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# 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

**Registration date**
04/04/2008

**Overall study status**
Completed

**Last Edited**
07/10/2008

**Condition category**
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
PI031161I

# 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

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

### Primary study design
Interventional

### Secondary study design
Non randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Other

### Participant information sheet

### 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 measure
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

## Secondary outcome measures
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

## Overall study start date
01/11/2003

## 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

### Age group
Not Specified

### Sex
Both

### Target number of participants
286

### 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
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18080

# Sponsor information

**Organisation**
Ministry of Health (Spain)

**Sponsor details**
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**Sponsor type**
Government

**Website**
http://www.isciii.es

**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

## 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? |
|---|---|---|---|---|---|
| Results article | Results | 23/09/2008 | | Yes | No |