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Impact of an Educational Program in the Management of Community-Acquired Pneumonia

Submission date	**Recruitment status**	[X] Prospectively registered
21/08/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/10/2015	Respiratory	

Plain English summary of protocol

Background and study aims
We are carrying out an educational program before hospital discharge in patients hospitalised with community-acquired pneumonia. Our goal is decrease additional healthcare visits and rehospitalisation within 30 days of hospital discharge. We also want to look at the time to return to activities of daily living, degree of satisfaction and achievement of the objectives of the educational program.

Who can participate?
Adult patients aged 18 years and over, diagnosed with community-acquired pneumonia and requiring hospitalisation.

What does the study involve?
Participants will be randomly allocated to receive either conventional health information or the new educational program before hospital discharge. Patient and family or caregiver receive the educational program in two sessions each about 30-45 minutes long and receive an information leaflet about self-management. Prior to hospital discharge and 30 and 90 days after hospitalisation we will invite participants to answer a survey about their use of healthcare services and the educational program or conventional health information.

What are the possible benefits and risks of participating?
Patients in the conventional health information group receive health information according to standard clinical practice. Patients in the educational program group will have an opportunity to receive individual discharge planning to improve knowledge, skills and attitudes about self-management of community-acquired pneumonia. Information obtained from this study may help improve health education in patients hospitalized with community-acquired pneumonia. By taking part in this study there are no risks of physical injury or harm.

Where is the study run from?
Institute of Biomedical Investigations of Bellvitge (Institut d'Investigació Biomèdica de Bellvitge) (IDIBELL) (Spain).

When is the study starting and how long is it expected to run for?
The study started in November 2011 and will run until October 2014.

Who is funding the study?
Institute of Biomedical Investigations of Bellvitge (Institut d'Investigació Biomèdica de Bellvitge) (IDIBELL) (Spain).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
EDU001NEUM

Study information

Scientific Title
Impact of an EDUcational program in the management of Community-Acquired Pneumonia: a prospective randomised controlled trial

Acronym
EDUCAP

Study objectives
1. Patients admitted with diagnosis of community-acquired pneumonia who receive the health education program will have a significantly decreased healthcare resource utilisation during the month after discharge: readmissions and consultations to primary care and emergency department
2. The satisfaction degree with the information to discharge in the intervention group will be higher than the control group

3. Patients who receive the educational program will have a decreased time to return to normal activities than the control group
4. Patients receiving the education program will achieve the objectives of the program

On 05/09/2014 the following changes were made to the trial record:
1. The acronym was changed from IEPMCAP to EDUCAP
2. The study design was changed from 'Prospective randomised controlled trial' to 'Prospective randomised multicenter controlled trial'
3. The anticipated start date was changed from 05/10/2009 to 01/01/2011
4. The anticipated end date was changed from 29/07/2011 to 31/10/2014
5. The target number of participants was changed from '182 participants in each group (total = 364)' to '102 participants in each group (total = 204)'

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee of Hospital Universitari de Bellvitge, 08/10/2009, ref: AC064 /09

Primary study design
Interventional

Study design
Prospective randomised multicenter controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Community-acquired pneumonia

Interventions
Patients will be randomly assigned to receive the educational program during hospitalisation to improve their own understanding of the disease and self-care management at home. The control group will receive the conventional health education.

The educative program is based in the planning model of health educational program (PRECEDE). The nurse will carry out the educational program to the intervention group. The patient and family or caregiver will receive the educational program. The duration is approximately 30 - 45 minutes and the patient will receive the information leaflet. The objectives of the educational program are: improve the hydration of the patient, maintain a good disease control and improve the treatment adherence, balanced diet, progressive physical activity and smoking and alcohol gradual decline.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Epidemiological, clinical and evolutive characteristics during the admission
2. Healthcare resources utilisation (readmissions and consultations to primary care and emergency department) within 30 days subsequent to discharge

We will conduct a complete medical history to obtain epidemiological, clinical and evolutionary variables during the hospitalisation. To achieve the variables related to the healthcare resource utilisation, all patients will be followed up a month after discharge. All variables will be collected in a Statistical Package for the Social Sciences (SPSS) database.

Key secondary outcome(s)
1. Patient satisfaction
2. Time to return to normal activities
3. Intermediate objectives of the educational program

To achieve the variables all patients will be followed up a month after discharge. At 3 months, we also will assess the educational program through a telephone call. All variables will be collected in a Statistical Package for the Social Sciences (SPSS) database.

Completion date
31/10/2014

Eligibility

Key inclusion criteria
1. Adult patients (aged 18 years and over), either sex
2. Diagnosed with community-acquired pneumonia
3. Requiring hospitalisation in the Infectious Diseases and Respiratory Departments of Hospital Universitari de Bellvitge

Updated 05/09/2014:
3. Requiring hospitalisation in the Infectious Disease or Respiratory Disease Departments of Hospital Universitari de Bellvitge, Respiratory Disease Department or Home-care Service of Hospital Clínic de Barcelona and Respiratory Disease or Internal Medicine Departments of Hospital Universitari Arnau de Vilanova de Lleida

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Derived from a nursing home or extended care facility
2. Cognitive deficit
3. Do not understand Spanish or Catalan languages
4. No signed informed consent

Added 05/09/2014:
5. Immunocompromised patients

Date of first enrolment
01/11/2011

Date of final enrolment
31/10/2014

Locations

Countries of recruitment
Spain

Study participating centre
Servei de Malalties Infeccioses (Pl.12)
Barcelona
Spain
08907

Sponsor information

Organisation
Institute of Biomedical Investigations of Bellvitge (Institut d'Investigació Biomèdica de Bellvitge) (IDIBELL) (Spain)

ROR
https://ror.org/0008xqs48

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Institute of Biomedical Investigations of Bellvitge (Institut d'Investigació Biomèdica de Bellvitge) (IDIBELL) (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	13/10/2015		Yes	No