

The PAMINO-project: evaluating a primary care based educational program to improve the quality of life of palliative patients

Submission date 02/04/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/04/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/09/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.pamino-bw.de/>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

F-PAMINO 01

Study information

Scientific Title

The PAMINO-project: evaluating a primary care based educational program to improve the quality of life of palliative patients

Acronym

PAMINO - Palliative Medical Initiative NOorth Baden

Study objectives

Patients of General Practitioners (GPs) who participated in the educational courses of the Palliative Medical Initiative NOorth Baden (PAMINO) have a higher quality of life at the end of their life than patients of general practitioners who did not participate in palliative care training.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee of the University of Heidelberg, March 2007, ref: 043/2007

Study design

(Prospective) two-armed controlled non-randomised evaluation study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

GP practice

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Oncological diseases

Interventions

This study compares the outcomes between a multifaceted-based interdisciplinary training concept in palliative care in a primary care setting and usual palliative care for patients with malignant tumours. We will compare GPs who have already completed the PAMINO course.

PAMINO contains a curriculum consisting of a qualifying training course, which is based on the training course of the German Medical Association (Bundesärztekammer) and the German Association for Palliative Medicine, as well as of subsequent network meetings and quality circles. The interdisciplinary training course is held at the University of Heidelberg and covers issues of psychology of pain, legal aspects, dialogues of clarification with patients, ethics and attitudes, pain therapy (in theory and case studies), symptom control and specialised pain therapy (including practical applications), dying and the requirements of dying people, communication and burn-out, palliation in geriatrics, and palliative care.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

As the primary outcome parameter, we observe the change of quality of life of patients in the intervention group (patients of general practitioners with PAMINO-training) compared to the control group (patients of general practitioners without PAMINO-training). Quality of life will be assessed by the German version of the Palliative care Outcome Scale (POS), and the Quality of Life Questionnaire Core-15 Palliative care (QLQ-C15-PAL) of the European Organisation for Research and Treatment of Cancer (EORTC).

All assessment tools (for patients, physicians, and family caregivers) are administered monthly from enrolment to either death of the patient or the end of the six-month observation period.

Secondary outcome measures

The training will have an effect on the following secondary outcomes:

1. A lower pain level as experienced by the patients and assessed by a Visual Analogue Scale (VAS)
2. Lower burden for family caregivers as assessed by the Burden Scale for Family Caregivers (BSFC)
3. Less utilisation of the health care system (primary and specialist care, nursing service) including emergency and hospital admittance
4. In a higher proportion of patients the favoured and actual site of death concur

The effects of the training on the following process indicators are observed:

1. Drug therapy, especially for pain, in adherence to the guidelines of the World Health Organisation (WHO)
2. Therapeutic elements of palliative medicine besides drug therapy
3. The existence of documents such as advance directives, do-not-resuscitate orders, and health care proxy, treatment plan
4. Prescription of pain medication
5. Realisation of substitution in case of unavailability of the treating family physician
6. Cooperation with nursing services

All assessment tools (for patients, physicians, and family caregivers) are administered monthly from enrolment to either death of the patient or the end of the six-month observation period.

Overall study start date

01/05/2007

Completion date

31/05/2009

Eligibility

Key inclusion criteria

1. The GPs participating in the study include consecutively adult outpatients (at least 18 years of age) of whom they are the family physician
2. Patients need to be in a palliative situation with an oncological disease
3. They have to give their informed and written consent to participate
4. Estimated life expectancy is six months at most

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

360

Key exclusion criteria

1. Patients with malignant tumours in a curative therapy situation or with an additional uncontrolled disease with a lower life expectancy than the tumour disease
2. Insufficient German language skills

Date of first enrolment

01/05/2007

Date of final enrolment

31/05/2009

Locations

Countries of recruitment

Germany

Study participating centre
University Hospital of Heidelberg
Heidelberg
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Sponsor information

Organisation

German Federal Ministry of Education and Research (Bundesministerium Für Bildung und Forschung [BMBF]) (Germany)

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Sponsor type

Government

Website

<http://www.bmbf.de>

ROR

<https://ror.org/04pz7b180>

Funder(s)

Funder type

Government

Funder Name

Bundesministerium für Bildung und Forschung (ref: 01GK0601)

Alternative Name(s)

Federal Ministry of Education and Research, BMBF

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/05/2007		Yes	No
Results article	results	15/01/2016		Yes	No