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Collaborative nurse-led self-management support for primary care patients with anxiety, depressive or somatic symptoms: Cluster-randomised controlled trial (findings of the SMADS study)☆

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ABSTRACT

Background: Collaborative, nurse-led care is a well-established model of ambulatory care in many healthcare systems. Nurses play a key role in managing patients' conditions as well as in enhancing symptom- and self-management skills.
Objective: The SMADS trial evaluated the effectiveness of a primary care-based, nurse-led, complex intervention to promote self-management in patients with anxiety, depressive or somatic symptoms. Change in self-efficacy 12 months post baseline was used as the primary outcome.
Design: The SMADS trial set up a two-arm, cluster randomised controlled trial in the city of Hamburg, a large metropolitan area in the North West of Germany.
Setting: We randomly allocated participating primary care practices to either the intervention group (IG), implementing a nurse-led collaborative care model, or to the control group (CG), where patients with the above psychosomatic symptoms received routine treatment.
Participants: Patients from 18 to 65 years of age, regularly consulting a participating primary care practice, scoring ≥ 5 on the anxiety, depressive or somatic symptom scales of the Patient Health Questionnaire (PHQ-D), German version.
Methods: A mixed model regression approach was used to analyse the outcome data. Analyses were based on the intention-to-treat population: All enrolled patients were analysed at their follow-up. Additionally, we reported results as effect sizes. The robustness of the results was investigated by performing an observed cases analysis.
Results: 325 participants (IG N = 134, CG N = 191) from ten practices in each study arm consented to take part and completed a baseline assessment. The mean group difference (ITT-LOCF, IG vs. CG) in self-efficacy at the post baseline follow-up (median 406 days) was 1.65 points (95% CI 0.50–2.8) in favour of IG ($p = 0.004$). This amounts to a small Cohen's d effect size of 0.33. An observed cases analysis (168 participants, IG = 56, CG = 105) resulted in a mean difference of 3.13 (95% CI 1.07–5.18, $p = 0.003$) between the groups, amounting to a moderate effect size of $d = 0.51$.
Conclusion: A complex, nurse-led intervention, implemented as a collaborative care model, increased perceived self-efficacy in patients with symptoms of anxiety, depression or somatisation compare to control patients. For the first time in the German healthcare system, the SMADS trial validated the belief that a nurse can successfully complement the work of a general practitioner – particularly in supporting self-management of patients with psychosomatic symptoms and their psychosocial needs.

☆ The study is registered at https://www.clinicaltrials.gov/ct2/show/NCT01726387.

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What is already known about the topic?

- Complex interventions including patient education, case management by nurses and a better integration of primary and secondary care improve patient outcomes.
- Nurse-led interventions enhance the self-care of patients with chronic conditions including depressive disorders.
- Nurse-led care is established in several health care systems (UK, USA, Australia, Sweden etc.) but not in Germany.
- Self-efficacy is an important prerequisite for successful self-management.

What this paper adds

- Results of the first primary care-based, nurse-led, complex intervention to support self-management of patients with anxiety, depressive or somatic symptoms in Germany.
- Patients in the intervention group reported a significant increase in self-efficacy (primary outcome) compared to the control group (intention-to-treat analysis) at the 12-months follow-up, the reduction of depressive and anxiety symptoms differed significantly among the groups.
- An account of the barriers and difficulties faced by scientifically driven researchers when implementing an innovative healthcare model into a profoundly sceptical professional environment.

1. Introduction

Anxiety, depressive and somatoform disorders (hereafter referred to as ADSom disorders) belong to the most common mental disorders in primary care (Toft et al., 2005). ADSom disorders play a substantial part in the utilisation of the healthcare system (Grabe et al., 2009). Also, ADSom disorders cause significant direct and indirect healthcare costs (Olesen et al., 2012).

Practice nurses play a key role in managing patients' conditions, enhancing clinical and self-management skills and the care intensity (Wagner, 2000). Nurse-led care is a well-established concept, addressing the aforementioned problems. It features a multi-professional approach to patient care, incorporating a structured management plan, follow-up schedules and enhanced inter-professional communication (Gunn et al., 2006). Evidence to support a nurse-led collaborative care model in patients with depressive symptoms has been verified in several systematic reviews. Thota et al. (2012) concluded that nurse-led care improves depressive symptoms, adherence to treatment, response to treatment, recovery from symptoms, quality of life and care satisfaction amongst patients. Ekers et al. (2013) reported a considerable and consistent benefit of nurse-led clinical trials over routine treatment for depressive disorders when summarising the results of fourteen different trials. In a review of different care models for depressive disorders, Christensen et al. (2008) concluded that nurse-delivered care combined with psychological or psychiatric care was effective. Aragones et al. (2012) and Richards et al. (2013) reported a significant reduction in depressive symptoms in cluster randomised collaborative care studies. Even beyond depression, nurses can make a difference. In a secondary analysis of trial data, Tyrer et al. (2015) compared nurse-delivered care with the treatment offered by assistant psychologists and graduate health workers. Improvement in anxiety and depressive symptoms were twice as likely in the nurse care groups as in those of the other professional groups. Oosterbaan et al. (2013) successfully implemented a collaborative care model for a broad range of common mental disorders. Gilbody et al. (2003) identified effective strategies in caring for patients with depressive disorders: clinician education, case management through nurses and a greater degree of integration of primary and secondary care.

Types and roles of nursing professionals in primary care vary considerably between healthcare systems (Freund et al., 2015). For example, nurse-led interventions are part of routine, ambulatory care in several healthcare systems (UK, USA, Australia, Netherlands etc.) but not in Germany. Nurses in those countries usually have an academic education and are employed as advanced practice nurses. This kind of professional education is about to emerge in Germany even though legal constraints prevent nurses from any autonomously organised, professional care regularly offered in those aforementioned healthcare systems. Thus, nurse-led interventions in ambulatory healthcare are largely unknown inGermany. We only know of one trial, that has tried to implement a nurse-led intervention (Herber et al., 2009). Nevertheless, patients with ADSom disorders can find many services in the German social security system: helpdesks, helplines, publicly funded self-help groups, non-profit counselling services, community-based social psychiatric support, day clinics, rehabilitation services, re-integration services after long sick leaves, specialist medical care (psychiatrist, psychotherapist). Although these services exist, patients with ADSom disorders have difficulties accessing services. Information has to be collected, paperwork has to be filled out, appointments have to be made and so on, all of which are impeded by their psychiatric symptoms (Thielke et al., 2007). Eventually, there is a lack of coordination amongst these services and the patients' primary care practice as it is beyond the scope of the GPs' daily work to coordinate the different services.

Hence, nurses can make a difference in improving healthcare.

1.1. Objective

The objective of the "Self-Management Support for Anxiety, Depression and Somatoform Disorders in Primary Care" (SMADS) trial was to evaluate the effectiveness of a primary care-based, complex intervention promoting self-management of patients presenting anxiety, depressive or somatic symptoms, the latter denoting unspecific physical complaints, a potential proxy for somatisation and somatoform disorder (Kroenke et al., 2010) The SMADS trial investigated whether a nurse, collaborating with a GP, addressing the psychosocial needs of ADSom patients, could enhance the patients' self-efficacy (a proxy for self-management) compared to receiving only routine care.

Perceived self-efficacy is an important prerequisite for successful self-management (Freund et al., 2013). The concept is theoretically and empirically well founded (Barlow et al., 2005) and was originally developed by Albert Bandura in the 1970s. Self-efficacy comprises one's confidence to carry out behaviour necessary to reach a desired goal. Self-efficacy is enhanced when patients succeed in solving patient-identified problems. Based on improved self-efficacy patients can regain control of their own lives, gaining new confidence in their ability to perform a task, hence increasing self-management (Bodenheimer et al., 2002).

As we focused on a group of patients presenting three different yet overlapping disorders, we chose self-efficacy as a primary outcome for the SMADS trial to obtain an overarching measure of effectiveness. Furthermore, we investigated if a nurse-led intervention had decreased the patients' symptom load and psychosocial burden and increased their quality of life. After all, we wanted to know whether a nurse-led intervention had any impact on these patients' coping strategies, considered a useful way to reduce stress and psychiatric symptoms.