

Effectiveness of a nurse-led case management home care model in primary health care: A quasi-experimental, controlled, multi-centre study

Submission date 17/03/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 04/04/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 07/10/2008	Condition category Other	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PI0311611

Study information

Scientific Title

Acronym

ENMAD

Study objectives

A nurse-led case management home care system improves:

1. Functional status of the patients
2. Use of social and health resources
3. Satisfaction (both patients and caregivers)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committees of the Andalusian School of Public Health (Spain). Date of approval: 21/02/2003

Primary study design

Interventional

Study design

Quasi-experimental, prospective, multi-centre study, with a concurrent control group

Study type(s)

Other

Health condition(s) or problem(s) studied

Long term home care.

Interventions

Patients and main caregivers were allocated to either the intervention or control group, depending on whether or not they had access to home care services delivered in line with the new model by their Healthcare Centre.

The period for enrolment of subjects and inclusion in the sample started at the various healthcare centres six months after case management nurses initiated the programme. This gave nursing staff sufficient time to adapt to their new functions and roles.

Main activities:

1. Action Plan and Follow-up: Protocol-dependent home visits and care delivery plan
2. Data management: Clinical record, pilot sheet, registry of home care and information system
3. Co-ordination with other members of the Primary Care Basic Teams (PCBTs)
4. Referral criteria
5. Healthcare education guidelines, support to patients and caregivers
6. Review of target population census
7. Home care visit with integral assessment and detection of needs upon request from team members
8. Establishing co-ordination mechanisms with PCBTs
9. Designing and implementing co-ordination mechanisms with other institutions and professionals
10. Arranging technical assistance at home
11. Enrolment of new cases

12. Specific activities with caregivers
13. Taking part in commissions for ongoing assistance
14. Tele-care

Duration of interventions: 2.5 years (30 months)

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Patient's functional capacity (Barthel and Lawton-Brody scales) at 0, 2, 6 and 12 months
2. Satisfaction (SATISFAD, specific questionnaire validated for assessment of satisfaction with home care services) at 2, 6 and 12 months
3. Hospital admissions
4. Accident & Emergency (A&E) visits
5. Home visits by nurses
6. Social worker interventions
7. Physiotherapy sessions
8. Caregiver visits to healthcare centre
9. Patient visits to healthcare centre

Key secondary outcome(s)

1. Caregiver burden (Zarit test) at 0, 2, 6 and 12 months
2. Family role/function (APGAR family test) at 0, 2, 6 and 12 months
3. Cognitive function (Pfeiffer test) at 0, 2, 6 and 12 months
4. Quality of life (Euro-QoL 5D) at 0, 2 and 6 months
5. Institutionalisation
6. Mortality
7. Management of therapeutic regimen

Completion date

30/12/2006

Eligibility

Key inclusion criteria

Patients and caregivers initiating the Home Care (HC) programme launched by the Andalusian Healthcare Service and targeting some of the following population sub-groups:

Sub-group 1: Terminally ill patients with advanced stage, progressive, incurable, multi-symptomatic disease with no reasonable chance of responding to specific treatment, with estimated survival not exceeding six months

Sub-group 2: Dependent patients who require assistance for their daily activities (Activities of Daily Living [ADL]) and are immobilised at home, namely subjects not included in Sub-group 1 who, for whatever cause, are forced to spend most of their time in bed and/or require help to move, which prevents them from leaving home, except for rare exceptions

Sub-group 3: Patients not included in Sub-groups 1 and 2, recently discharged from hospital, requiring home care during a short period of time, most likely for under two months

Sub-group 4: Main caregivers for any of the patients described in the previous sub-groups

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

1. Institutionalisation or change of residence to an area not covered by the study, thus preventing the minimum follow-up required
2. Hospitalisation for longer than seven days, except for terminally ill patients who were readmitted for disease stabilisation and symptom control

Note: With these criteria in mind, the population potentially requiring home care services in the healthcare districts under the scope of the study was estimated at 1,032,333. Malaga with 50.93% of the total potential population was in a position to contribute the largest number of subjects to the study, followed by the Costa del Sol district with 20.46%, Almeria with 20.60% and lastly Granada with 8.55%.

Date of first enrolment

01/11/2003

Date of final enrolment

30/12/2006

Locations**Countries of recruitment**

Spain

Study participating centre

Cuesta del Observatorio s/n

Granada

Spain

18080

Sponsor information**Organisation**

Ministry of Health (Spain)

ROR

<https://ror.org/00y6q9n79>

Funder(s)

Funder type

Government

Funder Name

Spanish Health Research Fund of the National Health Ministry (Spain)

Results and Publications

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?
Results article	Results	23/09/2008		Yes	No