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Poster Abstract

Allocation strategy for a controlled clinical trial to assess the Expert Patient Program Catalonia™ clinical effectiveness on diabetes.

Paloma Amil, *Preventative and Health Care Programme for Chronic Conditions Catalonia - Department of Health, Spain*

Carme Boix, *Catalonia Midlands District Health Authority, Catalan Health Institute, Spain*

Asunción González-Mestre, *Preventative and Health Care Programme for Chronic Conditions Catalonia - Department of Health, Spain*

Núria Sala, *Catalonia Midlands District Health Authority, Catalan Health Institute, Spain*

Maria-Dolors Álamo, *Catalonia Midlands District Health Authority, Catalan Health Institute, Spain*

Pere Roura-Poch, *Catalonia Midlands District Health Authority, Catalan Health Institute, Spain*

Correspondence to: ***Pere Roura-Poch,*** Vic Hospital Consortium, Spain, *E-mail: proura@chv.cat*

Abstract

Introduction: In Catalonia, self-care support is being developed through the Expert Patient Program Catalonia™ (EPPC™) integrated from primary health care which provides specific courses (taught by a patient, an equal) to improve patients' self-care skills. Whereas there is some evidence on acquiring self-care skills and improving perceived health between patients participating in this courses, its clinical effectiveness (on diabetes control, for example) remains unclear. To determine the clinical outcomes from attendance at a diabetes course under EPPC™ and to assess its effectiveness, a multicentre controlled clinical trial was designed and was implemented. The intervention arm consisted on following a course edition (once a week sessions during nine weeks) and the control arm was do not follow it. The assignment to both arms was in two steps: a randomization to take part in the trial followed by a masked assignment to one of both arms taking in consideration some patient preferences.

Methods: Twenty-five primary health care centres were selected to recruit 500 patients. In each centre, 75 diabetic patients were randomly selected and were invited to the presentation of the diabetes mellitus type II (DM2) EPPC™ course edition. Without knowing either on the day nor the hour of the intervention group sessions scheduled, the patients had to express their hourly preference for the sessions of the program. Informed consent was obtained. Patients were informed that they would not take part in the intervention group if their availability wasn't coincident with the DM2 EPPC™ sessions scheduled but, if it was, they would be included in the control group and quoted only for answering the questionnaires and for participating in comparisons.

Outcomes: Until September 2014 the basal data of 463 subjects from 22 primary health care centres (238 subjects in the intervention group and 225 subjects as controls) is homogeneous for main variables as age, sex, maximum level of studies attained, work situation, time from diabetes diagnosis, glycosilated hemoglobin, knowledge of disease, self care activities and quality of life (p>0'05).

Conclusions: Even though this inclusion strategy (based on random and on time availability of subjects) could generate some biases, it has been checked out that the intervention and control groups are homogeneous at inclusion for relevant basal data. These results confirm that the chosen strategy of randomization is suitable and that it is feasible to carry out controlled clinical trials to evaluate this kind of interventions.

Lessons learned: A randomization to two trial arms could have modified the participation to the assessed course edition. Without losing blindness, taking into consideration hourly patient availability in the strategy of assignment, it has ensured basal homogeneity of the two groups and a little amount of dropouts by schedule.

Limitations: Some limitations could appear during follow-up and, for example, patient withdrawal' will be analysed to known reasons and to avoid biases added.

Keywords

controlled clinical trial; learning between equals; expert patient program; health literacy

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PowerPoint presentation

http://integratedcarefoundation.org/resource/icic15-presentations