Cost-utility of collaborative nurse-led self-management support for primary care patients with anxiety, depressive or somatic symptoms: A cluster-randomized controlled trial (the SMADS trial)

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ABSTRACT

Background: Anxiety, depressive and somatoform disorders are highly prevalent and cause a huge economic burden. A nurse-led collaborative care intervention has been set up in order to improve self-management of patients with these mental disorders in primary care in Hamburg, Germany. The aim of this study was to determine the cost-utility of this nurse-led intervention from the health care payer perspective.

Methods: This analysis was part of a 12-month cluster-randomized controlled trial aiming to increase perceived self-efficacy of primary care patients with anxiety, depressive or somatic symptoms by collaborative nurse-led self-management support compared with routine care. A cost-effectiveness analysis using quality-adjusted life years was performed. Net-monetary benefit regressions adjusted for baseline differences for different willingness-to-pay thresholds were conducted and cost-effectiveness acceptability curves were constructed.

Results: In total, n = 325 patients (intervention group: n = 134; control group: n = 191) with a mean age of 40 from 20 primary care practices were included in the analysis. The adjusted differences in quality-adjusted life years and mean total costs between intervention group and control group were +0.02 and +€1145, respectively. Neither of the two differences was statistically significant. The probability for cost-effectiveness of the complex nurse-led intervention was 49% for a willingness-to-pay of €50,000 per additional quality-adjusted life year. The probability for cost-effectiveness did not exceed 65%, independent of the willingness-to-pay.

Conclusion: The complex nurse-led intervention promoting self-management for primary care patients with anxiety, depressive or somatic symptoms did not prove to be cost-effective relative to routine care from a health care payer perspective.

What is already known about the topic?

- The primary care-based, nurse-led, complex intervention to support self-management in Germany increased self-efficacy in patients with anxiety, depression or somatic symptoms compared to patients receiving routine care.
- Cost-effectiveness of nurse-led collaborative care for patients with depressive disorders and somatoform disorders is ambiguous.
- Nurse-led collaborative care is cost-effective for patients with panic disorder and for patients with generalized anxiety disorders.

What this paper adds

- The first primary care-based, nurse-led, complex intervention to support self-management in Germany did not prove to be cost-effective from a health care payer perspective compared with routine care.
- Patients in the intervention group did not have significantly different adjusted mean total costs 12 months post-baseline compared with patients in the control group.
- Patients in the intervention group did not have significantly higher health-related quality of life 12 months post-baseline compared with patients in the control group.
1. Background

Anxiety, depressive and somatoform disorders (hereafter ADSom disorders) are highly prevalent and cause a large economic burden. For the European total population in the year 2010, the 12-month prevalence was estimated to be 6.3% for somatoform disorders, 6.9% for depressive disorders and 14% for anxiety disorders (Wittchen et al., 2011). ADSom disorders are highly comorbid and are associated with multifaceted health burdens, e.g. with an increased mortality-risk and negative treatment outcomes as well as a reduced health-related quality of life (HRQoL) of patients (Olatunji et al., 2007; Sivertsen et al., 2015; Huijbregts et al., 2010; Mergl et al., 2007).

Within Europe, the 2010 estimates for total annual costs, including direct healthcare costs (e.g., inpatient care), direct non-medical costs (e.g., formal nursing care) and indirect costs (e.g., absenteeism from work), for patients affected by ADSom disorders ranged from €21 billion for somatoform disorders, to €74 billion for anxiety disorders and up to €92 billion for depressive disorders (Olesen et al., 2012). The annual health care costs attributable to somatoform disorders were estimated to be approximately €1352-€16,765 per individual (Konnopka et al., 2012). For anxiety disorders, annual attributable additional health care costs were estimated to be approximately –€370–€16,765 per individual with social phobia and generalized anxiety disorder, respectively (Konnopka et al., 2009). Additional health care costs attributed to depressive disorders were estimated to be approximately €933–€2203 per individual (Luppa et al., 2007).

In order to address the health and economic burden of ADSom disorders in primary care, nurse-led care is well established (Gunn et al., 2006; Wagner, 2000). Nurse-led care is a collaborative care approach with a network formed around the patient, which generally consists of a structured management plan as well as follow-up schedules (Gunn et al., 2006; Zimmermann et al., 2014). Networks within an outpatient collaborative care approach consist at least of a primary care physician (PCP) and a case manager, who usually is a nurse (Grochtdreis et al., 2015). Based on individual patients' specific needs and resources, the case manager develops management plans composed of evidence-based treatment based on clinical practice guidelines. In order to monitor the process and outcome of treatment, the case manager schedules follow-up appointments with the patient in a PCP practice (Gunn et al., 2006; Grochtdreis et al., 2015). As the focus of regular PCP consultations is mainly on acute care, patients with ADSom disorders might lack professional self-management support. This lack of support could be offset by nurse-led care (Zimmermann et al., 2014). The effectiveness of a nurse-led care intervention has recently been shown for German primary care patients in a cluster-randomized trial (Zimmermann et al., 2016). Patients who received this intervention had a higher perceived self-efficacy compared with patients who received routine care. Furthermore, depressive and anxiety symptoms were significantly reduced in favor of the patient group who received the nurse-led collaborative care intervention (Zimmermann et al., 2016).

Despite the symptomatic continuities and high comorbidity of ADSom disorders (Mergl et al., 2007; Löwe et al., 2008), cost-effectiveness of nurse-led collaborative care has merely been evaluated for patients with one particular disorder. Cost-effectiveness of nurse-led collaborative care for patients with depressive disorders was found ambiguous in two systematic reviews based on seven studies (Grochtdreis et al., 2015; van Steenbergen-Weijenburg et al., 2010). Furthermore, nurse-led collaborative care was found cost-effective for patients with panic disorder and for patients with generalized anxiety disorders (Goorden et al., 2014; Katon et al., 2006).

To our knowledge, no study has investigated the cost-effectiveness of collaborative nurse-led interventions for patients with ADSom disorders compared to routine care and the potential benefit of such a disorder-spanning treatment approach. Therefore, the aim of this study was to evaluate the cost-utility of a complex nurse-led intervention promoting self-management for primary care patients with anxiety, depressive or somatic symptoms (hereafter ADSom symptoms) from a health care payer perspective.

2. Methods

2.1. Sample

This study is part of 12-month cluster-randomized controlled trial to determine the effectiveness of a primary care-based, complex intervention promoting self-management of patients with ADSom symptoms. The primary endpoint of this trial was perceived self-efficacy. PCP practices were recruited within the city of Hamburg, a large German metropolitan area. Recruitment was conducted by postal letters and subsequently by personal telephone calls. Practice inclusion criteria were willingness to participate regardless of randomization results, availability of a separate room and non-presence of psychotherapeutic treatment within the practice. After practice recruitment, PCP practices were randomly allocated to the intervention group (IG) or the control group (CG) by the study biometrician, who was not involved in the fieldwork. After random allocation of PCP practices, study participants were recruited by the PCP. Recruitment took place between March 2013 and June 2014. Individual patient inclusion criteria were an age of 18–65 years, sufficient German language skills, sufficient auditory and visual capabilities and showing ADSom symptoms. Patients with a score of at least 5 points on any of the three symptom scales Generalized Anxiety Disorder-7 (GAD-7), Patient Health Questionnaire-9 (PHQ-9) or PHQ-15 were included in the study. Exclusion criteria were missing written informed consent for study participation and current psychotherapeutic treatment.

Study participants were assessed at baseline (T0), at week 8 post-baseline (T1) and 12 months post-baseline (T2). All outcome measures were assessed at each time point. A detailed description of the study methods can be found elsewhere (Zimmermann et al., 2014, 2016).

2.2. Intervention

Patients of the IG received nurse-led case management within the attended PCP practice (Zimmermann et al., 2014, 2016). After the PCPs, who are responsible for the care of the patients, delegated health services to the nurses working together with the PCP in their practices, the nurses performed an initial assessment to learn about patients' perspectives, personal resources and their motivation for change. Over the course of the trial, the nurses scheduled further individual appointments where they used counselling goal-setting techniques to promote self-management to the patients. Nine disorder-overlapping modules adhering to the German treatment guidelines for anxiety, depression and non-specific functional and somatoform physical complaints were developed and intended to implement case management elements in counselling (DGPPN et al., 2015; DKPM et al., 2012; Bandelow et al., 2014). If necessary, problem-solving techniques, relaxation exercises or strengthening self-confidence activities were used during the counselling process. These modules should individually and actively support the patient in finding psychotherapeutic treatment, inform the patient about the disease, modify the patient's behavior and support the patient in making contact with community based psycho-social services and self-help groups. Furthermore, the nurses closely coordinated their work with the PCP. The PCP actively recommended modules for the counselling. The nurses held case conferences with the PCP to share information over the course of the intervention, discussing the progress and creating ways to rescale the intervention plan, and the nurses were regularly supervised by the study physician and psychotherapist (EP). Patients of the CG received routine care within the attended PCP practice according to general clinical practice for ADSom patients, including medications and referral for other treatments as well as psychotherapy.
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