

Original Article

Treatment Fidelity of an Evidence-Based Nurse-Led Intervention in a Proactive Primary Care Program for Older People

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ABSTRACT

Keywords

intervention fidelity,
older persons,
complex
interventions,
primary care,
mixed-methods

Background: In a large randomized trial, Utrecht PROactive Frailty Intervention Trial (U-PROFIT), we evaluated the effectiveness of an integrated program on the preservation of daily functioning in older people in primary care that consisted of a frailty identification tool and a multicomponent nurse-led care program. Examination of treatment fidelity is critical to successful translation of evidence-based interventions into practice.

Aims: To assess treatment delivery, dose and content of nursing care delivered within the nurse-led care program, and to explore if the delivery may have influenced the trial results.

Methods: A mixed-methods study was conducted. Type and dose of nursing care were collected during the trial. Shortly after the trial, a focus group with nurses was conducted to explore reasons for the observed differences between the type and dose of nursing care delivered.

Results: A total of 835 older persons were included in the nurse-led care program. The mean age was 75 years, 64% were female and 53.5% were living alone. The most frequent self-reported conditions were loneliness (60.8%) and cognitive problems (59.4%). One-third of the patients with a geriatric condition received an additional assessment (e.g., Mini-Mental State Examination), and the majority of these patients received at least one nurse intervention (>85%). Most nursing care was delivered to patients at risk of falling and to those with urinary incontinence. Patients with nutrition problems seldom received nursing interventions. The nurses explained that differences in type and dose were influenced by the preference of the patient, the type of geriatric problem, and the time required to apply a nurse intervention.

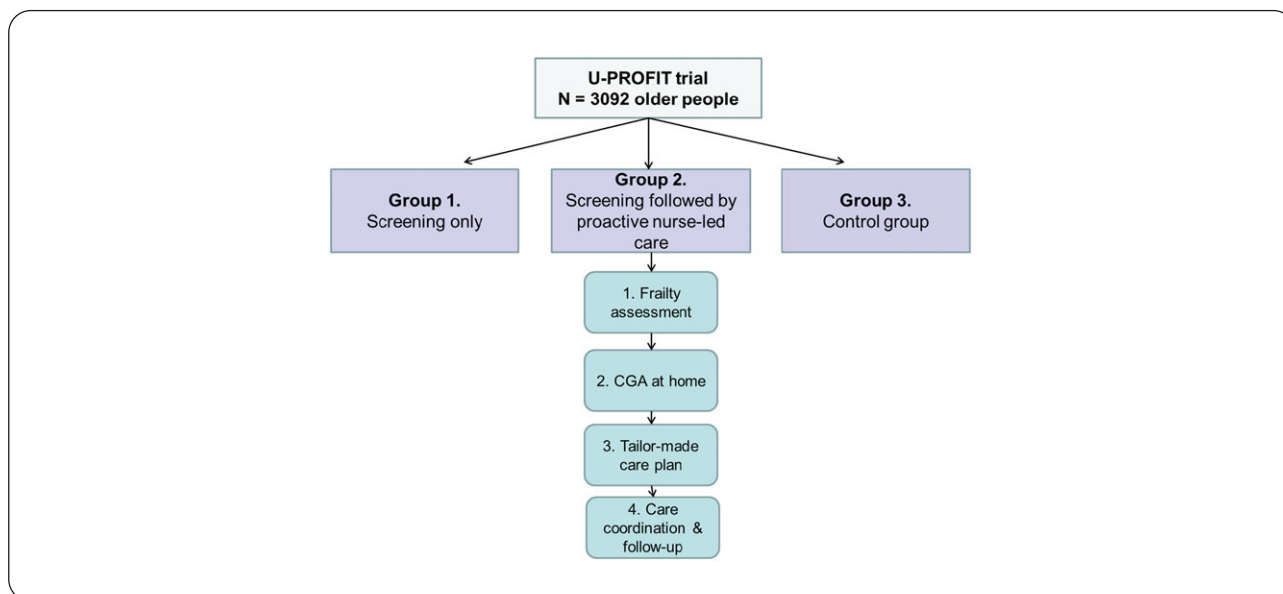
Linking Evidence to Action: All intervention components were delivered; however, differences were observed in the type and dose of nursing care delivered across geriatric conditions. The findings better explain the treatment fidelity and suggest that there is room for improvement that may result in more beneficial patient outcomes.

INTRODUCTION

Evaluating the effectiveness of complex interventions within randomized controlled trials is challenging (Blackwood, 2006; Craig et al., 2008; Hawe, Shiell, & Riley, 2004). Frequently, the intervention is considered effective if a positive result was obtained on the primary outcome (Nelson, Cordray, Hulleman, Darrow, & Sommer, 2012). However, to assess the reliability and validity of the trial results, it is important to know the extent to which the intervention was delivered as intended, which is defined as treatment fidelity (Bellg et al., 2004; Leeuw, Goossens, de Vet, & Vlaeyen, 2009; Schoenwald et al., 2011). Treatment fidelity provides valuable information on how the intervention was delivered and allows readers to judge if the implementation was adequate enough to truly affect outcomes

(Conn, Cooper, Ruppert, & Russell, 2008; Craig et al., 2008; Glasziou et al., 2010). Moreover, it contributes to a better understanding of the underlying mechanisms why the treatment was successful or not (Bellg et al., 2004) and is critical to successful translation of evidence-based interventions into clinical practice (Breitenstein et al., 2010).

In the literature, various definitions and constructs of treatment fidelity exist, as well as even more heterogeneous variation of measurements (Gearing et al., 2011; Schoenwald et al., 2011). Components of treatment fidelity often include: study or intervention design, provider training, treatment delivery, treatment receipt, and enactment of treatment skills (Bellg et al., 2004; Gearing et al., 2011). According to Gearing and colleagues (2011), intervention delivery is often



Note. Nursing care was stratified into five categories: problem assessment, specific nursing action, referral primary care, referral specialized care, and coordination. Nursing care was determined for frail older patients who received a home visit from the nurse and one problem assessment to detect the severity of geriatric problem. The y-axis presents the number of nursing care delivered.

Figure 1. Flowchart trial design and intervention components of nurse-led primary care program.

considered at the heart of fidelity as it involves measurement of fidelity during the course of the intervention (Gearing et al., 2011).

Recently, we developed and evaluated an evidence-based multicomponent, proactive, nurse-led primary care program aiming to preserve daily functioning in frail older people and maintain independent living (Bleijenberg, Ten Dam, Drubbel, et al., 2013). The nurse-led care program can be defined as a complex intervention because it consists of multiple interacting components, and it has a flexible, tailored approach (Craig et al., 2008). The effectiveness of this program combined with a frailty screening instrument has been evaluated in a three-armed cluster randomized trial with over 3,000 older people in the Netherlands. After 1 year of follow-up, a relatively small, but significant effect on the primary outcome of daily functioning was observed, with beneficial effects for well-educated older people (Bleijenberg, Drubbel et al., 2013). Besides an evaluation of the effectiveness, information regarding the delivery of the intervention is required to fully understand how the results were obtained and to facilitate replication.

Conn and Groves (2011) described five elements that need to be included in research reports: theory, intervention recipient, interventionist, intervention content, and intervention delivery (Conn & Groves, 2011). These elements address the why, who, what, how, where, and how much questions concerning the intervention (Conn & Groves, 2011; Craig et al., 2008). The first four elements were addressed previously (Bleijenberg, Ten Dam, Drubbel, et al., 2013; Bleijenberg, Ten Dam, Steunenberg, et al., 2013; Bleijenberg, Drubbel et al., 2013).

The aim of this study was to assess treatment delivery, dose and content of nursing care delivered within the care program, and to explore if the delivery may have influenced the trial results.

METHODS

Study Design

An explanatory sequential mixed-methods design (Ivankova, Creswell, & Stick, 2006; Morgan, 2007) was conducted alongside the Utrecht Primary care PROactive Frailty Intervention Trial (U-PROFIT) to determine the intervention delivery within the nurse-led care program (Bleijenberg et al., 2012). Quantitative data were collected between October 2010 and March 2012. A focus group was conducted with a subsample of nurses shortly after the trial was ended.

Setting and Participants

Details of the U-PROFIT trial and the inclusion criteria have been described previously (Bleijenberg et al., 2012). In short, a total of 39 general practices in the Netherlands participated. Older adults (60 years and over) were eligible when at least one of the following criteria was fulfilled: (a) frailty, (b) polypharmacy, or (c) a consultation gap. The level of frailty that was calculated with a frailty index based on electronic medical record (EMR) data of the GP using the Rockwood deficit approach (Drubbel et al., 2012); polypharmacy, defined as chronic use of five or more different medications; and a consultation gap that was defined as not having consulted the GP in the past 3 years,

Table 1. Overview of the Number of Assessments, Actions, Referrals, and Coordination Tasks Included in the Evidence-Based Care Plans per Condition

| Conditions | Problem assessments (N) | Nursing Care | | | |
|----------------------------|-------------------------|-----------------------------|----------------------------|--------------------------------|------------------|
| | | Specific nursing action (N) | Referrals primary care (N) | Referrals specialized care (N) | Coordination (N) |
| Falls | 10 | 19 | 1 | 1 | 4 |
| Urinary incontinence | 5 | 26 | 1 | - | 5 |
| Nutrition and malnutrition | 4 | 14 | 4 | - | 3 |
| Cognition | 5 | 15 | 7 | 3 | 5 |
| Vision problems | 4 | 9 | 4 | - | 3 |
| Hearing impairment | 3 | 20 | 3 | 2 | 2 |
| Polypharmacy | 3 | 10 | 1 | - | 4 |
| Physical functioning | 2 | 12 | 4 | - | 4 |
| Loneliness | 3 | 9 | 2 | - | 4 |
| Mood and depression | 4 | 12 | 4 | 1 | 6 |
| Caregiver burden | 4 | 18 | 3 | 1 | 6 |

except for the yearly influenza vaccination. Patients who fulfill one or more of these criteria were invited to participate in the trial (Bleijenberg et al., 2012). Older people living in a nursing home or in an assisted living facility or who were terminally ill were excluded.

Procedures

The EMRs of older adults aged 60 and over were screened by a software application in the general practice for the following criteria. Eligible patients were invited by their GP.

The primary outcome was daily functioning (ADL/IADL) measured with the Katz-15 index questionnaire (Laan et al., 2014). Secondary outcomes were quality of life, healthcare consumption, and cost-effectiveness, collected using questionnaires and EMR records. In this study, data from the participants assigned to the nurse-led care intervention group were used ($N = 835$). A flowchart of the trial design is shown in Figure 1.

Description of the Nurse-Led Primary Care Program

The multicomponent nurse-led primary care program included several components of assessment, evidence-based care planning, and care coordination. Specially trained registered nurses delivered the intervention in primary care. The nurses conducted the following steps.

First, patients at risk for adverse health outcomes and identified on the EMR data of the GP received a postal question-

naire to measure the level of frailty, complexity of care needs, and well-being. Second, a comprehensive geriatric assessment (CGA) was conducted at home for those who were identified as frail on the Groningen Frailty Indicator (GFI) questionnaire (GFI score of ≥ 4 ; Peters, Boter, Buskens, & Slaets, 2012; Steverink, Slaets, Schuurmans, & Van Lis, 2001) in the previous step. Next, the nurse developed an individualized care plan in close collaboration with the GP, the patient, the caregiver, and other healthcare professionals if necessary. Care coordination and the number of follow-up visits were provided by the nurses based on patients' needs (Figure 1).

An integrated, multidisciplinary, and flexible approach was chosen. A detailed description of the development of the program has been described previously (Bleijenberg, Ten Dam, Drubbel, et al., 2013). To increase the quality and feasibility in daily practice a multidisciplinary team of researchers, GPs, registered practice nurses, experts, and an independent panel of older persons were involved during the design of the intervention. All intervention components were tested in a small feasibility study (Bleijenberg, Ten Dam, Drubbel, et al., 2013).

Training of Nurses

Prior to the start of the trial, 21 registered practice nurses were recruited and employed for the study. All nurses worked in general practice and were extensively trained during a 6-week training period of 8 hours per week. During the training, the content of the program as well as its core components and delivery were discussed. Prior to the start of the intervention, all

nurses and GPs participated in a mandatory 4-hour training session focusing on collaboration skills and transforming primary care for older people. During the trial, monthly meetings were scheduled for the nurses to enhance ongoing learning and to improve treatment fidelity. An experienced nurse-leader led all the meetings. Individual patient cases were discussed in small groups to enhance problem-solving and feedback skills. In addition, experts of various geriatric topics were invited to support ongoing learning and improve nurses' knowledge.

Evidence-Based Care Plans

To enhance and encourage continuity of care delivery by nurses, evidence-based care plans were developed for the following 11 common geriatric conditions: falls, physical functioning, loneliness, mood or depression, vision impairment, hearing impairment, nutrition or malnutrition, cognitive problems, urinary incontinence, polypharmacy, and caregiver burden (all available upon request). The evidence-based care plans were developed using a stepwise approach consisting of literature and guidelines review, best practices experience from primary care nurses and expert opinions (Bleijenberg, Ten Dam, Drubbel, et al., 2013). The care plans included assessments, evidence-based and best practice interventions, and recommendations for each geriatric condition (Table 1). The information was summarized on flowcharts to be used as a practical tool for the nurses in clinical practice.

In this study, nursing care was regarded as the composite of assessments, interventions, and recommendations. Interventions and recommendations were categorized into specific nursing actions, primary care and specialized care referrals, and care coordination. As an example, for mood and depression, the geriatric depression scale (Yesavage et al., 1983) was labeled as assessment; "helping the patient with day structure" was labeled as a specific nursing action; and "discuss care plan with GP or other healthcare professionals" was labeled as care coordination.

Data Collection on Nursing Care Delivery

To determine the type and dose of nursing care delivered for each of the 11 conditions, the nurses were asked to report all performed assessments, specific nursing actions, primary care and specialized care referrals, and coordination tasks for each patient on a website specially developed for study purposes. The number of assessments, nursing actions, and referrals included in the evidence-based care plans differed by condition (Table 1).

Qualitative Data

A focus group was conducted to explore differences in the type and dose of nursing care delivered for each geriatric condition. A random subgroup of nurses was invited to participate in the focus group. The protocol for focus group meeting included the following topics: introduction, presentation of the quantitative results, discussion, and explanation of the differences in the delivery of nursing care within the program. The first author

Table 2. Baseline Characteristics Frail Older People ($N = 835$)

| | All patients $N = 835$ |
|---|--|
| Age, mean (<i>SD</i>) | 75.4 (8.4) |
| Female, n (%) | 538 (64.4) |
| Marital status, n (%) | 429 (51.4) |
| Married | 240 (28.7) |
| Widowed | |
| Having children, n (%) | 685 (87.0) |
| Education level primary school or less, n (%) | 203 (24.3) |
| Socioeconomic status, n (%) | |
| Low | 363 (44.5) |
| Average | 325 (39.9) |
| High | 128 (15.7) |
| Living situation, n (%) | |
| Alone | 388 (46.5) |
| Together with others | 447 (53.5) |
| Number of medications in chronic use, median (<i>IQR</i>) | 7.0 (5-9) |
| GFI score*, mean (<i>SD</i>) | 6.6 (2.0) |
| Intermed score**, mean (<i>SD</i>) | 14.57 (5.6) |
| Intermed score ≥ 20 , n (%) | 105 (8.2) |
| Self-rated health, excellent or good, n (%) | 192 (23) |
| Quality of life, mark between 0 and 10, mean (<i>SD</i>) | 7.02 (1.2) |

Notes. *GFI score ranges from 0 to 15. A score of ≥ 4 is indicated as frail. **Intermed score ranges from 0 to 60. A high score indicates high complexity of care.

wrote the protocol, presented the quantitative results, observed, took notes, and handled the technical equipment. The moderator performed the consent process for the protocol, introduced the groups, and led the discussion.

Analysis

Quantitative data were analyzed using descriptive statistics to describe the characteristics of the patients who received the nurse-led care program, including means (*SD*), medians (*IQR*), or n (%) where applicable. Frequencies and percentages of applied interventions were reported for each geriatric condition. SPSS version 20 (SPSS Inc., Chicago, IL, USA) was used.

The focus group was audiotaped, and the tape was transcribed verbatim to allow for systematic analysis (Kitzinger

& Barbour, 1999). The transcripts were studied by three independent researchers (NB, BS, and VHD) repeatedly, and initial themes were identified using open coding of the data. Differences in themes were resolved through discussions with BS, VHD, and NB. Member checking was employed to ensure content validity by obtaining agreement from the participating nurses on a summary of the focus group findings. The data were studied in a transparent and systematic way using triangulation, segmenting, and reassembling (Boeije, 2009).

Ethical Considerations

This study, as part of the U-PROFIT trial, was approved by the Institutional Review Board of the University Medical Center Utrecht with protocol ID 10-149/O. All participants signed an informed consent form.

RESULTS

In total, 835 older patients were identified as frail according to the GFI questionnaire and received a comprehensive assessment at home by the nurse. The mean age of the participants was 75.4 years (*SD*: 8.4), most were female (64.4%), and approximately half lived independently alone (46.5%; Table 2). The most frequent self-reported geriatric conditions were polypharmacy (95.6%), loneliness (60.8%), and cognition (59.4%; Table 2). Most nursing care was delivered to patients at risk for falls and urinary incontinence, while nutritional problems were least addressed (Figure 2).

Table 3 shows the dose of nursing care delivered. The dose of nursing care received of each geriatric condition was different for all patients since the intervention was tailored to the individual care needs of older people. In one-third of the patients with a geriatric condition (range 21.9%-48.1%), the nurses applied at least one problem assessment (Table 3). Most assessments were conducted for polypharmacy (48.1%) and physical functioning (44.1%). In patients with self-reported caregiver burden, mood and depression, or nutrition problems, only 20.4%, 21.9%, and 22.8% received a problem assessment, respectively (Table 3). Most patients who received an assessment also received at least one specific nursing action (range 85%-96%), however, those with cognitive and nutritional problems rarely received a specific nursing action. Figure 2 shows the mean dose of nursing care delivered per geriatric condition. Most actions were applied in patients at high risk of falls and urinary incontinence.

Few patients were referred to healthcare professionals in primary care or secondary care (Table 3). Patients at risk of caregiver burden (72.7%), those with vision problems (32.1%), hearing impairment (31.7%), at risk for falls (29.2%), and those with nutrition or malnutrition problems (28.4%) were most frequently referred to primary care professionals such as an elderly care advisor, ophthalmologist, audiometric specialist, occupational therapist, or dietician (specific type of referrals for each geriatric condition are available on request). Patients with a confirmed risk of falls were usually referred to specialized

care; 39.6% were referred to a fall clinic in the hospital. Only 10.6% of the patients with cognition problems were referred to a specialist in the hospital.

Care coordination and follow-up were provided to most patients who received an assessment for a geriatric condition, with a range from 41.4% for patients with hearing impairment to 82% for patients with mood and depression problems (Table 3). The vast majority of patients with mood and depression problems, patients at risk for caregiver burden and polypharmacy received intensive care coordination (Table 3).

Qualitative Findings

Based on the results of the focus group, three themes emerged that likely explained the differences in the type and dose of nursing care delivered between the geriatric conditions. First, the preference of both the patient and the nurse influenced the intervention delivery. Second, time required to apply an intervention was an influencing factor. Third, the type and dose of nursing care delivered was delivered to a selected group of patients, namely those who participated in the trial. This was illustrated by some statements from the nurses.

Falls are often an acute problem, and the evidence-based care plan included relatively “quick and easy-to-apply” actions, such as removing some mats and tables and giving advice. Also, it is not a taboo topic to discuss compared to for example, mood and depression.

Nutrition was not always perceived as important for both the patient as well as the nurse.

Nutrition was often not perceived as a problem. Although most patients suffered from multiple health problems, nutrition was no priority for them. On the contrary, sometimes, I did not want to disturb common habits when the situation was not hazardous.

Nurses perceived that mood or depression issues are time-consuming problems and explained that building trust and a establishing a good relationship is essential before nursing care can be successfully delivered. “Problems such as mood and depression required intensive care coordination because my first goal is to build up a confidence relationship with the patient before interventions can be applied.”

During the focus group, the variance in the number of referrals was discussed. The nurses explained that a high volume of care was delivered by themselves or the GP which reduced the number of referrals to specialized care. “Together with the GP, we are able to deliver a lot of care by ourselves, so referrals to specialized care are therefore less needed.” “During the trial, if patients needed to be referred to specialized care, the GP initiated this referral which was probably not registered. This may explain some of low numbers of the referrals to specialized care.” “Currently, I refer patients with low vision or hearing loss to an optician or hearing care professional within

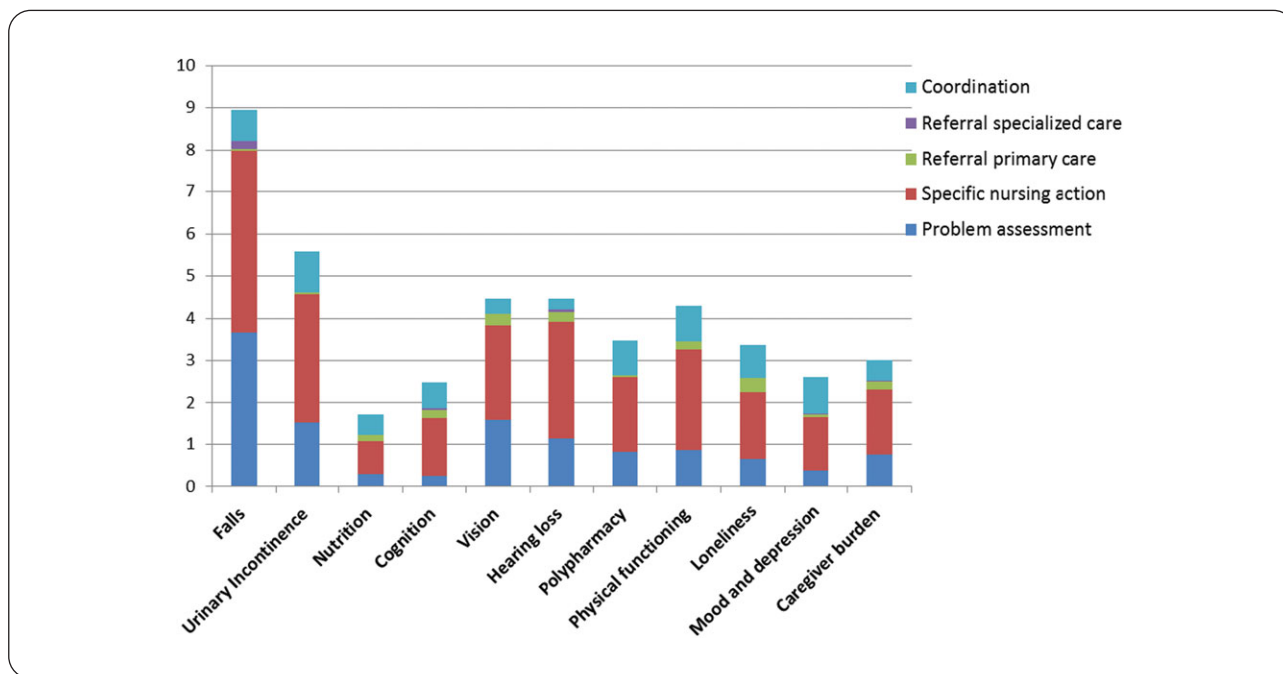


Figure 2. Nursing care delivered stratified per condition.

the primary care setting, while some years ago, these patients were referred to a specialist.”

The nurses emphasized the importance of care coordination and explained that the intensity of coordination was dependent on the type of problem of the patient. “Most frail patients suffer from multiple diseases, so multiple healthcare providers are involved. This requires good coordination and collaboration with the GP and other healthcare professionals.”

Due to the fact that the intervention was executed within a randomized trial, probably a selective group of older people were enrolled:

Patients that participated in the trial were relatively healthy and able to sign an informed consent. During the home visit, cognitive problems were often minor or even not an issue, because only one screening item assessed whether the patient perceived “memory loss”; this item did not seem to discriminate well.

DISCUSSION

This mixed-method study examined the intervention delivery of a nurse-led primary care program for older adults and demonstrated that the type and dose of nursing care differed between various geriatric conditions. Overall, most nursing care was delivered to patients with an increased risk of falls and urinary incontinence. All intervention components of the nurse-led program (e.g., the frailty assessment, CGA, the evidence-based care plans, care coordination, and follow-up visits) were delivered, however, it did not always match with the intended care delivery as agreed prior to the start of the trial. Differences were most noticeable for cognition, nutrition or malnutrition,

and mood or depression. The nurses explained that differences were related to the preference of the patient, type of problem, and time required to apply a specific nursing action (easy and quick-to-apply, vs. more time-consuming nursing actions).

Interpretation of the Fidelity in Relation to the Trial Results

The results of this study enhanced our understanding of the treatment fidelity (e.g., how the evidence-based nurse-led primary care program was delivered during the trial). The delivery of the care program is probably associated with the obtained trial results that showed a small but significant effect on the preservation of daily functioning (Bleijenberg, Drubbel et al., 2013). First, the results of this study showed that the nurse-led intervention program was suboptimally implemented: only one-third of the older people who reported to have (some) problems at one or more conditions (e.g., cognition or nutrition) did receive further diagnostic assessment. This implicates that if the intervention program was provided as intended, the trial might have shown more robust results. Despite the fact that the nurses were adequately trained, it can be questioned whether all patients received the optimal intervention intensity. Nurses commented that they needed some time to intervene. Especially in patients with problems regarding mood and depression, nurses first focused on building trust and a good relationship. Also, older people with depressive feelings may not wish to bother medical professionals (Murray et al., 2006) or may refuse treatment (Van der Weele et al., 2012). However, results of our qualitative study showed that the nursing care delivered was overall well regarded by the participating

Table 3. Number of Self-Reported Geriatric Problems and Overview of the Type and Dose of Nursing Care Delivered to 835 Older People*

| | Nursing Care | | | | | |
|--|-------------------------|--------------------|--------------------------|------------------------|----------------------------|---------------|
| | Patients with condition | Problem assessment | Specific nursing action* | Referral primary care* | Referral specialized care* | Coordination* |
| Falls, <i>n</i> (%) | 315 (37.7) | 106 (33.7) | 92 (86.8) | 31 (29.2) | 42 (39.6) | 60 (56.6) |
| Incontinence, <i>n</i> (%) | 421 (50.3) | 145 (34.4) | 139 (95.9) | 13 (9) | NA | 97 (66.9) |
| Nutrition and malnutrition, <i>n</i> (%) | 386 (46.2) | 88 (22.8) | 61 (69.3) | 25 (28.4) | NA | 58 (65.9) |
| Cognition, <i>n</i> (%) | 496 (59.4) | 161 (32.5) | 78 (48.4) | 29 (18) | 17 (10.6) | 87 (54) |
| Vision problems, <i>n</i> (%) | 350 (41.9) | 109 (31.1) | 104 (95.4) | 35 (32.1) | NA | 58 (53.2) |
| Hearing impairment, <i>n</i> (%) | 432 (51.7) | 145 (33.6) | 126 (86.9) | 46 (31.7) | 9 (6.2) | 60 (41.4) |
| Polypharmacy, <i>n</i> (%) | 798 (95.6) | 384 (48.1) | 324 (84.4) | 29 (7.6) | NA | 279 (72.7) |
| Physical functioning, <i>n</i> (%) | 270 (32.2) | 119 (44.1) | 101 (84.9) | 25 (21) | NA | 70 (58.8) |
| Loneliness, <i>n</i> (%) | 508 (60.8) | 163 (32.1) | 149 (91.4) | 30 (18.4) | NA | 106 (65) |
| Mood and depression, <i>n</i> (%) | 456 (54.6) | 100 (21.9) | 96 (96) | 16 (16) | 7 (7) | 82 (82) |
| Caregiver burden, <i>n</i> (%) | 108 (12.9) | 22 (20.4) | 21 (95.5) | 16 (72.7) | 2 (9.1) | 18 (81.8) |

Notes. *The number and percentage of specific nursing actions, referrals, and coordination is based on the number of patients who received a home visit from the nurse and one problem assessment to detect the severity of geriatric problem. NA: not applicable, referral to specialized care was not included in the evidence-based care plan and therefore not registered.

older adults. Timing of the visits, as well as the individual approach led to appreciation (Bleijenberg, Boeije, Onderwater & Schuurmans, 2015).

Second, the intervention delivery was affected by the relatively short time frame of the trial and the large caseload to which the nurses were exposed. Moreover, the provision of an evidence-based nurse-led care program requires time. The nurses experienced a learning curve; providing proactive, personalized care was difficult in the beginning but after 6 months nurses were more experienced (Bleijenberg, Ten Dam, Steunenbergh et al., 2013). We learned that more time is needed to fully implement an evidence-based multicomponent care program in daily practice.

Comparison With the Literature

Although various definitions of fidelity are used, the overall aim is to assess the extent to which a treatment is carried out as intended (Bellg et al., 2004; Gearing et al., 2011). The results of this study show that the intervention delivery can be improved which may contribute to more substantial treatment effects. Metzeltin and colleagues (2013) conducted a process evaluation to determine whether an interdisciplinary primary care approach for frail older people was implemented as planned (Metzeltin et al., 2013). The authors concluded that some parts of the protocol were insufficiently executed. Given the complexity of these types of interventions, implementation is

challenging and monitoring treatment fidelity should be incorporated in the initial planning and design of the study (Bellg et al., 2004).

In this study, most nursing care was delivered to patients with an increased risk of falls and urinary incontinence. The nurses argued that these interventions were often “simple” and “quick” to apply. Comparable findings were reported in a feasibility study of a fall-prevention program (Van Harten-Krouwel, Schuurmans, Emmelot-Vonk, & Pel-Littel, 2011). This may explain why time-consuming interventions, such as interventions for depression were less often applied in this study.

Strengths and Limitations

Some limitations of this study need to be addressed. First, we defined nursing care as the composite of assessments, interventions, and recommendations. Interventions and recommendations were categorized into specific nursing actions, referral to primary care and specialized care, and coordination to better elucidate the type of care provided. McCloskey and Bulechek (1994) described that the confusion about labels and failure to differentiate intervention from assessment and evaluation stem from the fact that nurses perform many activities to benefit the patient (McCloskey & Bulechek, 1994). Although existing nursing classification systems are necessary and enable clear communication, it may not be sufficient when evaluating details of treatment delivery or monitoring treatment fidelity

(Bakken et al., 2005; Bolton, Donaldson, Rutledge, Bennett, & Brown, 2007; Wakefield, Scherubel, Ray, & Holman, 2013). Second, despite the available tools to register the intervention delivery, the results may present an underestimation of the actual dose delivered. An explanation might be that not all actions and interventions were reported due to a lack of time or other reasons. This is known from the literature when an intervention program is delivered in a real-world setting (Bellg et al., 2004). Nonetheless, it is unlikely that the registration varied among the geriatric conditions, making the results valuable to determine the intervention delivery. Furthermore, the type and dose of nursing care was based on patients' needs. This flexible approach makes it challenging to quantify the extent in which the intervention was delivered as planned. Third, as previously mentioned, this study is susceptible to selection bias since only a selected group of older people participated in the trial. The vast majority of the patients were included based on the polypharmacy inclusion criterion, which explains the high proportion of older people with multiple medications. Finally, we did not collect data (numbers and reasons) on patients who refused nursing care on specific geriatric conditions and the exact number of home visits.

The strength of this mixed-methods study is that it evaluated the intervention delivery and determined the actual dose and type of nursing care delivered in response to identified problems during the trial. Treatment fidelity in nonpharmacological trials is rarely evaluated, but this evaluation is highly valuable since it provides important information concerning why a successful intervention works and how it can be optimized (Craig et al., 2008; Glasziou et al., 2010). Quantitative applied intervention results combined with qualitative data provide valuable insights into the "black box" of multicomponent interventions (Conn & Groves, 2011; Glasziou et al., 2010). The results of this study showed that the type and dose of applied interventions differed among the geriatric conditions due to the preference of the patient, type of problem, and type of intervention. This suggests that the nurse-led program was tailored to the patients' needs and preferences, which was one of our predefined aims (Bleijenberg, Ten Dam, Drubbel et al., 2013). A focus group with the nurses provided answers to questions that remain after analyzing the quantitative data. For transparency and replication (Conn & Groves, 2011), all registered assessments, specific nursing actions, referrals, and coordination per geriatric condition were collected and are available.

Implications for Research and Practice

The findings from this study showed that the actual delivery of nursing care plays an important role in the effectiveness of complex intervention trials (Inouye, Bogardus Jr, Williams, Leo-Summers, & Agostini, 2003). Although the relationship between the individual applied assessments, specific nursing actions and the overall treatment effect is complicated, the findings contribute to an improved understanding of the intervention delivery and the obtained trial results. The results

highlight the need to further improve the intervention delivery and provide valuable starting points for refinement.

Treatment fidelity is becoming all the more important when translating research findings into the real-world setting (Breitenstein et al., 2010; Schoenwald et al., 2011). Researchers who develop and evaluate multicomponent nurse-led interventions should verify the extent to which treatment was delivered as intended alongside a randomized trial. This is crucial to preserve both internal and external study validity (Bellg et al., 2004), to provide valuable insight into intervention success or failure, and leads to accurate interpretation of treatment effects. This knowledge is essential to successful translation of evidence-based interventions into practice.

CONCLUSIONS

This mixed-methods study evaluated treatment delivery by determining the type and dose of nursing care delivered in response to identified problems alongside a randomized trial. All intervention components were delivered, but differences were observed in the type and dose of nursing care delivered across geriatric conditions. The type and dose of nursing care was dependent on the preference of the patient, the type of problem, and the type of specific nursing action. The findings of this study better explain the trial results and suggest room for improvement of intervention delivery in order to increase beneficial patient outcomes. **WVN**



LINKING EVIDENCE TO ACTION

- Treatment fidelity provides detailed information on the delivery of the different aspects of an intervention.
- Determining treatment fidelity improves understanding of the underlying mechanism of an evidence-based intervention.
- The intervention delivery of an evidence-based nurse-led intervention in a proactive primary care program for older people proved suboptimal, suggesting that there is room for improvement, which may result in more beneficial patient outcomes.
- Treatment fidelity evaluation adds to further validation of evidence-based nursing interventions and is critical to successful translation of these interventions into practice.

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The authors gratefully acknowledge all the participants and nurses that participated in this study. We thank Bas Steunenberg for his contribution to the focus group, and Heather Greyson for her careful reading and her comments.

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Accepted 19 September 2015

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doi 10.1111/wvn.12151
WVN 2016;13:75–84