General Hospital Psychiatry 35 (2013) 579–586

Contents lists available at ScienceDirect

General Hospital Psychiatry

journal homepage: http://www.ghpjournal.com

Psychiatry and Primary Care

Recent epidemiologic studies have found that most patients with mental illness are seen exclusively in primary care medicine. These patients often present with medically unexplained somatic symptoms and utilize at least twice as many health care visits as controls. There has been an exponential growth in studies in this interface between primary care and psychiatry in the last 10 years. This special section, edited by Jürgen Unutzer, M.D., will publish informative research articles that address primary care-psychiatric issues.

Effectiveness of collaborative care for depression in Italy. A randomized controlled trial☆

Marco Menchetti, M.D. [a,*], Cecilia Sighinolfi, Psy.D., Ph.D. [a], Vittorio Di Michele, M.D. [b], Paolo Peloso, M.D. [c], Claudia Nespeca, M.D. [a], Pier Venanzio Bandieri, M.D. [d], Maria Bologna, M.D. [e], Angelo Fioritti, M.D. [f], Roberta Fravega, M.D. [g], Lucio Ghio, M.D. [g], Simona Gotelli, M.D. [c], Paolo Levantesi, M.D. [a], Maria Amparo Ortega, Psy.D. [c], Micaela Savorani, M.D. [a], Luigi Simoni, M.D. [h], Ilaria Tarricone, M.D., Ph.D. [a], Mara Morini, M.D. [i], Linda Gask, Ph.D., FRCPsych. [j], Domenico Berardi, M.D. [a]

[a] Department of Medical and Surgical Sciences, University of Bologna, Bologna, Italy
[b] Mental Health Department, Local Health Unit Pescara, Pescara, Italy
[c] Mental Health Department, Local Health Unit 3 Genova, Genova, Italy
[d] Mental Health Department, Local Health Unit Rimini, Rimini, Italy
[e] Mental Health Department, Local Health Unit Reggio Emilia, Reggio Emilia, Italy
[f] Mental Health Department, Local Health Unit Bologna, Bologna, Italy
[g] Neuroscience Department, University of Genova, Genova, Italy
[h] Local Health Unit Bologna, Bologna, Italy
[i] Primary Care Department, Local Health Unit Bologna, Bologna, Italy
[j] Centre for Primary Care, Institute of population Health, University of Manchester, Manchester, United Kingdom

ARTICLE INFO

Article history:
Received 6 March 2013
Revised 14 June 2013
Accepted 9 July 2013

Keywords:
Collaborative care
Usual care
Depression
Primary care physician
Primary care

ABSTRACT

Trial design: This was a multicenter cluster-randomized controlled trial.
Participants: A total of 227 patients ≥18 years old with a new onset of depressive symptoms who screened positive on the first two items of the Patient Health Questionnaire-9 (PHQ-9) were recruited by primary care physicians (PCPs) of eight health districts of three Italian regions from September 2009 to June 2011.
Intervention: PCPs of the intervention group received a specific collaborative care program including 2 days of intensive training, implementation of a stepped care protocol, depression management toolkit and scheduled meetings with a dedicated consultant psychiatrist.
Objective: The objective was to determine whether a collaborative care program for depression management in primary care leads to higher remission rate than usual PCP care.
Outcomes: Outcome was clinical remission as expressed on PHQ-9 <5 at 3 months.
Randomization: An independent researcher used computer-generated randomization to assign involved primary care groups to the two alternative arms.
Blinding: PCPs and research personnel were not blinded.
Results: The 223 PCPs enrolled recruited 227 patients (128 in collaborative care arm, 99 in the usual care arm). At 3 months ($n=210$), the proportion of patients who achieved remission was higher, though the difference was not statistically significant, in the collaborative care group. The effect size was of 0.11. When considering only patients with minor/major depression, collaborative care appeared to be more effective than usual care ($P=.015$).
Conclusions: The present intervention for managing depression in primary care, designed to be applicable to the Italian context, appears to be effective and feasible.

1. Introduction

Major depressive disorder is highly prevalent in the population and a causes of significant burden to patients and society [1,2]. Primary care physicians (PCPs) have emerged as main providers of care for patients

☆ Funding source: The study was funded by the Italian Ministry of Health.
* Corresponding author. Tel.: +39 051 524100; fax: +39 051 521030.
E-mail address: marco.menchetti3@unibo.it (M. Menchetti).

0163-8343/$ – see front matter © 2013 Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1016/j.genhosppsych.2013.07.009

suffering from depressive disorders. Despite the availability of effective treatments, it has been documented that the quality of care provided by PCPs is often suboptimal [3–6], with problems such as underrecognition [3], overrecognition [7], low use of antidepressant drugs [8,9] and early discontinuation of pharmacological treatment [10,11].

It has been suggested that strategies to improve depression care in medical settings should be based on an efficient and structured integration between primary care and mental health services. Educational and organizational interventions have been proposed to improve the management of depression in primary care [12–15]. Recent reviews have identified collaborative care programs as the most effective of these approaches [13,14,16]. The collaborative care model is based on the principles of chronic disease management and involves a number of different interventions. Several definitions have been used to refer to the collaborative care model [17,13]. Recently, Gunn et al. [18] considered a collaborative care intervention as a multiprofessional approach to patient care provided by a PCP and at least one other health professional (such as nurse, psychologist, psychiatrist, etc.). This approach includes a structured management plan, scheduled patient follow-up and enhanced interprofessional communication (such as written feedback, team meetings, individual consultation/supervision). The aims of collaborative care programs generally are as follows: improving the accessibility of the mental health service, improving the quality of the psychiatric treatment in primary care and its results, and improving the communication between the general practitioner and the specialist [19].

Despite the growing body of evidence that collaborative care models improve outcome of depression [20], its efficacy was clearly demonstrated in the United States [13] where the model was developed and in Chile [21]. Available data in European countries were not univocal, with studies finding higher efficacy of collaborative care [22–24] and others finding no differences in respect to usual care [25–28]. Discrepancies in the collaborative care effectiveness could be related to differences in the adopted model and/or in the organization of health care service across European countries. In Italy, the primary care system and mental health services are highly accessible, free and well developed. All residents are registered as patients with a PCP who is a private doctor funded by the Local Health Unit with a fixed allowance per patient. Access to hospital and community health services is possible only by referral from PCP, with few exceptions such as mental health services where self-referral is also accepted. So far, projects of collaboration and coordination between primary care and mental health are at their early stage and are differently developed in the different regions. The current transition from solo practice to primary care groups will ease the development and implementation of collaborative care interventions.

The present study describes the first research project on a collaborative care program in the Italian health care system. The aim of the study was to determine whether a collaborative care program for depression management in the adult population in primary care leads to higher remission rate of depressive symptoms at 3 months compared to the usual care provided by PCP. The primary outcome was measured on Patient Health Questionnaire-9 (PHQ-9 <5).

2. Methods

2.1. Design and setting

This cluster-randomized controlled trial was conducted in eight sites of three Italian regions: Emilia-Romagna ($n=5$), Abruzzo ($n=2$) and Liguria ($n=1$). Fifty-four primary care groups with approximately 750 PCPs covered the participating sites.

The study protocol planned to enroll 16 primary care groups (the first two in each site voluntarily accepting to participate) representing 30% of the total groups in the area. Exclusion criteria for primary care groups were ongoing structured and long-lasting collaborative projects with mental health services, ongoing research projects on mental health issues and low PCP number (<8). We then contacted the coordinators of the eligible groups asking for their availability to participate (Fig. 1). The primary care groups were randomized into two arms: experimental collaborative care intervention to manage depression (collaborative care) and usual management of depression (usual care). A researcher belonging to the steering group of the project outside the primary care groups and the Community Mental Health Centres (CMHCs) where patients were recruited and treated was in charge to allocate groups using computer-generated randomization sequence. In detail, the two primary care groups of each site were allocated into a different arm to prevent differences between intervention and control clusters.

Patients were asked to complete self-administered questionnaires and forms at the baseline and at the -3, 6- and 12-month follow-up visits. PCPs completed clinical forms including medical history and provided interventions. Patient recruitment started in March 2010 and had a duration of 1 year. A slight delay in the start of enrolment occurred in the three regions due to administrative reasons. The last follow-up was completed on June 2012.

All eligible patients signed a written informed consent after receiving from their PCP an explanation of the study procedures and having an opportunity to ask questions. The study was approved by the Ethics Committee of the Local Health Unit of Bologna on 24 February 2010 (ref: CE 09103). No protocol of the present study has been published or registered.

2.2. Patients

PCPs were asked to recruit all the patients aged ≥18 years with a new onset of depressive symptoms detected in the index period. Only patients screening positive on the first two items of the PHQ-9 [29] (scoring ≥2 on each of them) were included in the study using an efficient procedure of screening tested in primary care [30]. Those patients screening positive were administered the self-report PHQ-9 in order to diagnose a minor or major depression [*Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* (DSM-IV)].

Patient exclusion criteria were as follows: current or past (6 months) treatment with antidepressants or psychotherapy for a mood disorder, moderate to high suicide risk, current/past psychotic symptoms, cognitive impairment, mental retardation, poor knowledge of the Italian language or other conditions not allowing the comprehension of the study evaluation. A previous episode of depression or other previous nonpsychotic mental disorders did not represent an exclusion criterion.

2.3. Interventions

2.3.1. Collaborative care

We set up a collaborative care protocol with a multicomponent program for depressive disorders. It was designed considering previous experiences of other countries [23,24], guidelines about consultation psychiatry [31] and pilot projects conducted in Italy [32–34]. Unlike the collaborative care originally developed in the United States, our model did not involve a nurse case manager to coordinate care, monitor treatments and provide brief psychological interventions [35]. In Italy, primary care groups represent a recent evolution from solo practice in the health care organization, and the presence of nurses or other personnel potentially acting as a case manager is seldom widespread. Therefore, we trained PCPs in order to accomplish some tasks usually fulfilled by case managers (enhanced PCP care). In addition, a dedicated consultant psychiatrist of the CMHC was appointed to each primary care group to liaise closely with PCPs and to improve work at interface. In details, our collaborative care program included the following:

1. Two-day intensive training for PCPs. This aimed to improve their knowledge and skills on depressive disorders, using instruments