

ORIGINAL ARTICLE

Unravelling complex primary-care programs to maintain independent living in older people: a systematic overview

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Abstract

Objectives: Complex interventions are criticized for being a “black box”, which makes it difficult to determine why they succeed or fail. Recently, nine proactive primary-care programs aiming to prevent functional decline in older adults showed inconclusive effects. The aim of this study was to systematically unravel, compare, and synthesize the development and evaluation of nine primary-care programs within a controlled trial to further improve the development and evaluation of complex interventions.

Study Design and Setting: A systematic overview of all written data on the nine proactive primary-care programs was conducted using a validated item list. The nine proactive primary-care programs involved 214 general practices throughout the Netherlands.

Results: There was little or no focus on the (1) context surrounding the care program, (2) modeling of processes and outcomes, (3) intervention fidelity and adaptation, and (4) content and evaluation of training for interventionists.

Conclusions: An in-depth analysis of the context, modeling of the processes and outcomes, measurement and reporting of intervention fidelity, and implementation of effective training for interventionists is needed to enhance the development and replication of future complex interventions. © 2018 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Keywords: Complex interventions; Primary-care programs; Improvement; Development; Evaluation; Systematic overview

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What is new?**Key findings**

- Items regarding 1) problem identification, 2) theoretical framework, and 3) if and which effect the intervention had on the outcome measure were well described within the proactive primary-care programs.
- The context, modeling of processes and outcomes, fidelity, and training of interventionists were not adequately described.

What does this add to what was known?

- Several frameworks and reporting guidelines are available to guide and report the development and evaluation process of complex interventions. Complex care needs in older people require complex primary-care interventions. However, several recently developed and evaluated proactive primary-care programs have shown inconclusive results for relevant outcomes, such as the daily functioning of older people.
- In this article, a systematic overview was provided with the goal to evaluate the development and evaluation of proactive primary-care programs to enhance future complex interventions. Criteria from existing frameworks and reporting guidelines were used.

What are the implications and what should change now?

- To move further in the development and evaluation of complex interventions, more attention and research is needed that focuses on the following: 1) an in-depth analysis of the context; 2) modeling of processes and outcomes; 3) measuring and reporting intervention fidelity; and 4) conducting thorough and effective training for interventionists.

1. Introduction

Over the last decades, great emphasis has been placed on the development of complex interventions, which are defined as interventions with multiple interacting and synergetic components [1]. Several frameworks are available for the development and evaluation of complex interventions [1–5]. These frameworks highlight the importance of a systematic development and evaluation process [1,3,6]. Reporting guidelines have addressed the relevance of careful reporting to enhance replication and reduce research waste [7–13]. However, no systematic overview was found that combines insights from frameworks and from reporting

guidelines on the development and evaluation of complex interventions aiming to improve future designs and outcomes. In 2008, the Dutch Ministry of Health, Welfare, and Sport commissioned the Dutch National Care for Elderly Programme (NCEP) with a budget funding of 80 million euros. The NCEP had the goal of developing a more proactive, integrated health-care system for older patients. Research groups from the Netherlands could apply for a grant when they had a study proposal on how they could achieve proactive and integrated care for older people. As a result, more than 70 scientific projects were conducted and financed within the NCEP between 2009 and 2015 [14]. Of these 70 projects, nine large-scaled trials were all funded by the NCEP and all had the goal to preserve or improve daily functioning as a primary outcome among community-living older people in the Netherlands. These trials used the same questionnaire for evaluation, that is, the TOPIC-MDS [14]. All nine trials were proactive primary-care programs aimed at maintaining independent living in community-dwelling older people, which have been evaluated in controlled trials [15–23]. Proactive primary-care programs indicate early identification of patient at risk and early detection of possible health problems to prevent adverse health outcomes and acute care. These nine proactive primary-care programs consist of a nurse-led care plan and had a significant role in the execution of the proactive primary-care program for registered nurses or practice nurses in primary care.

To date, none of these proactive primary-care programs have demonstrated clinically relevant effects on daily functioning [15–23]. The multiple interacting and synergetic components of these proactive primary-care programs are often criticized for their “black box” concept. Not knowing the contents of the black box makes it difficult to understand why an intervention succeeds or fails. Within the nine controlled trials, uniform outcome parameters were collected and evaluated within comparable contexts, providing a unique opportunity to further study the process of development and evaluation of these complex interventions [1,8,24]. Therefore, we assessed the details of the development and evaluation processes of the nine proactive primary-care programs that have been evaluated within the NCEP. The aim of this study was to systematically unravel, compare, and synthesize the development and evaluation process of nine primary-care programs within a controlled trial to further improve the development and evaluation of complex interventions for (frail) older adults who live at home.

2. Methods**2.1. Design**

A systematic overview of all written data on the nine proactive primary-care programs—retrieved from the principal researcher of each proactive primary-care programme—was

conducted using a validated itemized list developed based on the literature on complex interventions. The itemized list was used as a tool to systematically extract data to unravel, compare, and synthesize the development and evaluation process of nine proactive primary-care programs within a controlled trial. Ethical approval was not required.

2.2. Eligibility criteria for the proactive primary-care programs

This study included randomized controlled trials that investigated the effectiveness of proactive primary-care programs in the Netherlands. The selection of studies was based on the fact that all included studies used the same questionnaire to evaluate the effect of the proactive primary-care program as indicated by the NCEP [14].

The following inclusion criteria were applied:

- The study was conducted within the NCEP between 2009 and 2015.
- The intervention included a nurse-led care plan as part of the proactive primary-care program for (frail) older persons.
- Registered nurses or practice nurses in primary care had a significant role in the execution of the proactive primary-care program.

2.3. Data collection

The principal investigators and research groups involved in the development and evaluation of the nine proactive primary-care programs were contacted by email. The researchers were invited to provide all available data and materials regarding the development and evaluation of the interventions, such as (research) reports, publications, theses, yearly reports for funders, educational/training materials, and information concerning the recruitment and training of the interventionists. The goal was to systematically unravel, compare, and synthesize the available information to gain insights into the similarities and differences in the development and evaluation of these proactive primary-care programs. For one proactive primary-care program (Programme 8), only published data could be obtained because the project was finished and the principal researcher was no longer available.

2.4. Development of the itemized list

To systematically unravel the obtained data and compare it with the best practices promoted in the literature, an itemized list was developed. First, items on transparent reporting [7–11,25], process evaluations [26–30] and guiding frameworks [1,6] were obtained from the literature. Second, the Medical Research Council (MRC) framework for developing and evaluating complex interventions was used as a guide to evaluate the content and methodology of the included proactive primary-care programs. The MRC framework includes

four phases: the development, feasibility/piloting, evaluation, and implementation of complex interventions [1]. The present study focused on the first three phases of the MRC framework because the implementation phase had not yet been completed and/or evaluated for all proactive primary-care programs. Third, information regarding the training, preparation, and education level of interventionists, that is, those who delivered the proactive primary-care program, was found to be important to report and was therefore added to the itemized list [9,31,32]. As a result, a preliminary list of 42 items was developed that comprised 24 items covering the MRC framework and 18 items covering the recruitment and training of the interventionists (Fig. 1).

2.4.1. Content validity of the itemized list

The content validity of the preliminary itemized list was assessed by an expert panel of 10 experts in the field of the development and evaluation of complex interventions. All experts were Dutch researchers in the field of medicine and nursing and had experience with developing, evaluating, implementing, and reporting complex interventions. The assessment was conducted in three steps (Fig. 1).

First, the experts were asked to score the relevance and clarity of each item on a five-point scale, with a higher score indicating greater relevance and clarity. Second, in a meeting with the expert panel, the items that received a score <3 for relevance and clarity from at least one expert were discussed. As a result, five items were found to be irrelevant, such as “was the control group in the care program described”, “motivation of the interventionists to carry out the care program”, and “what were the domains and competencies for training from the Dutch Federation of University Medical Centers (NFU)”. Third, the expert panel discussed whether items were missing from the list. Based on consensus, seven items were identified as missing, such as “investigating the needs of the provider and receiver” and “describing contextual factors”. One item, “were the components of the care program described” was clustered with an overarching item, “was the content of the care program described”. The final itemized list consisted of 43 items, of which 29 covered the development, pilot, and evaluation phases of the MRC framework, and 14 covered aspects of the recruitment and training of the interventionists. For a detailed description of each item, see [Appendix A](#).

2.5. Systematic data extraction

The itemized list was used as a tool to systematically assess (by LS) the extent to which the items related to development and evaluation were described in the nine proactive primary-care programs. One person (LS, who was not involved in one of the nine care programs) extracted the data and determined whether information was available or not. The assessment categorized each item as “described”, “partially described,” or “not described”.

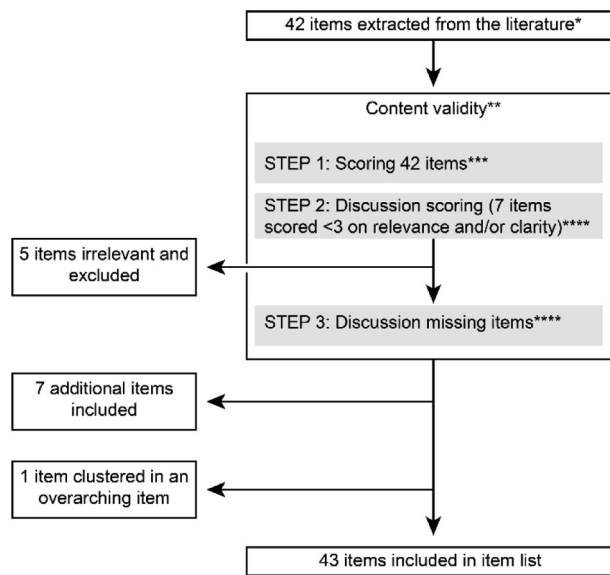


Fig. 1. Flowchart of the development of the itemized list. *Transparent reporting of complex interventions, process evaluations, and guiding frameworks. **Panel of 10 experts in complex interventions. ***Independent scoring by all experts to identify the relevance and clarity (separately) of each item, based on a 5-point scale. A score of 1 indicated strongly disagree and 5 indicated strongly agree. ****A meeting was organized to first discuss the independent scoring <3 on relevance and/or clarity and then discuss whether items were missing on the item list.

2.5.1. Member check of the systematic data extraction

The results of the systematic data extraction (summarized in Figs. 2 and 3) were sent to the principal investigator of each proactive primary-care program with a request to assess their internal validity. The principal researcher of each program was asked to check the analysis for errors and incorrect interpretations (validation step) [33]. In case of disagreement, the researcher was asked to provide written evidence (e.g., additional documents, files, or materials). If the provided evidence was sufficiently convincing and adequate (which was assessed by LS and NB independently), the category was changed. For example, item 7 (were the needs of the provider and receiver mapped) was, before member check, assessed as no information was described; however, the principal researcher delivered an additional document of their proposal which included information on the needs of the receiver. So, the assessment of item 7 changed into information partially described. In total, 34 (range 1–10 per program) of the 43 rated items were changed following the member check by eight research groups. Program 8 did not undergo a member check because the project was finished.

3. Results

All the proactive primary-care programs consisted of the early identification of older people at risk for functional decline, followed by multidisciplinary, integrated nurse-

led care for those older people at risk provided by specially trained practice nurses. The nurse-led care consisted of a comprehensive geriatric assessment at home, evidence-based care planning and care co-ordination. Although the overall aims were identical, the proactive primary-care programs differed in the methods used to identify patients at risk, intervention components, composition of the multidisciplinary team, age of the target group, and setting (urban or rural). The nine proactive primary-care programs involved 214 general practices and included a total of 15,058 older adults, of whom 9,155 (60.8%) were women with a mean age of 80.2 years. The proactive primary-care programs were implemented across different geographical areas in the Netherlands and had a 12- to 24-month follow-up period (see Appendix A for characteristics of the care programs).

The results of the systematic analysis of the development, piloting, and evaluation process regarding the MRC framework are provided in Fig. 2.

3.1. Development phase

Seven of the 12 items within the development phase were adequately described by all proactive primary-care programs. All proactive primary-care programs described their aim and content, and all were adequately based on existing theories and literature. The proactive primary-care programs clearly described who received and delivered the program's services. Two of nine proactive primary-care programs identified the needs of the older people in advance (programs 3 and 5). Three proactive primary-care programs identified the needs of the interventionists (programs 1, 5, and 6). No proactive primary-care program modeled the processes and outcomes. Two proactive primary-care programs (partially) described potential barriers and facilitators of the context in which the intervention should occur (programs 1 and 8), while no proactive primary-care program described contextual factors. The intensity of six proactive primary-care programs was unclear (programs 1–6). Detailed information on the development phase is provided in Appendix C.

3.2. Feasibility and piloting phase

Seven proactive primary-care programs conducted a pilot study to test feasibility and/or accessibility (programs 1–3, 5, and 7–9). However, only four of these proactive primary-care programs adequately described the results of the pilot study (programs 2, 3, 7, and 8). Detailed information on the feasibility and piloting phase is provided in Appendix D.

3.3. Evaluation phase

All the proactive primary-care programs evaluated the effectiveness of their primary and secondary outcomes, and eight conducted a cost-effectiveness study. Which

MRC stage	Item	Description	Program 1	Program 2	Program 3	Program 4	Program 5	Program 6	Program 7	Program 8	Program 9
Development	1	Was the problem defined?									
	2	Was the intervention goal defined?									
	3	Was there support in the literature?									
	4	Were there theoretical underpinnings of the intervention?									
	5	Was the content of the intervention described?									
	6	Intervention duration and intensity									
	7	Were the needs of the provider and receiver mapped?									
	8	Who delivered the intervention?									
	9	Who received the intervention?									
	10	Were contextual factors examined?									
	11	Were potential barriers and facilitators mapped?									
	12	Were process and outcome procedures/phases modeled?									
Piloting	13	Was a feasibility/pilot study conducted?									
	14	Were the results of the pilot described?									
Evaluation	15	Was the study design described?									
	16	Were the primary outcomes described?									
	17	Were secondary outcomes described?									
	18	Were outcomes in subgroups described?									
	19	Was fidelity described?									
	20	Was recruitment described?									
	21	Was the context described (e.g. barriers and facilitators)?									
	22	Was retention of the participants described?									
	23	Dose received (target group)									
	24	Dose received (satisfaction target group)									
	25	Dose received (satisfaction research group)									
	26	Intervention reached									
	27	Was the materials and tools used during implementation described?									
	28	Was a cost-effectiveness analysis conducted?									
	29	Were the results of the cost-effectiveness analysis described?									

Legend:
■ Fully described item
■ Partially described item
■ Non-described item

Fig. 2. Systematic analysis of the development, piloting, and evaluation phases. MRC, Medical Research Council.

effect the intervention had on the outcome measurement and the related costs compared to usual care were adequately described. Two proactive primary-care programs conducted an extensive process evaluation (items

19–26) (programs 3 and 8). Three items regarding the process evaluation, such as the recruitment of participants and the satisfaction with the dose of the intervention received on the part of both the providers (interventionists) and

Item	Description	Program 1	Program 2	Program 3	Program 4	Program 5	Program 6	Program 7	Program 8	Program 9
30	Was the method of recruitment of the interventionists described?									
31	Was the job description of the interventionists included in the job posting?									
32	Was the requested education level for interventionists described?									
33	Were the numbers of recruited interventionists and those who delivered the intervention described?									
34	Were the characteristics of the interventionists described?									
35	Was the method of the training described?									
36	Was the content of the training described?									
37	Was the individual who provided the training described?									
38	Were the duration and intensity of the training described?									
39	Did the interventionists undergo an assessment or exam, and if so, how were they tested?									
40	Were the test results described?									
41	Was the training evaluated?									
42	Were the materials and tools of the training available to the interventionists?									
43	Was there follow-up training?									

Legend:
■ Fully described item
■ Partially described item
■ Non-described item

Fig. 3. Systematic analysis of the recruitment and training of the interventionists.

receivers (older people), were adequately described by several proactive primary-care programs. Whether the proactive primary-care programs were delivered as planned (i.e., fidelity) was partially examined by six proactive primary-care programs (programs 1, 2, 4, 6, 7, and 9), and only three proactive primary-care programs extensively described the fidelity (programs 3, 5, and 8). The barriers and facilitators in the context of delivering care were described in two proactive primary-care programs (programs 3 and 8). These proactive primary-care programs also described the program's reach, for example, the extent to which the program reached frail older people. Detailed information on the evaluation phase is provided in [Appendix E](#).

3.4. Interventionists and training

The results of the systematic analysis of the interventionists and training are provided in [Fig. 3](#).

Two proactive primary-care programs provided information regarding the recruitment of interventionists, such as job description, educational level, and the number of recruited interventionists (programs 1 and 5). However, only one proactive primary-care program provided information regarding the characteristics of the recruited interventionists (program 1).

The main methods (programs 1–3 and 7–9) and the main content (programs 1–3, 5, and 7–9) of the training were described in most proactive primary-care programs. However, the proactive primary-care programs did not provide detailed information on didactical and teaching methods. Three proactive primary-care programs tested the knowledge of the interventionist after the training (programs 1, 7, and 9). However, only one proactive primary-care program described the results of this test (program 1). Four of the nine proactive primary-care programs provided information regarding the evaluation of the training (programs 1, 5, 7, and 8). No proactive primary-care program examined the effectiveness of the training, for example, by measuring behavioral changes. Detailed information regarding the interventionists and their training is provided in [Appendix F](#).

4. Discussion

This study systematically examined nine proactive primary-care programs to enhance the development and evaluation process of complex interventions for (frail) older people. Five main conclusions can be drawn from this systematic analysis. First, all the proactive primary-care programs had clear problem identification and theoretically underpinned content. Second, the context and current practice in which the proactive primary-care programs were conducted were not adequately described. Third, the modeling of processes and outcomes was absent in all of

the analyzed proactive primary-care programs. Fourth, fidelity was partially described in two-thirds of the proactive primary-care programs. Fifth, the training of the interventionists was evaluated in only three proactive primary-care programs. However, the effectiveness of the training was not reported by any of the proactive primary-care programs examined.

4.1. Strengths and weaknesses of principal findings

This study demonstrated that all the proactive primary-care programs had clear problem identification. In response to the problem identification, a theoretically underpinned intervention program was developed. If and which effect these developed care programs had on the outcome measurement and the related costs compared to usual care were also well described. This was not very surprising because the NCEP required these effectiveness and cost-effectiveness descriptions. In addition, the satisfaction of the older people who participated in the proactive primary-care programs was very well described for most proactive primary-care programs. This study revealed that most proactive primary-care programs paid insufficient attention to analyzing the context both before and during the evaluation phase. Understanding and investigating the context, such as current practices and existing the needs of the providers and patients, and knowledge of the target population and interventionists is crucial to enhance the effectiveness of complex interventions. Many reporting guidelines encourage comprehensive reporting of the context to enhance implementation and prevent the failure of replication [7,8,12,13,25]. Knowing the context can contribute to a better understanding of the implementation because interventions may be effective in one setting but not in others [6,9,12,34–36]. This is of influence whether the implementation strategy can be directly applied or will need adapting [12]. Furthermore, a comprehensive description of the context could also prevent the failure of replication [12,13]. To avoid this research waste, that is, correctable weaknesses in the design, execution, or analysis of complex interventions [37], every component of the proactive primary-care program should fit the context in which the proactive primary-care program is conducted [38,39]. To overcome the risk of inadequate implementation and the failure to replicate, future development of interventions should therefore focus on the implementation context [35,40]. In 2009, the literature regarding implementation was integrated into a single, consolidated framework to provide a pragmatic structure for approaching the complex, interacting, and multilevel constructs that may be faced during implementation [35]. The resulting Consolidated Framework for Implementation Research is promising and can be integrated throughout the development and evaluation of complex interventions [35,40]. In addition to this, the standard for reporting implementation studies statement was recently published, aiming to enhance transparent and

accurate reporting of implementation studies [12]. Furthermore, the modeling of processes and outcomes was absent in the proactive primary-care programs. It appears that modeling of processes and outcomes is the least examined and understood item of this study, which has also been reported in the literature [41]. Clarifying how an intervention works makes the “black box” more transparent [42]. The literature contains different models, such as the logic model, to assist with the general approach to building a complex intervention [43]. In 2015, Sermeus [41] proposed the following five-step modeling scenario as guidance for building a complex intervention: (1) evaluate existing evidence, (2) install a project team, (3) obtain consensus among stakeholders on crucial intervention components, (4) model the components in a process flow to provide the necessary resources, and (5) describe the components in concrete detail. More attention is needed to develop tools and methods to determine how interventions might work and to assist in modeling processes and outcomes. This study showed that intervention fidelity, that is, the extent to which the intervention was delivered as planned [30], was well described in only three proactive primary-care programs [44–46] and was partially described in six studies. Fidelity was difficult to compare across programs because it was measured differently [16,22,23,45,47–49]. Measuring intervention fidelity may reveal whether a lack of success is due to inappropriate service delivery or program inadequacies [26,29,50]. Intervention fidelity can be divided into five subcategories: content, frequency, duration, coverage, and timeliness [29,51]. Many prior studies, as well as the proactive primary-care programs in this study, have focused solely on frequency or duration [52]. Assessments of fidelity should focus on the effective components of an intervention [53]. However, when the effective components are unknown, the fidelity assessment should focus on the definitions of all intervention components before the start of the intervention [54], keeping the five subcategories of fidelity in mind [55]. The delivery of each component should then be compared with the description of how it was planned during development. Despite the extensiveness of this issue and the challenges that may be faced, all the subcategories of fidelity should be measured to achieve a comprehensive picture of fidelity [29,52,55]. To better evaluate fidelity, the five subcategories of fidelity should be considered when operationalizing and when measuring the fidelity of each intervention component. Interpreting fidelity should be balanced with the important issues regarding adaptation of intervention and implementation strategies [7,12,25]. Unfortunately, our study did not collect data regarding the adaptations that have been made within the nine proactive primary-care programs. To fit the implementation context, interventions are frequently adapted during the implementation process. These adaptations can consist of different types of adaptations such as planned or purposeful changes to the design or delivery of an intervention or unintentional deviations from

the intervention as originally developed [56]. To understand the nature of the adaptations that were made in particular contexts as well as the impact on intervention outcomes involves exploring whether these adaptations improve the contextual fit or compromise the functioning [24,56]. Exploring the adaptations may be best achieved with a comprehensive understanding of the intervention theory and qualitative methods [30]. A system for classifying the types of adaptations that are made when interventions are implemented was developed and provides helpful guides to report on the balance between fidelity and adaptation [56]. For future assessments of fidelity, a single, generic approach with the use of reporting guidelines regarding adaptations is highly recommended.

This study revealed that most proactive primary-care programs paid no or little attention to the recruitment and training of interventionists when developing and evaluating complex interventions. The content of the programs was mostly well described, but descriptions of the underlying didactical methods were lacking. Furthermore, training was evaluated in only three proactive primary-care programs, and none evaluated its effectiveness. The training of interventionists before intervention delivery is an important aspect of the transition from the planning-stage concept of the program to its effective implementation [34,57]. To understand whether the training is effective and whether the interventionists are able to apply the intervention in clinical practice, it is important to know whether the training is effective in changing the behavior of the interventionists [58]. Future complex interventions should pay more attention to the development and evaluation of interventionist training.

4.2. Strengths and weaknesses of this study

This study has several strengths. First, this is, to our knowledge, the first study that systematically examine, compare, and synthesize nine different proactive primary-care programs aimed at maintaining the independent living of older people at home. The findings of this systematic analysis contribute to enhancing our understanding of the development and evaluation process of complex interventions. The obtained insights into these processes will lead to recommendations for the development and evaluation of future complex interventions. Second, not only published data were used but also all the written evidence available for each proactive primary-care program were included. Detailed or extended information regarding programs is not always included in publications. The inclusion of all written evidence provides comprehensive insight into how the proactive primary-care programs were developed and evaluated. Third, a generic itemized list was generated based on the literature regarding complex interventions and was used as a tool to systematically examine the proactive primary-care programs. In future, this itemized list may be used by other researchers as a checklist in the

development and evaluation of complex interventions. Some weaknesses of this study should also be addressed. First, the included proactive primary-care programs were all developed and evaluated in the Netherlands and focused on the older Dutch population and the Dutch health-care context. Therefore, the generalizability of the findings to other European countries may be limited. However, the goal of this study was to obtain insights into the development and evaluation of complex interventions, which is not dependent on country. From the literature, it is known that the development and evaluation of complex interventions is not always adequate [58]. This study provides evidence identifying aspects that are in need of attention. Second, the assessment of items was based solely on descriptions of the written data [59]. Although many processes regarding the development of an intervention are performed subconsciously or are simply not recorded or are inaccurately recorded, it was not feasible to consider unwritten data. In addition, this study wanted to take into account and describe the adaptation of an intervention to a specific context. However, the written data collected for the systematic analysis did not include data on adapting interventions during implementation. Although we considered obtaining insights into the adaptation of the interventions by interviewing the principle researchers, we decided not to do so. Qualitative research methods to explore the extent of adaptation using unwritten data might have introduced recall bias because the trials were conducted between 2010 and 2014, which would have had an impact on our outcome measures [59,60]. Unwritten data, specifically adaptations of the intervention and implementation strategies are very important to address when designing and evaluating complex interventions and should have therefore more attention in the future. Third, no formal reliability analyses were conducted in our study. However, several steps were taken to improve the reliability of the results. Step one, the results of the systematic data extraction (summarized in Figs. 2 and 3) were sent to the principal investigator of each proactive primary-care program with a request to assess their internal validity. The principal researcher was asked to check the analysis for errors and incorrect interpretations [33]. Step two, in case of disagreement, the researcher was asked to provide written evidence (e.g., additional documents, files, or materials). Step three, if the provided evidence was sufficiently convincing (which was assessed by L.S. and N.B. independently), the category was changed. In total, 34 items (range 1–10 per program) were changed based on convincing additional documents. Most of the convincing additional documents were not provided during the first request of all the documents regarding the intervention which was the main reason that items changed. Fourth, the decision to label an item as “described” and “partially described” was based on the operationalization of the item list (Appendix A). When information on a specific item was not fully described because information was missing, then the decision was made to classify that as “partially described”. The first author

(L.S.), who was not involved in the design and conduct of the nine trials, rated the items. However, when L.S. was not sure about the rating, a second investigator (N.B.) was asked to independently judge a specific item of a specific study. Face validity was tested because the primary investigators were asked to review the final tables (Appendices B–F) and figures (Figs. 2 and 3).

4.3. How to move further in complex interventions

The implications of this work for future research, clinical practice, and policy can be summarized as follows: Every component of a complex intervention should be carefully developed based on the literature, the subcategories of fidelity, and the implementation context. Researchers should expect the intervention to produce at least marginal gains in terms of patient outcomes [1]. Richards emphasized the importance of the “amalgamation of marginal gains” [61]. A multicomponent intervention can obtain large effects only if all the components fit together perfectly [61]. Examining all components in-depth and fitting them to the context may lead to optimally designed interventions that contribute to improved patient outcomes [59]. In addition, an understanding of all components and underlying processes could also lead to the avoidance of ineffective components. In other words, the modeling of processes and outcomes is an important aspect of the development of complex interventions that could enhance the effect size of patient outcomes, which is often small in complex interventions. The measuring and reporting of intervention fidelity and adaptations to the implementation context requires much attention within the process evaluation. Generic approaches to measure intervention fidelity and understand adaptations to the implementation context could provide valuable, comparable, and exchangeable information for interpreting effects on patient outcomes. The implementation of thorough and effective training is an important aspect of obtaining sustainable behavior changes in interventionists, which is a condition for adequate implementation [54]. Furthermore, the generic itemized list could be a useful checklist in the development and evaluation of complex interventions as well as in the assessment of complex interventions for researchers and research funders.

5. Conclusion

This systematic analysis revealed that most proactive primary-care programs performed well, but several aspects of the development and evaluation process of complex interventions could be improved. To move further towards the development, evaluation, and implementation of complex interventions, more attention should be paid to the in-depth analysis of context, measuring and reporting of intervention fidelity and adaptation to the implementation context, and implementation of thorough and effective training for interventionists. Further research should

develop uniform methodology to enable standardized studies of context, modeling of processes and outcomes, intervention fidelity, adaptation to the implementation context, and educational efforts.

Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jclinepi.2017.12.013>.

References

- [1] Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M, et al. Developing and evaluating complex interventions: the new medical research council guidance. *BMJ* 2008;337:a1655.
- [2] Grol R, Wensing M, Eccles M. Improving patient care: the implementation of change in clinical practice. Edinburgh, Scotland: Elsevier; 2005:41–58.
- [3] Bartholomew L, Parcel G, Kok G, Gottlieb N. Intervention mapping: designing theory and evidence-based health promotion programs. Mountain View, CA: Mayfield; 2001.
- [4] Glasgow RE, McKay HG, Piette JD, Reynolds KD. The RE-AIM framework for evaluating interventions: what can it tell us about approaches to chronic illness management? *Patient Educ Couns* 2001;44(2):119–27.
- [5] Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. *Health Psychol* 2008;27:379.
- [6] Meijel BV, Gamel C, Swieten-Duijfjes BV, Grypdonck M. The development of evidence-based nursing interventions: methodological considerations. *J Adv Nurs* 2004;48:84–92.
- [7] Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:g1687.
- [8] Möhler R, Bartoszek G, Köpke S, Meyer G. Proposed criteria for reporting the development and evaluation of complex interventions in healthcare (CReDECI): guideline development. *Int J Nurs Stud* 2012;49(1):40–6.
- [9] Conn VS, Groves PS. Protecting the power of interventions through proper reporting. *Nurs Outlook* 2011;59:318–25.
- [10] Thabane L, Ma J, Chu R, Cheng J, Ismail A, Rios LP, et al. A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol* 2010;10:1.
- [11] Craig P. A new CONSORT extension should improve the reporting of randomized pilot and feasibility trials. *J Clin Epidemiol* 2017;84:30–2.
- [12] Pinnock H, Barwick M, Carpenter CR, Eldridge S, Grandes G, Griffiths CJ, et al. Standards for reporting implementation studies (StaRI) statement. *BMJ* 2017;356:i6795.
- [13] Boutron I, Altman DG, Moher D, Schulz KF, Ravaud P. CONSORT statement for randomized trials of nonpharmacologic treatments: a 2017 update and a CONSORT extension for nonpharmacologic trial abstracts. *Ann Intern Med* 2017;167:40–7.
- [14] Lutomski JE, Baars MA, Schalk BW, Boter H, Buurman BM, den Elzen WP, et al. The development of the older persons and informal caregivers survey minimum dataset (TOPICS-MDS): a large-scale data sharing initiative. *PLoS One* 2013;8:e81673.
- [15] Bleijenberg N, Drubbel I, Schuurmans MJ, Dam HT, Zuihthoff N, Numans ME, et al. Effectiveness of a proactive primary care program on preserving daily functioning of older people: a cluster randomized controlled trial. *J Am Geriatr Soc* 2016;64(9):1779–88.
- [16] Blom J, den Elzen W, van Houwelingen AH, Heijmans M, Stijnen T, Van den Hout W, et al. Effectiveness and cost-effectiveness of a proactive, goal-oriented, integrated care model in general practice for older people. A cluster randomised controlled trial: integrated systematic care for older people—the ISCOPE study. *Age Ageing* 2016;45:30–41.
- [17] Metzelthin SF, van Rossum E, de Witte LP, Ambergen AW, Hobma SO, Sipers W, et al. Effectiveness of interdisciplinary primary care approach to reduce disability in community dwelling frail older people: cluster randomised controlled trial. *BMJ* 2013;347:f5264.
- [18] Looman WM, Fabbriotti IN, de Kuyper R, Huijsman R. The effects of a pro-active integrated care intervention for frail community-dwelling older people: a quasi-experimental study with the GP-practice as single entry point. *BMC Geriatr* 2016;16:43.
- [19] Hoogendijk EO, van der Horst HE, van de Ven PM, Twisk JW, Deeg DJ, Frijters DH, et al. Effectiveness of a geriatric care model for frail older adults in primary care: results from a stepped wedge cluster randomized trial. *Eur J Intern Med* 2016;28:43–51.
- [20] Ruikes FG, Zuidema SU, Akkermans RP, Assendelft WJ, Schers HJ, Koopmans RT. Multicomponent program to reduce functional decline in frail elderly people: a cluster controlled trial. *J Am Board Fam Med* 2016;29(2):209–17.
- [21] Stijnen M, Vrijhoef H, Jansen M, Candel M, Duimel-Peeters I. Effectiveness of a nurse-led home visitation programme on health-related quality of life and disability among potentially frail community-dwelling older people in primary care: a longitudinal, quasi-experimental study. Towards proactive care for potentially frail older people in general practice 2015;121. Available at <https://cris.maastrichtuniversity.nl/portal/files/1420351/guid-669cd3de-34f4-4d7d-8086-5e7bdd334c7c-ASSET1.0#page=121>.
- [22] Suijker JJ, van Rijn M, Buurman BM, Ter Riet G, Moll van Charante EP, de Rooij SE. Effects of nurse-led multifactorial care to prevent disability in community-living older people: cluster randomized trial. *PLoS One* 2016;11:e0158714.
- [23] Uittenbroek RJ, Kremer HP, Spoorenberg SL, Reijneveld SA, Wynia K. Integrated care for older adults improves perceived quality of care: results of a randomized controlled trial of embrace. *J Gen Intern Med* 2017;32:516–23.
- [24] Hawe P, Shiell A, Riley T. Complex interventions: how “out of control” can a randomised controlled trial be? *BMJ* 2004;328:1561–3.
- [25] Möhler R, Köpke S, Meyer G. Criteria for reporting the development and evaluation of complex interventions in healthcare: revised guideline (CRReDECI 2). *Trials* 2015;16(1):204.
- [26] Grant A, Treweek S, Dreischulte T, Foy R, Guthrie B. Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. *Trials* 2013;14(1):15.
- [27] Baranowski T, Stables G. Process evaluations of the 5-a-day projects. *Health Educ Behav* 2000;27(2):157–66.
- [28] Saunders RP, Evans MH, Joshi P. Developing a process-evaluation plan for assessing health promotion program implementation: a how-to guide. *Health Promot Pract* 2005;6(2):134–47.
- [29] Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S. A conceptual framework for implementation fidelity. *Implement Sci* 2007;2:40.
- [30] Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ* 2015;350:h1258.
- [31] Lette M, Baan CA, van den Berg M, de Bruin SR. Initiatives on early detection and intervention to proactively identify health and social problems in older people: experiences from The Netherlands. *BMC Geriatr* 2015;15:143.
- [32] Glasziou P, Chalmers I, Altman DG, Bastian H, Boutron I, Brice A, et al. Taking healthcare interventions from trial to practice. *BMJ* 2010;341:c3852.
- [33] Creswell JW. Research design: qualitative, quantitative, and mixed methods approaches. Thousand Oaks, CA, USA: Sage Publications; 2013.
- [34] Campbell NC, Murray E, Darbyshire J, Emery J, Farmer A, Griffiths F, et al. Designing and evaluating complex interventions to improve health care. *BMJ* 2007;334:455–9.

- [35] Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 2009;4:50.
- [36] Shippee ND, Shah ND, May CR, Mair FS, Montori VM. Cumulative complexity: a functional, patient-centered model of patient complexity can improve research and practice. *J Clin Epidemiol* 2012;65:1041–51.
- [37] Ioannidis JP, Greenland S, Hlatky MA, Khoury MJ, Macleod MR, Moher D, et al. Increasing value and reducing waste in research design, conduct, and analysis. *Lancet* 2014;383(9912):166–75.
- [38] Chalmers I, Glasziou P. Avoidable waste in the production and reporting of research evidence. *Obstet Gynecol* 2009;114(6):1341–5.
- [39] Chalmers I, Bracken MB, Djulbegovic B, Garattini S, Grant J, Gülmezoglu AM, et al. How to increase value and reduce waste when research priorities are set. *Lancet* 2014;383(9912):156–65.
- [40] Kirk MA, Kelley C, Yankey N, Birken SA, Abadie B, Damschroder L. A systematic review of the use of the consolidated framework for implementation research. *Implement Sci* 2016;11:72.
- [41] Sermeus W. Modelling process and outcomes in complex interventions. In: Richards D, Hallberg IR, editors. *Complex interventions in health: an overview of research methods*. London: Routledge; 2015:111.
- [42] Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. Framework for design and evaluation of complex interventions to improve health. *BMJ* 2000;321:694–6.
- [43] Kellogg W. *Logic model development guide*. Michigan: WK Kellogg Foundation; 2004.
- [44] Metzelthin SF, Daniëls R, van Rossum E, Cox K, Habets H, de Witte LP, et al. A nurse-led interdisciplinary primary care approach to prevent disability among community-dwelling frail older people: a large-scale process evaluation. *Int J Nurs Stud* 2013;50(9):1184–96.
- [45] Muntinga ME, Van Leeuwen KM, Schellevis FG, Nijpels G, Jansen AP. From concept to content: assessing the implementation fidelity of a chronic care model for frail, older people who live at home. *BMC Health Serv Res* 2015;15:18.
- [46] Stijnen MM, Jansen MW, Duimel-Peters IG, Vrijhoef HJ. Nurse-led home visitation programme to improve health-related quality of life and reduce disability among potentially frail community-dwelling older people in general practice: a theory-based process evaluation. *BMC Fam Pract* 2014;15(1):173.
- [47] Bleijenberg N, Ten Dam VH, Drubbel I, Numans ME, Wit NJ, Schuurmans MJ. Treatment fidelity of an evidence-based nurse-led intervention in a proactive primary care program for older people. *Worldviews Evid Based Nurs* 2016;13(1):75–84.
- [48] Janse B, Huijsman R, Fabbicotti IN. A quasi-experimental study of the effects of an integrated care intervention for the frail elderly on informal caregivers' satisfaction with care and support. *BMC Health Serv Res* 2014;14:140.
- [49] Ruiks FG, van Gaal BG, Oudshoorn L, Zuidema SU, Akkermans RP, Assendelft WJ, et al. The association between implementation and outcome of a complex care program for frail elderly people. *Fam Pract* 2018;35:47–52.
- [50] Oakley A, Strange V, Bonell C, Allen E, Stephenson J, RIPPLE Study Team. Process evaluation in randomised controlled trials of complex interventions. *BMJ* 2006;332:413–6.
- [51] Hasson H. Systematic evaluation of implementation fidelity of complex interventions in health and social care. *Implement Sci* 2010;5:67.
- [52] Dusenbury L, Brannigan R, Falco M, Hansen WB. A review of research on fidelity of implementation: implications for drug abuse prevention in school settings. *Health Educ Res* 2003;18(2):237–56.
- [53] Fixsen DL, Naoom SF, Blase KA, Friedman RM, Wallace F. *Implementation research: a synthesis of the literature*. Louis: University of South Florida de la Parte Florida Mental Health Institute; 2005.
- [54] Bellg AJ, Borrelli B, Resnick B, Hecht J, Minicucci DS, Ory M, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol* 2004;23:443.
- [55] Hasson H. Intervention fidelity in clinical trials. In: Richards D, Hallberg IR, editors. *Complex interventions in health: an overview of research methods*. London: Routledge; 2015.
- [56] Stirman SW, Miller CJ, Toder K, Calloway A. Development of a framework and coding system for modifications and adaptations of evidence-based interventions. *Implement Sci* 2013;8:65.
- [57] Bradley F, Wiles R, Kinmonth AL, Mant D, Gantley M. Development and evaluation of complex interventions in health services research: case study of the Southampton heart integrated care project (SHIP). The SHIP Collaborative Group. *BMJ* 1999;318:711–5.
- [58] Sheeran P, Klein WM, Rothman AJ. Health behavior change: moving from observation to intervention. *Annu Rev Psychol* 2017;68:573–600.
- [59] Ioannidis JP. Why most clinical research is not useful. *PLoS Med* 2016;13(6):e1002049.
- [60] Hess DR. Retrospective studies and chart reviews. *Respir Care* 2004;49(10):1171–4.
- [61] Richards DA. Complex interventions and the amalgamation of marginal gains: a way forward for understanding and researching essential nursing care? *Int J Nurs Stud* 2015;52(7):1143–5.