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Improving quality of life for south Tyrolean palliative patients in home care

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29/08/2014

Recruitment status
No longer recruiting

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23/09/2014

Overall study status
Completed

Last Edited
23/09/2014

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Palliative care is an approach to improve the quality of life of patients suffering from a serious fatal illness and their families. Consideration of physical, psychosocial and spiritual domains and best symptom control are very important in palliative care. Patients, family caregivers and health professionals such as nurses and general practitioners face high emotional demands. This emotional stress might affect the well-being and quality of life of both family caregivers and health professionals and thus affect patient care. General practitioners and nurses in collaboration with family caregivers and specialists are the supporting pillars for palliative home care in rural areas like South Tyrol. Palliative care in general and particularly palliative home care requires a high degree of commitment from all involved people and a good communication network. The results of an initial study show that palliative specialist home staff think quality of communication within the team is rather moderate, although it plays an important role in palliative care. This study addresses the need for intervention in the areas of team communication and cooperation, dialogue with patients and family, patient-centred care, and the handling of emotional stress of nurses and general practitioners. We want to show that solution-oriented clinical supervision can improve quality of care through improvement of communication techniques, interpersonal skills, better collaboration between health professionals (networking), and better cooperation with patients and family caregivers.

Who can participate?
Adult patients with terminal illness in palliative therapy in home care and their primary family caregiver, primary nurse and general practitioner. Together they constitute a palliative network, consisting of four people: patient, family caregiver, nurse and general practitioner.

What does the study involve?
Participating palliative network teams will be randomly assigned to one of the two study groups. In the intervention group, health professionals (general practitioners and nurses together) will receive a solution-oriented supervision (two times) by a psychologist in collaboration with a specialist physician. The control group will receive usual palliative home care. No direct intervention is planned for patients and family caregivers.

What are the possible benefits and risks of participating?
Expected benefits in the future are an improvement of the quality of care for palliative patients at home, interconnected with the possibility to discuss and solve problems under the guidance of a specialist supervisor. No risks are expected.

Where is the study run from?
South Tyrolean Academy of General practice (SAKAM Südtiroler Akademie für Allgemeinmedizin), Italy.

When is the study starting and how long is it expected to run for?
Recruitment began in August 2014; The study ends in July 2016.

Who is funding the study?
The South Tyrolean Cancer Support (Südtiroler Krebshilfe), Italy.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Improving quality of life for south Tyrolean palliative patients in home care: a randomized controlled trial of home-based palliative care

Study objectives

The key issues of the study are:
1. Impact of the intervention 'theme-centred supervision' on quality of care to patients in palliative home care.
Is the intervention likely to:
1.1. Improve the health-related quality of life of patients.
1.2. Improve the quality of care process.
1.3. Improve the satisfaction with care and symptom control of patients and reduce their anxiety and depression.
1.4. Improve the health-related quality of life of family caregivers and satisfaction with care; reduce their emotional burden and depression.
1.5. Improve the health-related quality of life of health professionals (nurses and general practitioners); reduce their work-related burden.
2. Evaluating the quality of care of the palliative care in South Tyrol (comparing territorial and in-patient services of the Palliative Care teams).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of Bolzano; 21/05/2014; ref. 30/2014

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Patients with terminal illness in palliative therapy treated at home

Interventions
Randomization method: block random assignment. 19 health districts (home care services) will be randomly assigned to either the intervention or control group. The randomization will be generated by Microsoft Excel with the help of an independent statistician. Because of the size inequality of the 19 health districts, the number of working nurses will be determined and considered as the weighting factor for randomization. Random numbers will be multiplied with this weighting factor to create an order list for all 19 health districts. To achieve an approximately equal sample size for the two groups, health districts will be recruited in short blocks block size of 4 with a 1: 1 allocation, so that half of them can be allocated to group A (= intervention group) and the other half to B (= control group). An ABBA-design will be used to counterbalance the odd number of health districts.

Intervention:
The solution-oriented supervision for health professionals (nurses and general practitioners) is structured and standardised, based on systemic orientation. Communication, conversation and quality of relationship in the context of palliative home care are crucial. The supervision meetings are run by a psychologist (supervisor) and a physician. They will be focused on the following topics: (1) reflection of the applied individual forms of conversation of the health

professionals; (2) imparting of conversation techniques and strategies of clearly structured courses of conversation; (3) reflection about forms of the professional relationship level between health professionals and patients as well as relatives; (4) roles of care; (5) knowing, training and adjusting relevant communication techniques and strategies. The supervision meetings will take place twice in the period of one to two months (first meeting: one month after baseline assessment; second meeting: two to three and a half months after baseline). Participants (health professionals) will be asked about their satisfaction with the intervention, perceived changes in the care process, about their expectations, aims, and positive and negative experience. Protocols, observations, and statements of the participants as well as the superintendents will also be used for evaluation.

Control:
The control group only serves for comparison (standard care process, how it is usual in South Tyrol and they will not have additional intervention). Measurements (three times) take place in the same way as in the intervention group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Health-related quality of life (HRQOL) of patients.
Measurements are taken three times:
1. Baseline,
2. Two months after baseline (during intervention, between intervention 1 and intervention 2)
3. Six months after baseline (after intervention)
HRQOL of Patients measured by:
FACT-G (Functional Assessment of Cancer Therapy - general; Version 4): This patient self-reported questionnaire is the core instrument of the Functional Assessment of Chronical Illness (FACIT) for patients with any form of cancer. It consists of 27 items which can be classified to four QOL domains: Physical Well-Being (7 items; range 0 - 28), Social/Family Well-Being (7 items; range 0 - 28), Emotional Well-Being (6 items; range 0 - 24), and Functional Well-Being (7 items; range 0 - 28). Patients rate items using a five-point Likert scale (0 4). For each of these domains a summary score can be calculated, where high scores indicate a high level of well-being. A total score can be obtained by summarising all individual subscale scores (Webster, Cella & Yost, 2003).

Key secondary outcome(s))
1. Quality of care: POS (Palliative care Outcome Scale)
The questionnaire is a Patient-Reported Outcome Scale which measures outcomes and assesses quality of care in palliative care patients. The questionnaire consists of two almost identical scales one for patients and one for health professionals and caregiver - each of them consists of 11 items, which can be rated on a Likert scale from 0 to 4. Physical, psychosocial, spiritual, organizational and practical domains of palliative care can be measured with it. With the last item, an open question, patients and health professionals or caregivers are asked to indicate the main problem of the care process (Hearn & Higginson, 1999).

2. Patient-related secondary outcomes:
2.1. Symptom control measured by the scales of the FACT-G and POS

2.2. Anxiety and depression measured by the HADS (Hospital Anxiety and Depression Scale). This self-assessment questionnaire consists of 14 items, rated on a Likert scale from 0 3. Two scores can be calculated: HADS-A (7 items) and HADS-D (7 items) which range from 0 to 21 (Snaith, 2003).
2.3. Satisfaction with care (incl. communication and support) measured by a self-constructed Visual Analogue Scale (VAS); scale items can be rated along a continuous line between the two end-points 0 = unsatisfied and 100 = satisfied.
2.4. Sense of Coherence measured by the short-form of the Sense of Coherence Scale (SOC 13). This instrument consists of 13 items, which can be rated on a 7-point Likert scale. The theory of the Sense of Coherence is based on Antonovskys salutogenic approach. The Sense of Coherence as a personal resource is composed of the following three components: Comprehensibility, Manageability and Meaningfulness. The 13 items can be assigned to one of the three components (Antonovsky, 1987).
3. Family caregiver-related secondary outcomes:
3.1. HRQOL of family caregivers measured by the SF-12 (Short-Form Health Survey - 12 items). The Short-Form Health Survey is a self-reported generic health status measure. The questionnaire consists of 12 items assigned to eight subdomains: physical functioning (2 items), role physical (2 items), bodily pain (1 item), general health (1 item), vitality (1 item), social functioning (1 item), role-emotional (2 items), and mental health (2 items). In sum, two main quality of life scores can be assessed: physical and mental health (Ware et. al., 1996).
3.2. Depression measured by the Becks Depression Inventory (BDI-II). This self-reported questionnaire, consisting of 21 items, is an instrument to detect depression. Each of the items corresponds to a symptom of depression listed in the DSM-IV Classification. 19 items can be rated on a 4-point scale (0 to 3), whereas for the two items regarding appetite and sleep there are seven options to assess changes indicating an increase or decrease of the behaviour (Beck et. al., 1996).
3.3. Care-related burden: measured by the German adapted version of the Burden Scale for Family Caregivers (BSFC). This self-reported instrument, consisting of 28 items, is used to measure potential burden among family caregivers caring for a relative at home (Gräßel, 2001).
3.4. Satisfaction with care (incl. communication and support) measured by a self-constructed Visual Analogue Scale (VAS). Scale items can be rated along a continuous line between the two end-points 0 = unsatisfied and 100 = satisfied (the last measurements are taken also after the patients death).
3.5. Sense of Coherence: SOC 13
4. Health professionals-related secondary outcomes:
4.1. HRQOL of health professionals measured by the SF-12
4.2. Emotional Strain, Depression, Burnout measured by the work-related instrument COPSOQ (Copenhagen Psychosocial Questionnaire). The questionnaire is applied to assess psychosocial factors at work and is based on the consistence of 87 items which can be assigned to 25 scales. Four distinctive main constructs can be summarized: demands, influence and possibilities for development, interpersonal relations and leadership, and strain (effects/outcomes). A broad range of theoretical aspects are integrated in the questionnaire: (1) The job characteristics model. (2) The Michigan organizational stress model. (3) The demand-control-(support) model. (4) The sociotechnical approach. (5) The action-theoretical approach. (6) The effort-reward-imbalance model. (7) The vitamin model (Nübling, Stößel, Hasselhorn, Michaelis, Hofmann, 2006).
4.3. Teamwork measured by the COPSOQ and a self-constructed Visual Analogue Scale (VAS). Scale items can be rated along a continuous line between two end-points 0 = worst and 100 = best.
4.4. Sense of coherence: SOC - 13

Statistical methods: to test differences between the intervention and the control group, independent tests will be computed if the dataset is normally distributed, otherwise the Mann-

Whitney U-Test will be used.
To test bivariate relationships, Pearson correlation coefficient will be used when normal distribution is assumed, otherwise the Spearmans rho will be calculated.
Chi-Square test will be used to test frequency differences between nominally scaled variables of the two study groups.
Covariance analysis will be performed to control possible distortion effects caused by the assumed deterioration of the patients diseases. Therefore, effects of severity and progression of the diseases will be considered as intervening variables in the analysis.

Completion date
31/07/2016

Eligibility

Key inclusion criteria
1. Patients with advanced illness in palliative therapy, in home care (assessment by general practitioner in cooperation with mobile nursing service)
2. Age 18 years or above
3. Able to understand and sign informed consent
4. Able to fill out the questionnaires
5. Cared by family caregiver, nurse and general practitioner at home
6. Primary caregivers of the patient treated at home: family caregiver, nurse, general practitioner

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Karnofsky-Index less than or equal to 20; ECOG 4 (assessment by general practitioner)
2. Patients with strong cognitive impairment (no Alzheimer or dementia patients)
3. Life expectancy less than 2 months

Date of first enrolment
01/08/2014

Date of final enrolment
31/07/2016

Locations

Countries of recruitment
Italy

Study participating centre
Via dei Vanga 18
Bolzano
Italy
39100

Sponsor information

Organisation
South Tyrolean Cancer Support (Südtiroler Krebshilfe) (Italy)

Funder(s)

Funder type
Other

Funder Name
South Tyrolean Cancer Support (Italy)

Funder Name
South Tyrolean Academy of General Practice (SAGP) (SAKAM Südtiroler Akademie für Allgemeinmedizin) (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration