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Original Article

Effectiveness of a Geriatric Care Model for frail older adults in primary care: Results from a stepped wedge cluster randomized trial

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ABSTRACT

Background: Primary care-based comprehensive care programs have the potential to improve outcomes in frail older adults. We evaluated the impact of the Geriatric Care Model (GCM) on the quality of life of community-dwelling frail older adults.

Methods: A 24-month stepped wedge cluster randomized controlled trial was conducted between May 2010 and March 2013 in 35 primary care practices in the Netherlands, and included 1147 frail older adults. The intervention consisted of a geriatric in-home assessment by a practice nurse, followed by a tailored care plan. Reassessment occurred every six months. Nurses worked together with primary care physicians and were supervised and trained by geriatric expert teams. Complex patients were reviewed in multidisciplinary consultations. The primary outcome was quality of life (SF-12). Secondary outcomes were health-related quality of life, functional limitations, self-rated health, psychological wellbeing, social functioning and hospitalizations.

Results: Intention-to-treat analyses based on multilevel modeling showed no significant differences between the intervention group and usual care regarding SF-12 and most secondary outcomes. Only for IADL limitations we found a small intervention effect in patients who received the intervention for 18 months ($B = -0.25$, 95%CI $= -0.43$ to -0.06, $p = 0.007$), but this effect was not statistically significant after correction for multiple comparisons.

Conclusion: The GCM did not show beneficial effects on quality of life in frail older adults in primary care, compared to usual care. This study strengthens the idea that comprehensive care programs add very little to usual primary care for this population.

Trial registration: The Netherlands National Trial Register NTR2160.

1. Introduction

The rising number of frail older adults is a major challenge for health care systems in aging societies [1,2]. Many frail older adults have complex care needs because of the presence of multiple chronic diseases and/or functional disabilities [3]. It is widely recognized that the primary care setting is well situated to provide care for frail older adults [4,5,6]. Comprehensive care programs have been developed to enhance the quality of care provided to older adults in this setting. These programs are usually characterized by patient-centered care based on comprehensive geriatric assessments [7,8]. Since there is much heterogeneity in the components of comprehensive care programs, it has been difficult to draw conclusions on their effectiveness [9,10]. However, comprehensive care programs that were modeled after the Chronic Care Model (CCM) have shown beneficial effects on quality of care and health outcomes in patients with specific chronic conditions [11,12]. Key components of the CCM include patient empowerment, decision support with access to a multidisciplinary team, clinical information systems and steering of the care process [13,14].

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So far, few comprehensive care programs containing multiple components of the CCM were specifically focused on frail older adults in primary care [15,16]. Therefore, we developed the Geriatric Care Model (GCM), a comprehensive care program based on the CCM [17]. The GCM combines tailored care based on geriatric assessments with management by geriatric expert teams. It is designed to target health risks at a timely stage, to stimulate active involvement of patients in the care process and to improve the coordination between health care professionals. In the "Frail older Adults: Care in Transition" (ACT) study in the Netherlands, the GCM was implemented in primary care to improve the quality of care, and subsequently improve outcomes in community-dwelling frail older adults. The aim of this study was to evaluate the impact of the GCM on quality of life and several other patient outcomes.

2. Methods

2.1. Study design

Between May 2010 and March 2013, we conducted a 24-month stepped wedge cluster randomized controlled trial in 35 primary care practices in the Netherlands. A stepped wedge design is a one-way crossover trial in which several allocation groups start at different time points with the intervention [18]. All patients were included at baseline, measured at the same follow-up times, and switched from usual care (control group) to GCM care at some point during follow-up. The stepped wedge design was chosen to avoid contamination bias, and for ethical and logistic reasons [19]. The medical ethics committee of the VU University Medical Center approved the ACT study (approval number 2010/003). A detailed description of the study protocol has been published elsewhere [17].

2.2. Participants

Frail older adults were recruited through 35 primary care practices in two regions in the Netherlands: Amsterdam (18 practices, urban area) and West-Friesland (17 practices, urbanized rural area). Community-dwelling older adults aged 65 and over, who had a PRISMA-7 score of 3 or more [20] were eligible for participation. First, primary care physicians (PCPs) provided the names and addresses of older patients they considered to be frail based on the loss of resources in the physical domain and/or the psychosocial domain [21]. These patients received information by mail and were approached by telephone to be assessed for eligibility, including the administration of the PRISMA-7 questionnaire. PRISMA-7 is a brief 7-item questionnaire containing risk factors for functional decline [20,22], which has previously been used in frailty studies [23]. In a pilot study, a PRISMA-7 score of 3 or more showed good agreement with established frailty measures [24]. If participants met the eligibility criteria and agreed to participate, they were visited by trained interviewers, who collected baseline and follow-up data by means of computer assisted personal interviewing. Interviewers were not involved in the intervention. The baseline data collection took place between May 2010 and February 2011. Signed informed consent was obtained from all study participants before data collection.

2.3. Randomization and blinding

Primary care practices were pre-stratified by region and randomly allocated to one of a total of four allocation groups before the patient recruitment started. This was done using a computer-based 'Random Allocation Software' program. The allocation group designated the starting moment of the intervention at practice level (at 0, 6, 12 or 18 months after baseline). PCPs and practice nurses were not informed about a patient's enrolment in the study until the patient moved from the control to the intervention condition. Due to logistic considerations, both interviewers and participants were not blinded to group assignment, and were aware of the start of the intervention.

2.4. Intervention

GCM care (Fig. 1) was delivered to patients in the intervention condition [17]. Trained practice nurses (n = 21), who were based at the primary care practices, worked together with PCPs and carried out the intervention at the patient level in four steps. Every six months, a practice nurse visited the frail older adult at home. During the first home visit, a multidimensional geriatric assessment was conducted (Step 1) using the interRAI Community Health Assessment (CHA) version 9.1 [25]. After each assessment, practice nurses wrote a tailored care plan in consultation with the PCP of the patient (Step 2). During a second home visit, the practice nurse and the older adult formulated care goals and actions for the final care plan (Step 3). During and after the intervention period, the older adult and the practice nurse evaluated the outcomes of the actions listed in the care plan. There was regular contact by telephone, and if necessary, an additional home visit was scheduled after 3 months (Step 4). The GCM was managed by two geriatric expert teams (one in each region) consisting of an experienced geriatric nurse and a geriatrician. Geriatric expert teams had the following tasks: (1) (quality) management and training, (2) multidisciplinary consultations for complex patients, and (3) building and maintaining local care networks.

2.5. Usual care

In this study, primary care practices in the control condition offered usual care, which was not restricted in any way. Primary care in the Netherlands plays an important role in the organization of community care for older adults. PCPs offer both (sub)acute and chronic care to community dwelling older adults, and are gatekeepers to specialized hospital care. Older adults consult their PCP on their own initiative. However, some of the participating practices provide proactive care for people with specific chronic diseases (e.g., for the management of diabetes). For older adults without chronic disease, proactive care is limited to the invitation for the annual flu vaccination.

2.6. Measurements

Outcomes were measured at the individual patient level at baseline, and at 6, 12, 18, and 24 months. The primary outcome was quality of life measured by the 12-item Short Form questionnaire (SF-12) [26]. The SF-12 consists of a mental health component score (MCS) and a physical health component score (PCS). The score has a range from 0 to 100, with higher scores indicating better quality of life. Secondary outcomes were health-related quality of life (EuroQol (EQ5D)) [27], functional limitations (the Katz index, consisting of a 6-item basic Activities of Daily Living (ADL) scale, and a 7-item Instrumental Activities of Daily Living (IADL) scale) [28], psychological wellbeing (5-item Rand-36 mental health subscale) [29,30], social functioning and self-rated health (both determined using single questions derived from Rand-36 [31], and dichotomized due to skewed distributions), and hospitalizations. Total and acute hospital admissions during the study period were obtained from electronic medical records of hospitals.

At baseline, we assessed educational level, partner status, a frailty index, chronic diseases and health care use in the previous year by self-report [32]. To establish the degree of frailty, a frailty index was constructed using 46 deficits in health [33]. Chronic diseases were assessed by asking respondents whether they currently or in the past 12 months had one of 5 major chronic diseases [34].