 12 months. Data from the patients are collected by means of face to face and telephone interviews. Data from the informal caregivers are collected by means of self-administered questionnaires. For the patients allocted to the intervention group, after discharge, the new multidisciplinary integrated care programme will take place largely at the participants' home by a team of health care professionals. The risks related to the programme are comparableto the risks related to usual care. So there are no extra risks associated with the new programme. The new programme aims to support the patients in a way that leads to a positive effect on the ability to live independently, functional status, social participation, and quality of life of the patient. Furthermore the programme aims to support the informal caregivers and to reduce their care

burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) admitted to a stroke-unit in a nursing home
2) 65 years or older
3) community-dwelling before admission to the nursing home

Exclusion criteria

1) patients who are incapacitated

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-10-2010
Enrollment:	256
Type:	Actual

Ethics review

Approved WMO Date:	08-09-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-11-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-04-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-05-2012

Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL32492.068.10