

ARTICLE

Process evaluation plan of a patient-centered home visitation program for potentially frail community-dwelling older people in general practice

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Abstract

Background: Evaluation studies examining the effectiveness of interventions tend to offer little insight into the mechanisms responsible for changes in outcomes. The present study has conducted a thorough process evaluation alongside a longitudinal quasi-experimental trial investigating the effects of a home visitation program for the early detection of health problems among potentially frail community-dwelling older people (≥ 75 years). We aim to describe the rationale for and steps undertaken in developing a process evaluation plan to identify the factors that influence the success or failure of this complex, patient-centered intervention within the primary care setting.

Method: Using a theoretical framework underlying the process evaluation, process evaluation questions are formulated per component of the framework (i.e., implementation fidelity, dose delivered, dose received, reach, recruitment and context). The process evaluation plan shows how both quantitative (e.g., structured registration forms) and qualitative methods (e.g., semi-structured interviews) are applied in gathering process data for a complex, patient-centered intervention integrated within general practices. Process data are gathered with either formative or summative purposes among practice nurses and general practitioners from participating general practices and a purposive sample of older people.

Conclusion: Conducting a process evaluation alongside a clinical trial will assist in deciding to what extent the intervention is effective, as well as what factors contribute to the intervention's effectiveness. The insights gained are imperative for the development of patient-centered interventions that are likely to be sustained when implemented in the intended context.

Keywords

Frail elderly, general practice, geriatric assessment, home visit, patient-centered care, person-centered medicine, primary care, process evaluation, program implementation

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Introduction

Most evaluation studies are primarily concerned with obtaining robust evidence of the effectiveness of interventions, while offering little insight into the underlying mechanisms through which changes in outcomes may occur. As a result, there has been a growing interest in process evaluation to understand the steps

undertaken during implementation of an intervention. Process evaluation data help to identify factors responsible for the success or failure of an intervention, including for whom and under what circumstances the intervention is effective [1]. Hence, process evaluation looks inside the "black box" to differentiate between interventions that have shortcomings in themselves (intervention failure) or

interventions that are badly delivered (implementation failure) [2,3].

Although process evaluation is frequently applied in the field of public health to evaluate health promotion and disease prevention programs [1], its merit for the evaluation of patient-centered healthcare interventions within the primary care setting is increasingly recognized as well. Primary care studies incorporating a process evaluation predominantly focus on implementing evidence-based interventions or clinical guidelines into practice. For example, a process evaluation conducted by Flottorp and colleagues [4] revealed reasons why general practices failed to implement guidelines for sore throat and urinary tract infections. In general, primary healthcare professionals experience various barriers to the implementation of evidence-based research findings into everyday practice [5,6]. Process evaluation can assist in identifying these barriers at an early stage, which may allow interventions to be disseminated and adopted more successfully [7] after their effectiveness has been established.

Nevertheless, the use of qualitative methods alongside controlled trials of complex healthcare interventions remains uncommon and process data are often poorly integrated with trial results [8]. As most trials tend to focus solely on outcomes, recent studies emphasize the importance of embedding a process evaluation in controlled trials of complex interventions [9,10]. The Medical Research Council (MRC) defines complex interventions as:

“...interventions with several interacting components (...) they present a number of special problems for evaluators. (...) Many of the extra problems relate to the difficulty of standardizing the design and delivery of the interventions, their sensitivity to features of the local context, the organizational and logistical difficulty of applying experimental methods to service or policy changes and the length and complexity of the causal chains linking intervention with outcome” [11].

The integration of outcome and process data contributes to a more thorough understanding of how the intervention functions in the intended context, allowing better judgment of transferability of research results into practice [2,12,13]. In other words, it defines how the intervention should be implemented in comparable settings to ensure similar outcomes are reached [2]. Moreover, combined outcome and process data may also reveal minimally required elements for optimal performance of the intervention in other, less comparable settings.

This paper presents the process evaluation plan of the [G]OLD-study (‘Getting OLD the healthy way’), a cluster quasi-experimental trial conducted in The Netherlands which aims to evaluate whether a preventive home visitation program for potentially frail community-dwelling older people (aged ≥ 75 years) within general practice will lead to improved health-related quality of life and reduced disability. The delivery of care for older people within primary care is redesigned by applying components of the Chronic Care Model (CCM) [14] and the Guided Care Model [15]. This resulted in the [G]OLD-

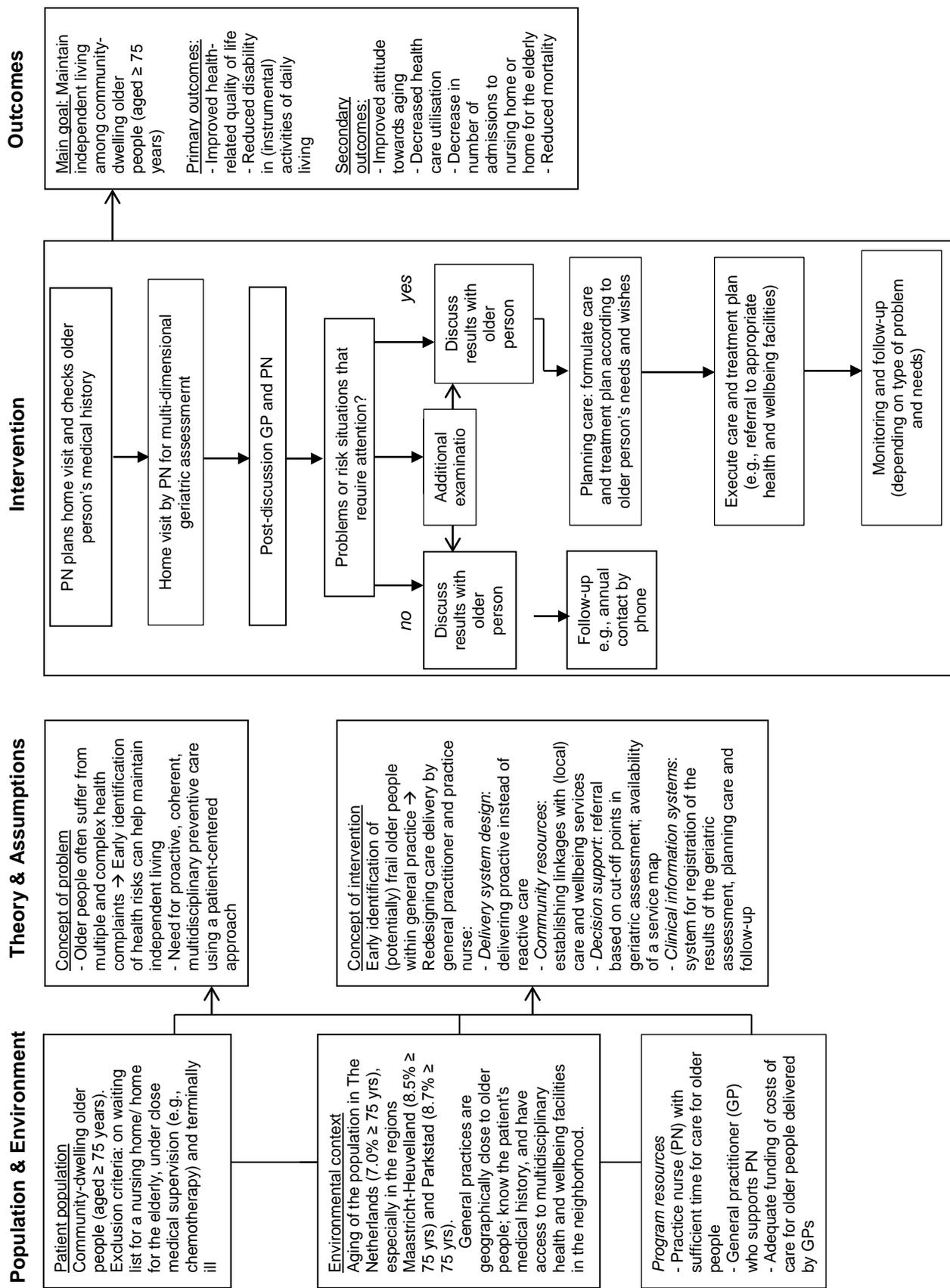
protocol: a patient-centered home visitation program consisting of a comprehensive multidimensional geriatric assessment of older people’s health and wellbeing, followed by, if necessary, individualized care (referral to appropriate care and/or wellbeing facilities) and follow-up. Figure 1 presents the logic model of the [G]OLD home visitation program, developed according to the 4 properties of logic models as claimed by Conrad and co-workers [16]. It delineates the essential components of the home visitation program and how the theory underlying the intervention, the intervention components and expected outcomes are linked to one another. In this way, the logical model serves as a framework for defining important intervention aspects that should be considered in the process evaluation [16].

Baranowski and Stables [17] argue, among others, for more thoroughly conducted process evaluations and greater consistency in concepts used to structure process evaluations. Therefore, we designed the process evaluation according to the steps for developing a process evaluation plan as suggested by Saunders and colleagues [18]. They propose 7 key elements of process evaluation, adapted from Baranowski and Stables [17] and Linnan and Steckler [1], including fidelity (quality of implementation), dose delivered (completeness), dose received (exposure), dose received (satisfaction), reach (participation rate), recruitment and context. We are particularly interested in the process of delivering and implementing the home visitation program within a dynamic and complex primary care setting and, therefore, we pay special attention to the element ‘context’ using the Normalization Process Model [19].

This model provides a conceptual framework for understanding the factors that affect the success or failure of a complex intervention within primary care in relation to the workability and integration of the intervention components. It includes 4 domains: (1) how work is enacted by the people doing it (interactional workability); (2) how work is understood within the networks of people around it (relational integration); (3) the place of work in a division of labour (skill-set workability) and (4) the organizational sponsorship and control of work (contextual integration). The model states that when a complex intervention is workable and integrated, it is more likely to become routinely embedded within everyday practice (‘disposed to normalization’) [19,20]. In this way, the model aids in the identification of contextual factors specific for primary care that may affect program implementation or program outcomes. For examples of how this model can be applied, see May and colleagues [20].

The different components and domains mentioned above, together with the logic model of the home visitation program, serve as a starting point for the development of the process evaluation plan for the [G]OLD-study. Overall, the current process evaluation aims to: (1) monitor and assess the implementation of the home visitation program within general practice and (2) generate findings that aid in the interpretation and explanation of the program effects obtained in the parallel controlled trial.

Figure 1 Logic model [G]OLD preventive home visitation program



Method

Process evaluation design

The process evaluation is conducted parallel to the longitudinal, quasi-experimental study examining the effects of the home visitation program and data collection is structured using a triangulation design model [21]. Some results of the process evaluation are used to inform the implementation process and to perform midcourse corrections when fidelity of implementation is threatened (formative purposes). However, most process data will not be available until after completion of the implementation of the program (summative purposes). Process data will be analyzed and interpreted before the outcomes of the effect study. In this way, hypotheses may be generated that can subsequently be statistically tested [10]. For instance, if the process evaluation shows variability between general practices in the quality of implementing the home visitation, how is this related to trial outcomes?

Process evaluation data are collected from all participating general practices who implement the home visitation program, as we expect that practice characteristics (e.g., number of professionals working within general practice) and factors related to the neighborhood in which practices are located, may influence the implementation process. For example, close proximity of other primary care professionals may facilitate collaboration in organizing and/or delivering appropriate care to older people [22]. Moreover, the number and type of health problems detected during the multi-dimensional assessment may depend on socio-economic circumstances of older people as these appear to be associated with health outcomes [23].

The protocol for the [G]OLD-study was judged by the Medical Ethical Committee (MEC) of the Maastricht University Medical Centre (MUMC+) as not needing formal ethical approval. Nonetheless, the MEC approved the study protocol for the [G]OLD-trial and accompanying process evaluation.

Setting

Thirteen general practices offer proactive care to people aged 75 or older according to the home visitation program (intervention group), whereas 11 general practices provide usual care (control group). Usual care encompasses reactive care to older people who present themselves with health problems or complaints. During the trial, control practices should not be engaged in any form of proactively assessing (potentially) frail older people's health status followed by targeted treatment or care and follow-up within the continuum of care.

Participating intervention practices are located in the regions Maastricht-Heuvelland and Parkstad in the south of the province Limburg in The Netherlands, where aging of the population is especially pronounced. In 2007, the Dutch College of General Practitioners stated that the responsibility for preventive care for older people should be assigned to general practitioners (GPs), supported by a

practice nurse (PN) [24]. In The Netherlands, practice nurses substitute GPs in chronic disease management by providing screening, treatment, care and education to patients suffering from, for example, diabetes mellitus, chronic obstructive pulmonary disease (COPD) and those at risk for vascular diseases. Nurses possess complementary expertise compared to GPs (e.g., in health education) [25] and when appropriately trained, they can achieve equally high or even better quality of care and positive health outcomes in patients as GPs [26,27]. Thus, it is assumed worthwhile to delegate care for older people to PNs. In the [G]OLD-study, the PN, supervised by the GP, is therefore in charge of conducting the home visits and reorganizing care for older people. Before the start of the trial, all 13 PNs from the intervention practices participated in a 2-day training to provide them with the necessary knowledge and skills for executing the different aspects of the home visitation program.

Program implementation as planned

The steps of the [G]OLD-protocol are illustrated in the flowchart in Figure 1 (see 'Intervention'). First, the PN contacts eligible older people to schedule a date for the home visit. The PN prints relevant information from the GP's information system concerning medical history and medication use to prepare for the home visit. The next step is visiting the older people at home and performing a comprehensive geriatric assessment of the person's physical, psychological, mental and social functioning using the so-called [G]OLD-instrument. This multi-dimensional instrument is specifically developed to assist PNs in uncovering (early signs of) health and/or wellbeing problems or complaints that may now or ultimately be detrimental for maintaining independent living [28]. After the home visit, the PN discusses the results of the geriatric assessment with the GP. If the older person is doing completely fine and no follow-up actions are needed, the PN communicates this to the older person and checks his/her health status again after one year (either by phone or by means of a re-assessment with the [G]OLD-instrument). However, if there are any (health) problems or risk situations that require attention, the PN formulates a care and treatment plan, if necessary with help of the GP and in agreement with the older person's needs and wishes. The PN subsequently executes the care and treatment plan, for example, by referring the older person to appropriate health and/or wellbeing facilities in the neighborhood. The PN monitors progress and coordinates care and follow-up; the number of follow-up contacts depends on the type of problem and the older person's needs and wishes. Sometimes, the PN and GP may be uncertain about the presence of health problems or risk situations. An additional examination might be necessary to confirm or reject previous assumptions before a care and treatment plan is formulated. To guarantee adequate delivery of the home visitation program, no steps are allowed to be omitted.

In addition to the steps of the intervention protocol, we propose that re-designing health care for older people within general practices can only be successfully

accomplished if 4 aspects are realized [14]. General practices should be prepared to change their mindset from delivering reactive care towards offering proactive care (delivery system design). Although the home visitation program may be applied to a diverse patient population, it is specifically designed to identify health problems among the apparently healthy older people at an early stage. Furthermore, general practices should establish linkages with other professionals or organizations offering (local) care and/or wellbeing services to older people (community resources). In particular, the organization of multi-disciplinary meetings between different professionals is strongly recommended to effectively organize care for older people with complex and/or multiple health problems. Third, general practices should be appropriately equipped with decision-aids to help them decide about the presence or absence of health problems and, subsequently, where older people should be referred to within the range of health and wellbeing services available (decision support). Therefore, cut-off points are incorporated in the [G]OLD-instrument per test or question and a service map is developed for different municipalities providing an overview of care or wellbeing facilities available for specific health or wellbeing problems. Finally, to provide continuity in care for older people, a system should be developed within existing clinical information systems for general practices to register the results of the geriatric assessment and to plan and monitor care and follow-up (clinical information systems).

Process evaluation questions

For each component of the process evaluation, several process evaluation questions are formulated (Table 1). Since it is not advisable nor practically feasible to measure every program element into extensive detail [1], the questions focus on the elements of the home visitation program that are minimally required for acceptable program delivery (see logic model, Figure 1). Furthermore, in prioritizing process evaluation questions, the workload or burden imposed on those responsible for collecting the data was also taken into consideration.

Data collection

Multiple data collection strategies are used to gather process data. Quantitative and qualitative process data are collected concurrently and the findings will be integrated (triangulation) to attain a complete understanding of the quality and process of implementation [21,29]. The choices for the data collection tools are based on the nature of the process evaluation questions, as well as on how the most valid and reliable information can be obtained in an efficient and least burdensome way for those involved. Process data are gathered using the following methods or tools:

- Individual semi-structured interviews with GPs, PNs and older people. Also, short semi-structured interview by phone with GPs from control practices.

- Feedback meetings with PNs.
- Structured registration forms, filled-out by PNs: (1) registration of the results of the multi-dimensional geriatric assessment in the [G]OLD-instrument; (2) form to write down the results of the post-discussion with the GP; (3) care and treatment plan & (4) registration of number of follow-up contacts (derived from GP Information System), compliance of older people with recommendations formulated in the care and treatment plan and extent to which older people benefited from the home visitation program.
- Evaluation forms for training, filled-out by PNs.
- [G]OLD care diary for older people.
- Continuous registration and notes by the research team.

An overview of the data collection tools/procedures and data sources per process evaluation component and accompanying process evaluation question(s) is provided in Table 2. The GPs and PNs of participating general practices are the most important sources from which process data are collected, as they are the key actors within the home visitation program.

Semi-structured interviews

Semi-structured interviews were carried out with all PNs (n=13) individually from participating general practices in the intervention group. PNs performed the home visits among older people consecutively within 13 months time (estimated time required for visiting older people enrolled in the research project, given the available time of PNs for care for older people). During this intervention period, each PN was interviewed 3 times: after 3 months, 6 months and at the end of the intervention period. Questions asked differed between the interview rounds and interviews lasted approximately 30 to 60 minutes. The first interview round focused on the initial implementation of the different steps of the [G]OLD home visitation protocol and experiences of PNs thus far. In the second interview, progress compared to the previous interview and collaboration with GPs and other healthcare providers was discussed. Finally, the last interview round again evaluated progress, as well as results achieved within general practice, by implementing the home visitation program and future utilization of the program after the intervention period. The various interview rounds enable detecting interim problems threatening the fidelity of implementation.

At the end of the intervention period, 1 GP from each participating general practice was interviewed (duration approximately 30 minutes). Using a semi-structured format, GPs were asked about their experiences regarding implementation of the home visitation program within their practice. In general practices with more than 1 GP, the one who most closely collaborated with the PN in implementing the home visitation program was approached for the interview.

Table 1 Process evaluation questions

Fidelity (quality of implementation)	<ol style="list-style-type: none"> 1. To what extent were all elements of the home visitation program implemented as planned? 2. Is care delivery for older people within general practices successfully re-designed? <ol style="list-style-type: none"> a. Did GPs and PNs change their mindset from delivering reactive care to proactive care for older people? b. To what extent are linkages established with other professionals or organizations? c. Did general practices receive adequate and useful decision-aids to support decision-making? d. Is a registration system realized that is (practically) useful for general practices?
Dose delivered (completeness)	<ol style="list-style-type: none"> 3. To what extent did PNs follow all steps of the [G]OLD intervention protocol (as depicted in Figure1)?
Dose received (exposure)	<ol style="list-style-type: none"> 4. To what extent were older people compliant with follow-up actions formulated in the care and treatment plan?
Dose received (satisfaction)	<ol style="list-style-type: none"> 5. To what extent were GPs and PNs satisfied with organizing care according to the home visitation program? 6. To what extent were older people satisfied with the home visit? 7. To what extent did older people benefit from the home visit and, if necessary, subsequent follow-up actions?
Reach (participation rate)	<ol style="list-style-type: none"> 8. What proportion of the intended target population participated? 9. What were the reasons for non-participation of older people? 10. Is the right target population reached according to GPs and PNs? 11. What proportion of participating older people completed all steps of the [G]OLD intervention protocol? 12. What were the reasons for drop-out of older people enrolled?
Recruitment	<ol style="list-style-type: none"> 13. What procedures were used to recruit general practices and older people for participation?
Context (in general)	<ol style="list-style-type: none"> 14. What barriers and facilitators influenced implementation of the home visitation program within general practices? 15. To what extent did the control group receive the intervention or similar types of proactive care (contamination)?
Interactional workability	<ol style="list-style-type: none"> 16. To what extent is congruence accomplished between PNs and older people and GPs and PNs regarding detected (health) problems and/or follow-up actions?
Relational integration	<ol style="list-style-type: none"> 17. Do PNs have sufficient knowledge, expertise and skills to perform the activities as part of the home visitation program? 18. To what extent do PNs feel confident that they can assess and address older people's (complex) health problems?
Skill-set workability	<ol style="list-style-type: none"> 19. Is the division of work between GP and PN acceptable?
Contextual integration	<ol style="list-style-type: none"> 20. Does the home visitation program for older people fit within the range of healthcare services offered by general practices? 21. Are sufficient resources (e.g., time, staff and money) available for the adequate performance of the home visitation program by general practices?

If conflicting opinions exist between GPs within a practice regarding the program, the other GP(s) was/were interviewed as well. Interviews with GPs and PNs took place within the GP's practice. Additionally, GPs in the control group (1 per general practice) are interviewed by phone at the end of the follow-up period (18 months after baseline). A semi-structured format is used to determine the extent to which control participants might have received structured, proactive care similar to the home visitation program (contamination).

Finally, older people were invited to share their experiences and views with respect to the home visit by the PN and subsequent follow-up actions (if applicable). Semi-structured interviews were conducted of approximately 30 minutes in older people's homes. The home setting is preferred to make older people feel at ease, which may result in richer descriptions of their experiences and opinions. The interview was conducted between 3 to 5 weeks after the home visit to make sure any follow-up actions (if applicable) are communicated to the older person and older people still remember details of the visit.

Those cognitively impaired, as judged by the PN, were excluded from participation in the interviews. While sampling older people, strong heterogeneity among older people should be kept in mind [30] and therefore older people were purposefully sampled based on the principle of maximum variation. The variables gender, age, household status (living alone vs. living together) and health status were deemed important characteristics to consider when recruiting older people for the interviews to obtain a sample representative for those enrolled in the research project. By including a broad group of older people, we also attempted to circumvent the problem that older people tend to provide less detailed descriptions of their situation or experiences [31]. From each PN, 1 older person (or 2 if the PN assessed the health status of the partner as well) he or she visited was selected for an interview. After this initial interview round, data saturation was reached. One member of the research team (MMNS) was responsible for conducting all semi-structured interviews.

Table 2 Data collection method and data source per process evaluation component and process evaluation question

Process evaluation component	Process evaluation question*	Data collection tool(s) / procedure(s) and data source(s)
Fidelity (quality of implementation)	Implementation as planned ⁽¹⁾ , re-designing care ⁽²⁾	Semi-structured interviews with GPs and PNs; feedback sessions with PNs; structured registration forms filled-out by PN
Dose delivered (completeness)	Steps [G]OLD-protocol followed by PN ⁽³⁾	Semi-structured interviews with PNs; feedback sessions with PNs; structured registration forms filled-out by PN; semi-structured interviews with older people
Dose received (exposure)	Compliance older people to follow-up actions ⁽⁴⁾	Registration of compliance per older person according to opinion of PN on structured form; [G]OLD care diary for older people
Dose received (satisfaction)	Satisfaction GP+PN ⁽⁵⁾ Satisfaction older people ⁽⁶⁾ Benefit older people ⁽⁷⁾	In-depth questions during semi-structured interviews with GPs and PNs In-depth questions during semi-structured interviews with older people Benefit judged by PN and registered on structured form
Reach (participation rate)	Number of participants ⁽⁸⁾ Reasons non-participation ⁽⁹⁾ Opinion reach GP+PN ⁽¹⁰⁾ Completion steps protocol ⁽¹¹⁾ Reasons drop-out ⁽¹²⁾	Registration no. of participants and non-participants in trial database Reminder non-responders (by phone) and notes research team reasons for non-participation Semi-structured interviews GPs and PNs; feedback sessions with PNs Structured registration forms filled-out by PN; registration no. of drop-outs in trial database Notes research team reasons for drop-out
Recruitment	Recruitment procedures ⁽¹³⁾	Narrative report by research team of recruitment activities
Context (in general)	Implementation issues ⁽¹⁴⁾ Contamination ⁽¹⁵⁾	Semi-structured interviews with GPs and PNs; notes research team Short semi-structured interview by phone with GPs participating in the control group
Interactional workability	Congruence PN and GP, and PN and older people ⁽¹⁶⁾	Semi-structured interviews with PNs
Relational integration	Expertise PN ⁽¹⁷⁾ Confidence PN ⁽¹⁸⁾	Semi-structured interviews with GPs, PNs and older people; evaluation form training PN Semi-structured interviews with PNs; evaluation form training PN
Skill-set workability	Division of work GP+PN ⁽¹⁹⁾	Semi-structured interviews with GPs and PNs
Contextual integration	Fit within care services ⁽²⁰⁾ Resources available ⁽²¹⁾	Semi-structured interviews with GPs and PNs Semi-structured interviews with GPs and PNs

* Bracketed numbers correspond to the numbers of the process evaluation questions presented in Table 1.

Feedback meetings

Twice during the intervention period, a feedback meeting was organized for all participating PNs. During these meetings, PNs were informed about the progress of the research project and other research-related aspects, such as the logistic issues concerning collecting (process) data and returning data to the research team. Interim results of the individual semi-structured interviews with PNs were fed back to the whole group and, if necessary, corrections to program implementation were made to guarantee the program is delivered with fidelity. PNs were offered the possibility to interact with other PNs and discuss the interim results. A research assistant made notes of the discussion for evaluation purposes.

Structured registration forms

The [G]OLD-instrument, including the registration form for the post-discussion with the GP and the care and treatment plan were distributed to PNs during the training sessions before the onset of the intervention period. PNs were requested to return the forms per older person stepwise during the intervention period after the care and treatment plan is formulated. Upon receipt, a research assistant checked the documents on completeness and accuracy of reporting, thereby serving as a proxy for complete and acceptable delivery of the first steps of the [G]OLD intervention protocol by PNs. Any issues discovered that threatened implementation fidelity were discussed with PNs in person or during a feedback meeting. At the end of the follow-up period (18 months after baseline), which differed per older person since the home visits were conducted consecutively by PNs during 13 months, PNs were asked to register in a structured document for each older person the number of follow-up contacts, compliance to recommendations and extent to which the older person benefited from the home visitation program. Although the latter 2 aspects were based on the PN's judgment, we believe PNs had little reason to give social-desirable answers.

PNs documented in the [G]OLD-instrument the results of the multi-dimensional assessment (answers given by older people to tests and questions), as well as more process-related information such as the duration of the visit and whether other people were present during the assessment. In the structured form for the post-discussion with the GP, PNs could check from a list which problems, complaints or issues had been discussed with the GP, what the main findings were and which follow-up actions would be undertaken (e.g., additional examination, treatment, referral). The PN formulated a care and treatment plan in agreement with the older person's wishes that contains details per detected problem or complaint regarding the goals to be achieved, who will take action (divided into actions by general practice and actions by other professionals within the continuum of care) and when the problem will be evaluated. A case-manager was assigned who is responsible for coordinating care and monitoring over time and PNs were required to formulate an overall

goal to be reached (e.g., improvement of functioning, maintaining current level of functioning).

Evaluation forms

At the end of each training session (2 days in total), PNs were requested to fill out an evaluation form. For both training sessions the same structured format was used, including open-ended questions concerning their satisfaction with the training in general and close-ended questions evaluating their opinion concerning knowledge gained and skills acquired, extent to which they felt prepared to conduct the home visits and the need for additional training.

[G]OLD care diary

Older people received the [G]OLD care diary before the home visit, together with the baseline questionnaire as part of the effect study. They were asked to register details of their contacts with healthcare and/or wellbeing providers (date of contact, name of professional or organization, reason for contact, a grade representing satisfaction with contact, *etc.*) during 18-months follow-up. For process evaluation purposes, this information is used as an indicator of compliance to recommended follow-up actions according to the care and treatment plan. At 18-months, older people are requested to send back the care diary together with the final follow-up questionnaire of the effect study.

Continuous registration

During the recruitment and intervention period, members of the research team provided narrative descriptions of procedures applied during the recruitment process and factors influencing the implementation of the home visitation program mentioned outside the semi-structured interviews with GPs and PNs. Furthermore, non-participation and drop-out rates, as well as the reasons for non-participation and drop-out (if mentioned by older people or the PN), were documented during the recruitment phase and the intervention and follow-up phase, respectively.

Data analysis

Quantitative process data will be analyzed using the software package SPSS for Windows, version 17.0. Descriptive statistics will be computed (e.g., means, frequencies) for quantitative variables, such as the amount of non-participants and drop-outs, follow-up contacts after the home visit, compliance of older people with follow-up actions as judged by the PN and number and duration of home visits conducted by PNs.

All individual semi-structured interviews are digitally recorded (accept for the telephone contact with GPs from control practices; in this case, notes are made), after obtaining verbal consent from participants and transcribed

verbatim. The analysis process is supported by the software package NVivo 7, in which transcripts are anonymously transferred. The researcher (MMNS) will code the transcripts and another member of the research team will code one quarter of the transcripts. A general inductive approach [32] will be applied in which the analysis is largely guided by the process evaluation objectives. Systematic and rigorous reading and coding of the transcripts will allow major themes to emerge. Other qualitative data will be assessed using conventional content analysis to allow themes to emerge from the data [33]. This will be applied to, for example, the open-ended questions included in the evaluation forms of the training for PNs and the notes made by the research team of the feedback sessions with PNs. Descriptions of procedures applied will be summarized in a narrative report.

Discussion

This paper presents into detail the development of a theory-based process evaluation plan for the [G]OLD home visitation program aimed at identifying potentially frail community-dwelling older people (aged ≥ 75 years) within general practice. When combined, the findings from the effect study and process evaluation inform the potential implementation of the [G]OLD-home visitation program on a larger scale.

In general, studies describing into detail the rationale for conducting a process evaluation alongside a clinical trial and the methods chosen to gather process data are relatively rare. In agreement with Ellard *et al.* [34], we believe that if process evaluations are funded and undertaken, both the process evaluation plans as well as process evaluation findings should be published more often, particularly with respect to complex, patient-centered healthcare interventions. The insights gained are imperative for the development of evidence-based interventions that are likely to be sustained when implemented in the intended context. Moreover, it is essential to develop a process evaluation plan prospectively to follow the implementation of a complex intervention from its initial use until continued use (for examples of prospective process evaluation plans, see Grimshaw *et al.* [35] and Ellard *et al.* [34]). A prospective plan prevents evaluators from collecting unnecessary data and additionally helps to plan the collection of process data in an efficient way (i.e., using data collection tools that can be used for various purposes) [36].

With respect to home visitation programs for (frail) older people, only few studies so far incorporated a detailed process evaluation alongside the main trial (see for example Alessi *et al.* [37], Van Haastregt *et al.* [38] and Nicolaidis-Bouman *et al.* [39]). Although many more home visitation programs have been developed thus far, their effectiveness remains a controversial issue [40]. Trials in this field may benefit from a thorough process evaluation to determine, among others, the factors that facilitate or hinder adequate implementation of the intervention. This information can assist in clarifying

favorable or unfavorable intervention effects, thereby providing insight into the contradictory results obtained so far. Especially since the current home visitation program is fully embedded within primary care practices, we consider a process evaluation to be of utmost importance to assess the implementation and routinization process within a complex and dynamic context into detail.

Process evaluation may serve many purposes, depending on the main objectives of the evaluation, available resources, the nature of the intervention and the setting in which it is implemented. The present process evaluation plan may serve as an example for other evaluators aiming to incorporate a comprehensive process evaluation in a trial of a complex, patient-centered healthcare intervention. Although part of the theoretical framework underlying the process evaluation plan originally guides the development of a process evaluation for health promotion interventions [18], we believe the described components and steps are also applicable to patient-centered interventions implemented in primary care, particularly when combined with the more detailed contextual factors derived from the Normalization Process Model [19,20]. There are many different variables that influence normalization or routinization (see Rogers [41]), but this model specifically addresses factors related to the primary care setting. Nevertheless, a challenge we faced during the design of the process evaluation was deciding which aspects of the complex intervention to evaluate. The logical model we developed contributed in the decision-making process, as it helped to focus on the most important aspects of the content and delivery of the home visitation program within general practice. In addition, a challenge while executing the process evaluation is the use of formative process data. We need to consider to what extent interim adjustments or changes to the intervention protocol can be made to ensure the home visitation program is implemented with fidelity, without threatening the integrity of the parallel controlled trial.

Competing interests and authors' contributions

The authors declare that they have no competing interests. IGPD as main applicant and MWJJ as project leader were involved in writing the grant proposal for the evaluation study as a whole. MMNS developed the process evaluation plan, with helpful comments of the co-authors. MMNS drafted the manuscript with input from the other authors. All authors read, commented on and approved the final manuscript.

Acknowledgments and Conflicts of Interest

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