



Long-term effects of a collaborative care intervention on process of care in family practices in Germany: a 24-month follow-up study of a cluster randomized controlled trial ☆☆☆☆☆☆☆☆☆



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ABSTRACT

Objective: The aims of this study were (1) to assess the long-term effects of a collaborative care intervention for patients with depression on process of care outcomes, and (2) to describe whether case management was continued after the end of the original one-year intervention.

Methods: This 24-month follow-up of a randomized controlled trial took place 12 months after the end of the 1-year intervention. Data collection occurred by means of self-rating questionnaires and from medical records. We calculated linear mixed and logistic generalized estimating equation models.

Results: Of the 626 patients included at baseline, 439 (70.1%) participated in this follow-up. Intervention recipients gave higher ratings than control recipients in terms of mean overall Patient Assessment of Chronic Illness Care (PACIC) scores (3.12 vs. 2.86; $P=.019$), but no difference was found in medication adherence (mean Morisky score 2.59 vs. 2.65, $P=.56$), prescribed antidepressant medications (60.2% vs. 55.1%; $P=.25$), visits to the family physician (15.96 vs. 14.46, $P=.58$) or mental health specialist (3.01 vs. 2.94, $P=.94$) over the 12 month follow-up period. Case management was continued for 47 (22.5%) selected intervention patients after the original intervention had ended.

Conclusion: At 24 months, intervention and control recipients had different PACIC ratings, but other process of care outcomes did not differ.

Practice implications: The main effects of the intervention are apparent at 12 months.

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☆☆☆ Authors' contributions

Conception and design of the PRoMPT trial: Gensichen J, Gerlach FM, König J.
Data collection: Mergenthal K, Rauck S, Petersen JJ, Gensichen J.

Statistical analysis and interpretation: König J, Petersen JJ, Pagitz M, Paulitsch MA, Gensichen J.

Drafting of the article: Petersen JJ, Gensichen J, Haase L, Schmidt K.

Critical revision of the article for important intellectual content: all authors.

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1. Introduction

Depression is a leading cause of disease burden and has therefore been identified as a global health priority [1,2]. The global point prevalence of major depressive disorder is 4.7% [3] and it is estimated that up to 90% of patients are treated in primary care [4]. Substantial evidence shows that collaborative care in primary care settings is effective in reducing depression symptoms, improving patient satisfaction and mental health quality of life [5–7]. A review on collaborative care for depression and anxiety found that only 17% of relevant trials had been conducted in European countries, whereas most trials (76%) were conducted in the United States [6]. Most (87%) interventions involved three health professionals (primary care provider, case manager, mental health specialist) and only 13% involved two of them (primary care provider and case manager). In the United States, collaborative care interventions have often been developed and implemented in managed healthcare settings [5]. Given the different healthcare systems, there is a clear need to assess which collaborative care interventions are most effective in European

primary care settings [5,6]. Following a 14-week collaborative care intervention in a UK primary care setting, a recent publication describes positive effects lasting up to 12 months in depression symptoms and satisfaction with care [8]. In Germany, family practices are usually privately owned and work independently of one another. In this setting, extensive collaborative models would be difficult to implement. Furthermore, practices located in rural areas often have limited access to mental health specialists. In view of these challenges, the development and implementation of collaborative care interventions must be adapted to such small organizational units and take into account limited personnel and financial resources. German family practices usually employ one or more healthcare assistants, who generally perform administrative tasks and provide basic medical care [9]. Healthcare assistants are less qualified than the nurses and mental health workers who usually perform case management in this kind of collaborative care intervention [7]. We have previously reported that collaborative care provided by family physicians and healthcare assistants in primary care practices in Germany over a 12-month period is effective in improving depression symptoms in patients with major depression [10]. Since the improvements in depression symptoms are presumably associated with improved care delivery by the practice team, we also assessed process of care outcomes, i.e. the patients' assessment of depression care (as measured using the "Patients' Assessment of Chronic Illness Care" questionnaire, or PACIC) [11], medication adherence (Morisky) [12], prescribed antidepressant medication and number of family physician and mental health specialist contacts. We showed that the intervention led to improved PACIC and adherence to antidepressant medication scores after 12 months, whereas the other process of care outcomes did not differ between the two groups [10].

We conducted a long-term follow-up study after 24 months, i.e., 12 months after the end of the intervention, and showed that in terms of depression symptoms, there was no longer a statistically significant difference between the two groups [13].

The aim of the present study was (1) to assess whether, compared to control recipients, patients with major depression who had received a collaborative care intervention involving a healthcare assistant and family physician in German family practices showed improved long-term process of care outcomes after 24 months, i.e. 12 months after the end of the original intervention and (2) to describe whether intervention practices continued case management for selected intervention patients after the trial intervention had officially ended.

2. Methods

2.1. Study design

This cluster-randomized, controlled trial with the family practice as the unit of randomization took place in central Germany between 2005 and 2008. Data were collected at baseline, after 6, 12 and 24 months. The intervention lasted 12 months (between baseline and the 12-month assessment). Details on the methods employed in the trial have been published elsewhere [10,14]. The institutional review board of Goethe-University Frankfurt/Main approved the study protocols [10,13].

2.2. Participants and recruitment

Inclusion criteria for patients were a diagnosis of major depression with an indication for antidepressive treatment, aged 18–80 years, access to a private telephone, ability to give informed consent, and ability to communicate in German. The diagnosis of major depression was based on a score of more than 9 points and a categorical diagnosis in the Patient Health Questionnaire (PHQ-9) [15], and confirmed by

the family physician. Exclusion criteria were confirmed pregnancy, severe alcohol or illicit drug consumption, or acute suicidal ideation.

2.3. Intervention

We designed our case management intervention in accordance with the Chronic Care Model [16,17]. The aim of the Chronic Care Model is to ensure care is planned, proactive and patient-centered, rather than reactive and focused on acute episodes. The model identifies key elements of high-quality care provision for patients with chronic illnesses, i.e., especially self-management support, provision of clinical information systems, delivery system redesign, and decision support.

One healthcare assistant from each practice assigned to the intervention group received interactive training in depression, communication skills, telephone monitoring, and behavioral activation for the patient [18–20]. Over a period of 1 year, the healthcare assistants contacted their patients by telephone once a month, and monitored their symptoms and adherence to medication [21]. Healthcare assistants also encouraged patients to follow self-management activities, such as medication adherence and activated them to participate in pleasant and/or social activities. The assistants provided this information to the family physician in a structured report that stratified the urgency of the contact in accordance with symptom severity. This intervention was provided in addition to usual care.

2.4. Outcomes and follow-up

Data collection occurred by means of self-reporting questionnaires for patients, case report forms (CRFs) that practice teams filled in for each patient, questionnaires for family physicians and healthcare assistants, and data extraction from medical records. Participating practices were regularly monitored by the study team to ensure that the data were correct and complete. We used the PACIC questionnaire to assess patients' perception of care provided by the family practice team [11]. The PACIC questionnaire contains 20 items on five subscales that are based on conceptual categories of the Chronic Care Model, i.e., patient activation, delivery system design/decision support, goal setting/tailoring, problem solving/contextual counseling and follow-up/coordination. The category 'delivery system redesign/decision support' contains for example the item 'Satisfied that my care was well organized'. Each item is scored on a five-point Likert scale that ranges from 1 ('almost never') to 5 ('almost always'), with higher scores indicating better patient-perceived quality of chronic illness care. We evaluated patient medication adherence using a modified Morisky patient self-report scale [12], on which patients are scored from 0 to 3 on the basis of their answers to the following 3 questions (higher values indicate higher adherence): Did you ever forget to take your medicine during the last 2 weeks? During the last 2 weeks, did you sometimes stop taking your medicine when you felt better? During the last 2 weeks, did you stop taking your medicine when you felt worse? We assessed the number of family physician and mental health specialist contacts, as well as prescriptions for antidepressant medications, by using data from patient records and CRFs. In order to assess whether intervention practice teams continued to provide case management after the official end of the intervention, we used self-developed questions that the family practice teams filled in for each patient. In case of continuation, we also assessed the frequency of case management, where it was conducted, and which healthcare professionals remained involved.

2.5. Statistical analysis

For the descriptive analyses, we calculated mean value, standard deviation and the frequency distributions of the response categories. We calculated mean overall PACIC and mean subscale scores by

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