The effectiveness of a nursing intervention to support family caregivers in end-of-life care: a cluster Randomised Controlled Trial

Published: 26-04-2019 Last updated: 15-05-2024

We hypothese that the new nurse-led supportive intervention will improve the well-being of family caregivers and decrease acute admissions.

Ethical review Positive opinion

Status Other

Health condition type Family issues **Study type** Interventional

Summary

ID

NL-OMON29019

Source

NTR

Brief title

InCaSu@home

Condition

Family issues

Health condition

Patients with cancer, or advanced organ failure or COPD or heart-failure.

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus Medical Center and Rotterdam University of Applied Sciences **Source(s) of monetary or material Support:** ZonMw (844001313)

Intervention

Psychosocial intervention

Explanation

Outcome measures

Primary outcome

The primary outcome is burden measured by the Self-Rated Burden Scale (SRB), 1 item.

Secondary outcome

Secondary outcomes are: - burden measured by the Caregiver Reaction Assessment (CRA), 24 items, - preparedness for caregiving measured by the Preparedness for Caregiving Scale (PCS), 8 items, - acute admissions of patients (incidence).

Study description

Background summary

Background Family caregivers are crucial in end-of-life care. However, family caregiving may experience burden and feel insufficiently prepared for their role. Although nurses in the primary health care are in a unique position to support family caregivers at home, few nursing interventions are available to support family caregivers in this context. Therefore, this study aims to evaluate the feasibility and effects of a structured nurse-led supportive intervention on family caregivers in end-of-life care at home. Design We will conduct a pilot cluster randomised controlled trial to evaluate the effects of a new nurse-led supportive intervention on the well-being of family caregivers at home. The clusters will consist of home care services in the southwest of the Netherlands. Population The study population will consist of 184 family caregivers of terminal ill patients receiving home care.

Study objective

We hypothese that the new nurse-led supportive intervention will improve the well-being of family caregivers and decrease acute admissions.

Study design

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Family caregivers (both intervention- and control group) will be invited to complete the questionnaires at 2-4 time points: - at baseline (T0), - one months after baseline (T1), - two months after baseline (T2), - 4-6 weeks following the patient's death (T3).

Intervention

A structured nurse-led intervention to support family caregivers in end-of-life care at home. The control group will receive care as usual.

Contacts

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Eligibility criteria

Age

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

Inclusion criteria

- Family caregivers of patients with a life-expectancy up to six months (identified by the Surprise Question), - 18 years or older, - able to provide written informed consent, - and able to complete Dutch questionnaires.

Exclusion criteria

- Family caregivers of patients who had 2 weeks maximum to live.
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Study design

Design

Study phase: N/A

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Control: N/A, unknown

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Other

Start date (anticipated): 14-06-2019

Enrollment: 184

Type: Actual

IPD sharing statement

Plan to share IPD: No

Plan description

N/A

Ethics review

Positive opinion

Date: 26-04-2019

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

ID: 48129

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register ID

NTR-new NL7702

CCMO NL68453.078.18 OMON NL-OMON48129

Study results

Summary results

N/A