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ABSTRACT

Introduction: The present provision of services is not dedicated to promoting the maintenance of function and does not target frail older persons at high risk of the main causes of morbidity and mortality. Therefore, the aim of this study is to evaluate the effects of a proactive intervention in comparison with conventional care to a group of persons aged 75 and older selected by statistical prediction.

Methods and analysis: In a pragmatic multicentre primary care setting (n = 1600), a prediction model to find elderly (75+) persons at high risk of complex medical care or hospitalisation is used, followed by proactive medical and social, in comparison to usual care. The study started in April 2017 with a run-in period until December 2017, followed by a two-year continued intervention phase that will continue until the end of December 2019. The intervention includes several tools (multi-professional team for rehabilitation, social support, medical care home visits, telephone support etc.). Primary outcome measures are: healthcare cost, number of hospital care episodes, hospital care days and mortality. Secondary outcomes are: number of outpatient visits, cost of social care and informal care, number of prescribed drugs, health-related quality of life (HRQoL), cost-effectiveness, sense of security, functional status and ability. We also study the care of elderly persons in a broader sense, covering the perspectives of the patients, the professional staff and of the management and political level, by using semi-structured interviews, qualitative methods and a questionnaire.

Ethics and dissemination: Approved by the regional ethical review board in Linköping (Dnr 2016/347-31). The results will be presented in scientific journals and scientific meetings during 2019–2022 and are planned to be used for the development of future care models.

Trial registration. Enhanced primary care for the elderly. Clinical Trials Gov ID: NCT03180606

Key words. health care fragile elderly

Strengths and limitations of the study

- This study is a pragmatic clinical trial on proactive healthcare for people 75 years and older in primary care, meaning that it has a close connection with clinical reality, which will enhance any future implementation
- The case-finding method is a statistical prediction model which allows the “screening” of large numbers of patients

- The developed clinical evaluation and management model integrates primary care with community care and social services
- The project also focuses on the perspectives of the patients, the professionals in the healthcare system and the governance mechanisms, which may explain the perceived shortcomings of today's healthcare for the elderly
- A fairly long run-in period due to clinical realities and organisational inertia in the healthcare system as well as a long intervention period of two years are clinical necessities, but this increases the risk of non-controlled influences on the project

INTRODUCTION

The healthcare situation of the elderly is a challenge for healthcare systems in many countries, and healthcare providers struggle to meet the needs of a growing number of older people [1]. In Sweden, the largest consumers of medical services (60%) are persons 80 years and older (15% of the population), a group that is predicted to increase by 50% over the next 15 years. Several studies report that a majority of the aged population is satisfied with their health [2], manage life at home and consider themselves healthy [3 4]. Only a minority of the aged population is in need of hospital care. In most cases, the healthcare system does not distinguish between different groups among the heterogeneous old-age population; instead, both hospital and primary care are organised using a passive and reactive (acting when symptoms or problems occur) approach. There have been many attempts to define and measure frailty among the elderly in order to detect persons with significant care needs (e.g.[5]. However, "frailty" is difficult to define as a medical condition and there is no consensus on the operational definition of the concept [6]. Furthermore, scale evaluation requires a manual resource utility for each individual evaluation, which is not easily applied within a broader clinical context that lacks a primary geriatric perspective (e.g. primary care and acute ward disciplines).

The current healthcare system in many countries is not designed to identify individuals with healthcare needs or to direct care resources towards those with the greatest need for care prior to hospitalisation. Since the use of "frailty scales" involves merely a fraction of the flow of hospitalised elderly, statistical prediction models have been proposed as an effective means of evaluating larger target groups to enable resource-limited interventions for those with the greatest needs [7]. However, the clinical use of prediction in routine clinical primary care of the elderly remains to be clarified. Proactive interventions provided to the elderly within a certain age-range, and/or with multi-morbidity but with low predictive value for hospitalisation, may direct healthcare resources towards groups that are not in most need of them. Likewise, interventions for small, specific groups (e.g. newly hospitalised, specific medical diagnoses or patients above a certain frailty index score) will neglect large groups of elderly in need of healthcare or miss the larger care-flows of geriatric hospital care.

This study will evaluate whether a proactive primary care intervention into a predicted risk population of the elderly results in care that is more effective and of higher quality than that of a control group who receive standard care. In addition, in a set of parallel sub-studies, factors that may facilitate or act as barriers to the development of healthcare for older persons will be studied from several perspectives, including those of the elderly themselves and of the healthcare of the elderly.

METHOD AND ANALYSIS

The study consists of two parallel lines of research. The first, linked to the primary scientific question, is an intervention study of proactive care for older persons in primary care. The second is a set of sub-studies on different perspectives of elderly care, ranging from the patient, the professionals and governance to societal aspects.

Patient involvement

The public was represented health care politicians with responsibility for health care for elderly. They supervised, participated in the construction of and approved the aims and the contents of the study. They follow they progress of the project every 6 months. The patient's perspective of the study is obtained by in-depth interviews at different time points of the study.

Intervention study of proactive care for older persons in primary care

Primary scientific question

Can the prediction of fragile older individuals at high risk of hospital care, combined with proactive healthcare, lead to a decrease in healthcare utilisation and costs?

Design, randomisation and setting

This intervention study is designed to follow a shift in the paradigm of elderly care that had already been decided by the care providers. This led us to use a study design that enables us to detect the real-world effectiveness of the intervention in a broad patient group in a real, non-selected clinical context with clinically meaningful outcome parameters. Consequently, our design follows a selected pragmatic clinical trial model, in which defined primary care health centres using the new work routines constitute our intervention group and the remaining centres are used as controls [8].

The pragmatic clinical trial follows the fact that the intervention to be provided is close to the future *modus operandi* of healthcare for the elderly, but it still allows a scientific evaluation before it is implemented further in healthcare organisations. It is a prospective, controlled, multicentre study performed in primary care centres in south-east Sweden. A case-finding algorithm (prediction for hospital care) is used to identify eligible persons within the whole population in the region. The intervention will be performed at nine selected primary care centres (provided by the sponsoring County Council of Östergötland), and the predicted patients there form the intervention group. A similar number of control patients with similar risk scores (for hospitalisation) are predicted in healthcare centres with similar characteristics

to the intervention centres, but they receive care as usual, and these centres are not made aware of the control patients. There is no randomisation at the patient level, but the case-finding algorithm was used in the selection and the patients with the highest risk scores were included until the preferred number of patients was reached. There was no randomisation of healthcare centres; these were provided by the healthcare sponsor (County Council of Östergötland). The control healthcare centres were matched in terms of location (city, countryside), size and socio-economic distribution.

Sample size

A pilot study (not published) showed that 60% of the target population had at least one hospitalisation during a 12-month period. The hypothesis is that this figure will be reduced by 20% in the intervention group in this study. A sample size calculation based on this reduction, a power of 0.8 and a significance level of 0.05 led to a minimum of 270 participants per group. Considering the frail and elderly population, we estimate a 40% drop-out rate and we have therefore increased the sample size to 378 per group. Since we are using a pragmatic clinical trial design, featuring heterogeneity within both the participating population and the participating healthcare centres, this reduces the likelihood of detecting meaningful changes; therefore, it is reasonable to double the number of participants per group, giving a final number of 800 included individuals per group.

Prediction of patient cases

The prediction model is described elsewhere (manuscript submitted). In short, the data was obtained between November 2015 and October 2016 from the computerised information system of the County Council of Östergötland, where statistics for all the healthcare in the county is stored. For example, for the whole population there are records of: number of visits to primary or hospital care, number of days in hospital, diagnostic codes for each visit, etc. We used an in-ward hospital stay between November 2016 and January 2017 as the dependent variable. The prediction variables are based on a previous study [4], including number of GP visits and International Classification of Diseases, 10th Revision, (ICD-10) codes, use of assistive technology, emergency room (ER) visits, age and gender. The aim is to identify participants aged 75 or older who are likely to be hospitalised during the next three months. Risk scores were calculated for all individuals using logistic regression. Individuals were ranked according to the risk scores (for hospital care), from high to low. A cut-off value was chosen so that 800 individuals from the participating healthcare centres with the highest scores were selected for proactive intervention for a period of two years. The same cut-off value was then used to choose individuals from the control healthcare centres.

Evaluation form.

A four-page evaluation form has been developed and is used to standardise the evaluation of each individual (the Primary Care Assessment Tool for the Elderly- PASTEL). The goal is to create a time-efficient, easy-to-use tool for a doctor-nurse team. It is intended to be used by primary care nurses and doctors with different levels of experience. The PASTEL form is

based on the holistic approach of Comprehensive Geriatric Assessment (CGA) [6] and includes different aspects of health and function that are often of importance to the older patient. It also includes the Clinical Frailty Scale [9].

The form contains three parts. The first consists of an interview guide with mostly multiple-choice questions and a self-rating of health. The second part is a checklist for a brief physical examination and laboratory testing, a medication review and questions about the individual's opinion about their present and future needs for care. The third part is used for a team meeting to make a common estimation of frailty and to decide on the need for further investigation and actions to support the elderly person.

Intervention

The intervention group is approached by a primary care team, who evaluates the client's social and medical condition and establishes a proactive care plan for individuals in need. The primary care team is represented by the general practitioner (GP) responsible for the patient, a registered nurse (RN) dedicated to elderly care and, when needed, a physiotherapist, occupational therapist and/or social worker. The proactive intervention consists of a complete check-up/follow-up and intervention into medical, psychiatric, functional and social aspects of the client in a stepwise, resource-differentiated way according to needs based on the clinical judgement of the team (Fig. 2). The evaluation process used communication over the phone as well as visits to the primary care centre, depending on the priority of the client's needs. Examples of common actions/measures are: evaluation of medication, initiation of home care, diet counselling, advice on physical activity and support for loneliness and isolation. The formation of an "elderly team" with dedicated nurses who function as personal nurses for the frail individuals is the key component of the intervention, together with the standardised evaluation of frailty based on comprehensive geriatric assessment.

Outcome measures for intervention

Primary outcome measures are: healthcare cost, number of hospital care episodes, hospital care days and mortality. Secondary outcomes are: number of outpatient visits, cost of social care and informal care, number of drugs, number of prescribed drugs not recommended for the elderly, health-related quality of life (HRQoL), cost-effectiveness, sense of security and functional ability.

Data on healthcare consumption will be obtained from the administrative healthcare database and data on healthcare costs from the cost-per-patient database. Cost for social care and informal care will be estimated by number of contacts multiplied by a defined unit cost. Use of medications at the group level will be studied by extracting group data from the National Medication Database, before, during and after the study.

Statistical analysis for intervention study

Primary outcomes. Primary outcome measures for intervention vs control population (healthcare cost, number of hospital care episodes, hospital care days and mortality) will consist of analyses for years 1 and 2 respectively, using the intention to treat (ITT) and last observation carried forward (LOCF) method. Differences in means and proportions between groups will be analysed using a t-test. Differences in categorical data will be analysed using a Chi-squared test. If the baseline mean risk score differs between the intervention and control groups, primary outcomes adjusted for risk score will be analysed using linear or logistic regression.

Monitoring

Every six months, each primary care centre is monitored by the project group, providing opportunities for dialogue and problem solving. Every six months, or earlier when needed, each primary care centre reviews the patients included in the study and actions are considered depending on the results of the review. Every six months, the primary care teams gather for a network meeting to discuss common issues and share experiences.

Data management

No biomaterials are included in the study. All patient data will be processed lawfully according to the General Data Protection Regulation (GDPR). The data file used for the prediction model, for the intervention group and the control group was retrieved from Region Östergötland's administrative databases. The data file that will be used for analysis in both the main study and the sub-studies contains personal data from Region Östergötland's administrative databases as well as data reported by the patient. The file will only be available to the overall project manager and individuals responsible for each sub-project, i.e. the co-authors of this paper. The file will be stored in databases with a high level of security at Region Östergötland and Linköping University and also protected by personal passwords. Questions regarding data are replied to through the corresponding author upon request. We used the SPIRIT reporting guidelines [10].

Sub-studies on different perspectives of elderly care, from patient to professionals and governance to societal aspects.

Scientific questions

What are the experiences of the previous and new healthcare model for older people from a wider individual, social, professional and societal perspective? What are the governance mechanisms that may facilitate or act as barriers to the development of healthcare for older people? What is the cost-effectiveness of the intervention in comparison to care as usual?

Based on these overall questions, there are four main research perspectives with specific research questions:

1. *The perspective of the older patients and their families:* How does the change in healthcare provision towards proactive primary elderly care impact upon individual participation and subjective well-being as well as objective indicators of quality of life beyond health? How does the change in healthcare provision towards proactive primary elderly care shape the receipt of informal help and support from spouses, offspring and the wider network? How can the change result in socially structured outcomes, how does the focusing of care contribute to the life-course accumulation of (dis)advantage in old age and how does this contribute to social inequality dynamics? Studied through a questionnaire from the patient's perspective, in-depth patient data and interviews from the patient's perspective.
2. *The professional perspective on the healthcare system:* How does the change in healthcare provision towards proactive primary elderly care change the satisfaction and support of the professionals within the healthcare system? Qualitative studies of selected parts of the healthcare system, i.e. using a shadowing method targeting the home-care organisation that is experienced by the nurses who are shadowed, and implementation studies using semi-structured interviews. An implementation study explores the organisational readiness to implement the new work routines in primary care. Investigating organisational readiness can provide knowledge about early factors that are important for implementation. Also, most of the care given to the frail elderly occurs outside of the primary care setting. The municipality is responsible for care at home and in nursing homes. Another research question is therefore concerned with how collaboration is organised between primary care and social care.
3. *The governance perspective:* What are the mechanisms and explanations for today's elderly care, from the political level down to operative healthcare management? Implementation studies using semi-structured interviews.
4. *Cost-effectiveness:* What is the cost-effectiveness of the intervention compared to usual care? Data will be collected through questionnaires and registries.

Methods for sub-studies

Questionnaire for the patient's perspective and in-depth patient data. We will study how the change in healthcare provision impacts upon individual well-being, the support they receive from their private networks of families and friends and their satisfaction with and the support of the healthcare system. A longitudinal study design enables us to follow changes over time. Moreover, we will analyse whether the focusing of care contributes to the life-course accumulation of (dis)advantage in old age and how this contributes to social inequality dynamics. The longitudinal patient questionnaire study collects data on three occasions, t1–t3, over a period of 36 months. The information from the questionnaires will be combined with a registry-based assessment of social-structure and life-course information at t1 and referenced with nationally representative life-course data on health, occupation and family from Statistics Sweden (SCB) and the National Board of Health and Welfare (Socialstyrelsen). Measures in the questionnaire include the EQ-5D-3L and EQ-VAS [11] for health-related quality of life (HRQoL) estimates, activities of daily living/functions by the ADL Staircase [12] and RAND-36 for self-reported functional health [13]. A measure for sense of security in care is also used (SECP) [14]. The dizziness handicap inventory is used to detect

the presence of a risk of falls [15] and its related health consequences. A visual analogue scale (0–100 mm) and a pain-drawing instrument is used to evaluate pain experience [16].

Interviews from the patient's perspective. In one sub-project, we focus on how frail older people experience care services if included in the intervention. Twenty semi-structured interviews with elderly patients will be conducted. A selection of elderly patients will be made, and this selection will include patients who have experiences of the intervention. Interviews are intended to provide access to the feelings, thoughts and experiences of patients. The starting point is that the interview is a knowledge-producing activity, and it is during the interview and in the interaction with the individual and the researcher that knowledge is produced [17]. Another sub-project aims to investigate how the elderly experience their everyday lives and the opportunities for rehabilitation from an availability and participation perspective. Do the elderly receive the rehabilitation they consider themselves to need? A qualitative study with a strategic selection of approximately 20 participants from the intervention group will be conducted.

Qualitative studies of selected parts of the healthcare system. A qualitative approach (shadowing) [18] is used to study the working conditions for nurses in primary care in relation to challenges in their professional responsibility connected to their work. The proposed sub-project addresses key issues in order to obtain knowledge about how competence levels and the distribution of tasks match the needs of frail older people living at home. The ongoing development in the field of the care of older people can be studied through the concept of task-shifting [19]. Questions of task shifting are implicit in discussions concerning the relationship between general competence and specialist competence within professional groups or the resource deficit in relation to ageing populations. The main aim is therefore to explore and characterise task-shifting processes in practices, competencies, responsibilities and roles from the perspective of registered nurses working within the main project. A second aim is to explore the challenges of handling drugs and the pharmaceutical preparations related to nurse practices in home care, and how these challenges are processed.

Implementation studies. In order to meet the future challenges posed by an ageing population, it is not only important to develop and evaluate new care models, but also to ensure that these models are implemented successfully by organisations providing care. Three separate studies investigate the implementation of the new work routines for improved care among the frail elderly.

To study the implementation of the model, the project will use a framework that specifies four types (or domains) of determinants, which function as barriers and/or facilitators for successful implementation. Research in implementation science has established that successful implementation depends on an interplay between these determinants: (1) the effectiveness of the strategies chosen to support the implementation; (2) the characteristics of the new practices (routines, methods, etc.) being implemented; (3) beliefs, attitudes and motivations among the front-line implementers; and (4) the context of the implementation. The framework will provide a basic structure of interviews which will be carried out with representatives of different levels of the healthcare system: from political leadership and primary-care management to practitioners on the front line of primary care. Study I focuses

on the role of professionals in implementing the new work routines, including adopting a holistic approach to care. This study also investigates readiness to change at both an individual level (e.g. resources, attitudes) and an organisational level (e.g. system that support change).

Study II. Preliminary results from Study I indicate that successful collaboration between primary care providers and the municipalities is essential in achieving proactive care and implementing the new work routines. Indeed, most care of the frail elderly occurs outside of a primary care setting. The second study therefore investigates these conditions or collaborations via interviews with managers representing both organisations. A concept mapping approach will be used to identify and quantify the factors affecting implementation. Interviews will be audio-recorded and transcribed verbatim.

Finally, a third study will focus on investigating the governance mechanisms that influence the present situation as well as the uptake of new models through policy-making and implementation. Despite good intentions and various policies, Swedish elderly care has not undergone any extensive change; thus, the same challenges and development needs are being discussed today as 20 years ago.

For this reason, this sub-project will investigate the mechanisms that facilitate or impede evidence-based policy-making and implementation from the political level to the regional level in elderly care. Questions that will be studied are: What influences policy-making and implementation at different levels? What are the strategies for policy implementation? How is policy implementation monitored and evaluated at different levels? Three levels of policy-making and implementation will be studied. Level 1: politicians and Ministry of Health and Social Affairs. Level 2: state agencies and authorities at national level, i.e. NBHW (Socialstyrelsen) and the Swedish Association of Local Authorities and Regions. Level 3: politicians, executive boards and managers at county council and regional level. Interviews will be audio-recorded and transcribed verbatim.

Statistical analysis for sub-studies

The outcomes of the sub-studies are: number of outpatient visits, cost of social and informal care, number of drugs, number of prescribed drugs not recommended for the elderly, health-related quality of life (HRQoL), cost-effectiveness, sense of security and functional ability. The measures will be analysed for years 1 and 2 respectively using the intention to treat (ITT) and last observation carried forward (LOCF) method. Differences between groups will be analysed using a t-test. We intend to estimate the cost-effectiveness in terms of cost/QALY (quality-adjusted life years) from a lifetime perspective using simulation models. The QALY weights will be obtained from the EQ-5D-3L.

Time plan

An overview is presented in Fig. 1. The project started with the development of the case-finding algorithm (manuscript in progress) in 2017. Based on this model, the case-finding process was undertaken at the beginning of March 2017.

Selected patients were presented to each healthcare centre for the start of the intervention programme in April 2017. A run-in period of April–December 2017 was used, during which

healthcare centres were informed about and introduced to the new work model, and patients were subsequently enrolled onto the programme. All selected high-risk patients will have received an initial healthcare and/or social care plan. More than 90% of the selected patients were included by the end of December 2017. The intervention/follow-up period is planned to last for two years, until the end of 2019 (Fig 1).

An initial questionnaire was sent to all selected patients in the intervention and control healthcare centres during May–June 2017. The questionnaire will also be distributed to enrolled participants in years 2 and 3. Interviews with professionals in participating primary care health centres and communities were performed during June–September 2017. Interviews with elderly participants in order to capture the patient's perspective on the study were performed during December 2017–July 2018. Interviews with elderly participants in order to capture the patient's perspective on rehabilitation will take place during November 2018–February 2019. Interviews with high-level decision-makers and politicians were conducted during January–September 2018.

A first preliminary outcome analysis after 13 months of intervention will be performed in January 2019. The intervention and collection of healthcare data ends on 31 December 2019. The analysis of primary and secondary outcome measures starts in 2020. The scientific writing-up and participation in academic conferences has already started for some of the sub-projects. The writing period for the intervention study begins in spring 2020. Dialogue with owners/stakeholders at a political level takes place every six months during the course of the project.

Possible evidence for changes in elderly care across the whole County of Östergötland will be available in autumn 2020, when the implementation process of the new care model can be broadened. Members of the research group are participating in workshops at a national level concerning healthcare development.

Figure 1. Overview of the project over time.

Figure 2. Overview of the intervention.

Ethics and dissemination

This study was subject to ethical evaluation and approved by the regional ethical review board in Linköping (Dnr 2016/347-31). They judged all aspects of the study including design and safety. By adding an academic study to an ongoing change in the healthcare process for the elderly, we do not per se include or exclude treatment possibilities for individuals or groups of individuals. The study itself is "inert" within the healthcare system. Therefore, we do not see that the use of aggregated patient data from the healthcare system can be of any harm to the participants. On the contrary, we find strong ethical motives for the study, which is an academic attempt to detect the real-world effectiveness of a politically determined intervention into a large patient group. The patients who responded to the questionnaire did so using an informed consent.

The data will be presented in scientific journals and communicated at scientific meetings during the period 2018–2022. The outcome data of the study will be presented to the healthcare provider (County Council of Östergötland) for a discussion on the evidence relating to future care models for elderly persons. The data will also be used by healthcare managers and decision-makers for the development of future care models.

DISCUSSION

Clinical trials on complex healthcare processes are rare and difficult to design with adequate scientific quality. On the other hand, delimited clinical trials may also only be valid within an academic setting and the outcome difficult to reproduce in clinical reality. In order to counteract the scientific challenges facing trials in complex clinical settings and processes, the use of a pragmatic clinical trial design is one, or perhaps the only, alternative [8]. In terms of the primary context of elderly care, this study is intended to find answers to basic scientific questions about the future healthcare of the elderly.

One challenge for the study was to find older patients in need of healthcare, hopefully before escalating needs would develop. Managing thousands of patients during this screening for possible illness may be impossible in healthcare using face-to-face methods. Statistical models for case findings have recently proven valid and are recommended in the clinical healthcare of old persons [7] so this *modus operandi* was used in this study.

There is a great need for improved healthcare for the elderly and a simultaneous knowledge gap regarding scientific data on what care models to use in the future. This study aims to fill some of that gap and may hopefully generate some clinically meaningful data that can be used for the future development of healthcare for older persons.

Authors contributions

Jan Marcusson: principal investigator, design, analysis and scientific writing.

Magnus Nord: clinical project leader, design, clinical site visits, data collection, analysis, scientific writing

Ylva Böttiger: design, analysis, scientific writing

Huan-Ji Dong: design and analysis of prediction model. Scientific writing.

Maria Johansson, Anneli Peolsson: clinicians and scientists responsible for rehabilitation, design of the postal questionnaire, data collection, analysis, scientific writing

Jenny Alwin, Lars-Åke Levin: design and health economic analysis, design of the postal questionnaire, data collection, analysis, scientific writing

Petra Dannapfel, Kristin Thomas, Bonnie Poksinska, design and analysis of implementation studies, data collection, analysis, scientific writing

Annette Sverker, Anna Olaison, Elisabet Cedersund, design of interviews and analysis of the patient's perspective, scientific writing

Susanne Kelfve, Andreas Motel-Klingebiel: design of postal questionnaire, analysis of well-being, network support, satisfaction and social inequality based on questionnaire and registry data, scientific writing

Ingrid Hellström, Agneta Kullberg: design and analysis of professional perspective, scientific writing

Johan Lyth analysis, scientific writing

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Competing interests: None.

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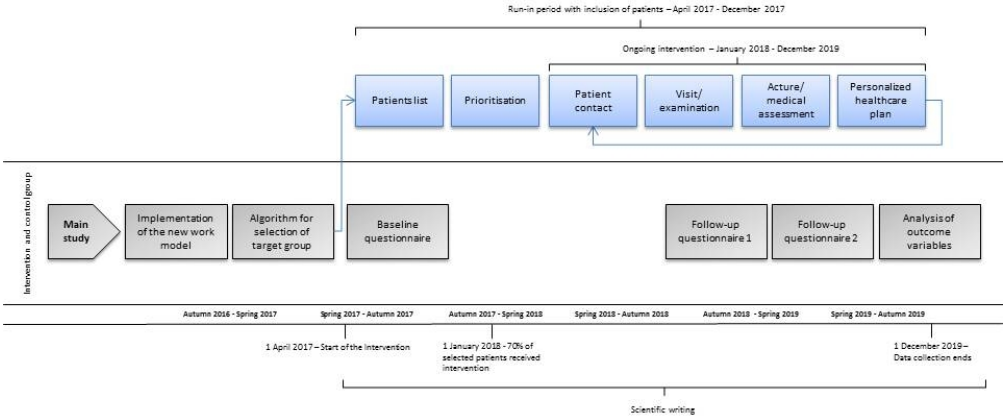

Figure 1. Overview of the project over time.

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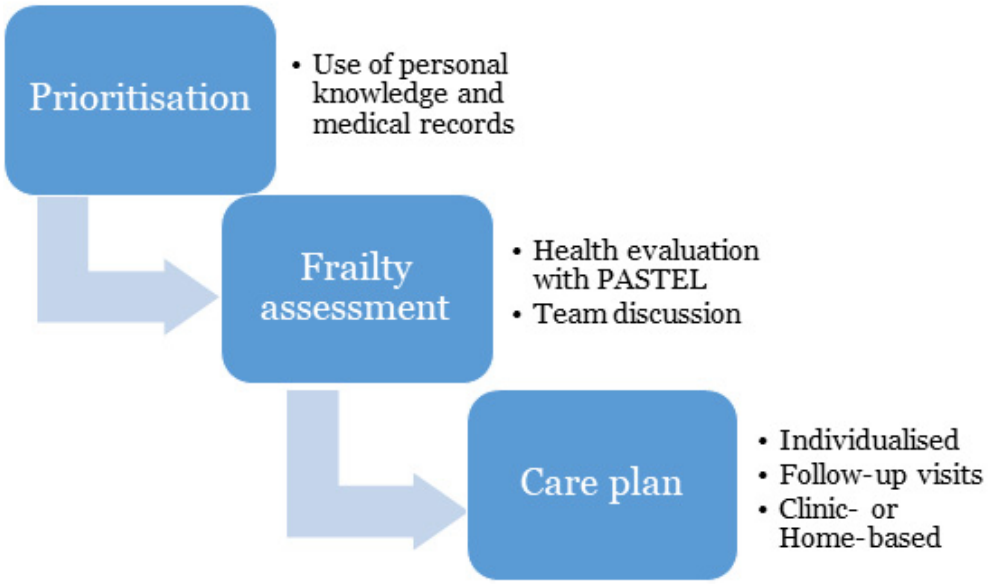

Figure 2. Overview of the intervention.

195x159mm (72 x 72 DPI)

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2

Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	n/a
Funding	#4	Sources and types of financial, material, and other support	15
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 14
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	15
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	15
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	14
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies	4-5

		(published and unpublished) examining benefits and harms for each intervention	
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	5-6
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or	n/a

		improving / worsening disease)	
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	n/a
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	7
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11-12
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	n/a

Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg,	8

		questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	8
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	8
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	n/a
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	n/a
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be	8

		found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	12
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	8
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	12
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	12
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	12

Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	n/a
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	15
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	8
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	12-13
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Informed consent	#32	Model consent form and other related documentation given	n/a

materials		to participants and authorised surrogates	
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

BMJ Open

Proactive healthcare for frail elderly persons – study protocol for a prospective controlled primary care intervention in Sweden

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Proactive healthcare for frail elderly persons – study protocol for a prospective controlled primary care intervention in Sweden

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ABSTRACT

Introduction: The provision of health care services is not dedicated to promoting maintenance of function and does not target frail older persons at high risk of the main causes of morbidity and mortality. The aim of this study is to evaluate the effects of a proactive medical and social intervention in comparison with conventional care to a group of persons aged 75 and older selected by statistical prediction.

Methods and analysis: In a pragmatic multicentre primary care setting (n = 1600), a prediction model to find elderly (75+) persons at high risk of complex medical care or hospitalisation is used, followed by proactive medical and social, in comparison to usual care. The study started in April 2017 with a run-in period until December 2017, followed by a two-year continued intervention phase that will continue until the end of December 2019. The intervention includes several tools (multi-professional team for rehabilitation, social support, medical care home visits, telephone support etc.). Primary outcome measures are: healthcare cost, number of hospital care episodes, hospital care days and mortality. Secondary outcomes are: number of outpatient visits, cost of social care and informal care, number of prescribed drugs, health-related quality of life (HRQoL), cost-effectiveness, sense of security, functional status and ability. We also study the care of elderly persons in a broader sense, covering the perspectives of the patients, the professional staff and of the management and political level, by using semi-structured interviews, qualitative methods and a questionnaire.

Ethics and dissemination: Approved by the regional ethical review board in Linköping (Dnr 2016/347-31). The results will be presented in scientific journals and scientific meetings during 2019–2022 and are planned to be used for the development of future care models.

Trial registration. Enhanced primary care for the elderly. Clinical Trials Gov ID: NCT03180606

Key words. care frail elderly

Strengths and limitations of the study

- This study is a pragmatic clinical trial on proactive healthcare for people 75 years and older in primary care, meaning that it has a close connection with clinical reality, which will enhance any future implementation
- The case-finding method is a statistical prediction model which allows the “screening” of large numbers of patients

- The developed clinical evaluation and management model integrates primary care with community care and social services
- The project also focuses on the perspectives of the patients, the professionals in the healthcare system and the governance mechanisms, which may explain the perceived shortcomings of today's healthcare for the elderly
- A fairly long run-in period due to clinical realities and organisational inertia in the healthcare system as well as a long intervention period of two years are clinical necessities, but this increases the risk of non-controlled influences on the project

INTRODUCTION

The healthcare situation of the elderly is a challenge for healthcare systems in many countries, and healthcare providers struggle to meet the needs of a growing number of older people [1]. In Sweden, the largest consumers of medical services (60%) are persons 80 years and older (15% of the population), a group that is predicted to increase by 50% over the next 15 years. Several studies report that a majority of the aged population is satisfied with their health [2], manage life at home and consider themselves healthy [3 4]. Only a minority of the aged population is in need of hospital care. In most cases, the healthcare system does not distinguish between different groups among the heterogeneous old-age population; instead, both hospital and primary care are organised using a passive and reactive (acting when symptoms or problems occur) approach. There have been many attempts to define and measure frailty among the elderly in order to detect persons with significant care needs (e.g.[5]). However, "frailty" is difficult to define as a medical condition and there is no consensus on the operational definition of the concept [6]. Three major frailty models have been suggested: physical frailty model, deficit accumulation model of frailty, and the biopsychosocial or multidimensional model [7]. Furthermore, evaluation using clinical instruments requires and trained staff for each individual evaluation, which is not easily applied within a broader clinical context that lacks a primary geriatric perspective (e.g. primary care and acute ward disciplines).

The current healthcare system in many countries is not designed to identify individuals with healthcare needs or to direct care resources towards those with the greatest need for care prior to hospitalisation. Since the use of "frailty scales" involves merely a fraction of the flow of hospitalised elderly, statistical prediction models have been proposed as an effective means of evaluating larger target groups to enable resource-limited interventions for those with the greatest needs [8]. However, the clinical use of prediction in routine clinical primary care of the elderly remains to be clarified. Proactive interventions provided to the elderly within a certain age-range, and/or with multi-morbidity but with low predictive value for hospitalisation, may direct healthcare resources towards groups that are not in most need of them. Likewise, interventions for small, specific groups (e.g. newly hospitalised, specific medical diagnoses or patients above a certain frailty index score) will neglect large groups of elderly in need of healthcare or miss the larger care-flows of geriatric hospital care.

This study will evaluate whether a proactive primary care intervention into a predicted risk population of the elderly results in care that is more effective and of higher quality than that of a control group who receive standard care. In addition, in a set of parallel sub-studies, factors that may facilitate or act as barriers to the development of healthcare for older persons will be studied from several perspectives, including those of the elderly themselves and of the healthcare of the elderly.

METHOD AND ANALYSIS

The study consists of two parallel lines of research. The first, linked to the primary scientific question, is an intervention study of proactive care for older persons in primary care. The second is a set of sub-studies on different perspectives of elderly care, ranging from the patient, the professionals and governance to societal aspects. An overview of the project and time-line is presented in Fig. 1.

Insert figure 1 here. Overview of the project over time

Patient involvement

The public was represented health care politicians with responsibility for health care for elderly. They supervised, participated in the construction of and approved the aims and the contents of the study. They follow they progress of the project every 6 months. The patient's perspective of the study is obtained by in-depth interviews at different time points of the study.

Intervention study of proactive care for older persons in primary care

Primary scientific question

Can the prediction of frail older individuals at high risk of hospital care, combined with proactive healthcare, lead to a decrease in healthcare utilisation and costs?

Design, randomisation and setting

This intervention study is designed to follow a shift in the paradigm of elderly care that had already been decided by the care providers. This led us to use a study design that enables us to detect the real-world effectiveness of the intervention in a broad patient group in a real, non-selected clinical context with clinically meaningful outcome parameters. Consequently, our design follows a selected pragmatic clinical trial model, in which defined primary care health centres using the new work routines constitute our intervention group and the remaining centres are used as controls [9].

The pragmatic clinical trial follows the fact that the intervention to be provided is close to the future *modus operandi* of healthcare for the elderly, but it still allows a scientific evaluation before it is implemented further in healthcare organisations. It is a prospective, controlled, multicentre study performed in primary care centres in south-east Sweden. A case-finding algorithm (prediction for hospital care) is used to identify eligible persons within the whole population in the region. The intervention will be performed at nine selected primary care centres (provided by the sponsoring County Council of Östergötland), and the predicted patients there form the intervention group. A similar number of control patients with similar

risk scores (for hospitalisation) are predicted in healthcare centres with similar characteristics to the intervention centres, but they receive care as usual, and these centres are not made aware of the control patients. There is no randomisation at the patient level, but the case-finding algorithm was used in the selection and the patients with the highest risk scores were included until the preferred number of patients was reached. There was no randomisation of healthcare centres; these were provided by the healthcare sponsor (County Council of Östergötland). The control healthcare centres were matched in terms of location (city, countryside), size and socio-economic distribution. A pre-study analysis of the primary outcome measures of the two patient groups revealed no significant differences between them.

Sample size

A pilot study (not published) showed that 60% of the target population had at least one hospitalisation during a 12-month period. The hypothesis is that this figure will be reduced by 20% in the intervention group in this study. A sample size calculation based on this reduction, a power of 0.8 and a significance level of 0.05 led to a minimum of 270 participants per group. Considering the frail and elderly population, we estimate a 40% drop-out rate and we have therefore increased the sample size to 378 per group. Since we are using a pragmatic clinical trial design, featuring heterogeneity within both the participating population and the participating healthcare centres, this reduces the likelihood of detecting meaningful changes; therefore, it is reasonable to double the number of participants per group, giving a final number of 800 included individuals per group.

Prediction of patient cases

The prediction model is described elsewhere (manuscript submitted). In short, the data was obtained between November 2015 and October 2016 from the computerised information system of the County Council of Östergötland, where statistics for all the healthcare in the county is stored. For example, for the whole population there are records of: number of visits to primary or hospital care, number of days in hospital, diagnostic codes for each visit, etc. We used an in-ward hospital stay between November 2016 and January 2017 as the dependent variable. The prediction variables are based on a previous study [4], including number of GP visits and International Classification of Diseases, 10th Revision, (ICD-10) codes, use of assistive technology, emergency room (ER) visits, age and gender. The aim is to identify participants aged 75 or older who are likely to be hospitalised during the next three months. Risk scores were calculated for all individuals using logistic regression. Individuals were ranked according to the risk scores (for hospital care), from high to low. A cut-off value was chosen so that 800 individuals from the participating healthcare centres with the highest scores were selected for proactive intervention for a period of two years. The same cut-off value was then used to choose individuals from the control healthcare centres.

Evaluation form.

A four-page evaluation form has been developed and is used to standardise the evaluation of each individual (the Primary Care Assessment Tool for the Elderly- PASTEL). The goal is to create a time-efficient, easy-to-use tool for a doctor-nurse team. It is intended to be used by primary care nurses and doctors with different levels of experience. The PASTEL form is based on the holistic approach of Comprehensive Geriatric Assessment (CGA) [6], which can be regarded as combination of diagnostic and therapeutic processes where problems are identified and managed. The assessments cover medical, psychiatric, functional, and social domains required to enable a multifaceted therapeutic plan.
It also includes the Clinical Frailty Scale[10].

The form contains three parts. The first consists of an interview guide with mostly multiple-choice questions and a self-rating of health. The second part is a checklist for a brief physical examination and laboratory testing, a medication review and questions about the individual's opinion about their present and future needs for care. The third part is used for a team meeting to make a common estimation of frailty and to decide on the need for further investigation and actions to support the elderly person in order to enhance recovery and promote independence.

Intervention

The intervention group is approached by a primary care team, who evaluates the client's social and medical condition and establishes a proactive care plan for individuals in need. The primary care team is represented by the general practitioner (GP) responsible for the patient, a registered nurse (RN) dedicated to elderly care and, when needed, a physiotherapist, occupational therapist and/or social worker. The proactive intervention consists of a complete check-up/follow-up and intervention into medical, psychiatric, functional and social aspects of the client in a stepwise, resource-differentiated way according to needs based on the clinical judgement of the team (Fig. 2).

Insert figure 2 here. Overview of the intervention

The evaluation process used communication over the phone as well as visits to the primary care centre, depending on the priority of the client's needs. Examples of common actions/measures are: evaluation of medication, initiation of home care, diet counselling, advice on physical activity and support for loneliness and isolation. The formation of an "elderly team" with dedicated nurses who function as personal nurses for the frail individuals is the key component of the intervention, together with the standardised evaluation of frailty based on comprehensive geriatric assessment.

Outcome measures for intervention

Primary outcome measures are: healthcare cost, number of hospital care episodes, hospital care days and mortality. Secondary outcomes are: number of outpatient visits, cost of social care and informal care, number of drugs, number of prescribed drugs not recommended for

the elderly, health-related quality of life (HRQoL), cost-effectiveness, sense of security and functional ability.

Data on healthcare consumption will be obtained from the administrative healthcare database and data on healthcare costs from the cost-per-patient database. Costs for social care and informal care are collected from the "Questionnaire for the patient's perspective and in-depth patient data" (see below) and will be estimated by number of contacts multiplied by a defined unit cost. Use of medications at the group level will be studied by extracting group data from the National Medication Database, before, during and after the study.

Statistical analysis for intervention study

Primary and secondary outcome measures for intervention vs control population will consist of analyses for completed year 1 and 2 respectively, using the intention to treat (ITT) and last observation carried forward (LOCF) method. Differences in means and proportions between groups will be analysed using a t-test. Differences in categorical data will be analysed using a Chi-squared test. If the baseline mean risk score differs between the intervention and control groups, primary outcomes adjusted for risk score will be analysed using linear or logistic regression.

Monitoring

Every six months, each primary care centre is monitored by the project group, providing opportunities for dialogue and problem solving. Every six months, or earlier when needed, each primary care centre reviews the patients included in the study and actions are considered depending on the results of the review. Every six months, the primary care teams gather for a network meeting to discuss common issues and share experiences.

Data management

No biomaterials are included in the study. All patient data will be processed lawfully according to the General Data Protection Regulation (GDPR). The data file used for the prediction model, for the intervention group and the control group was retrieved from Region Östergötland's administrative databases. The data file that will be used for analysis in both the main study and the sub-studies contains personal data from Region Östergötland's administrative databases as well as data reported by the patient. The file will only be available to the overall project manager and individuals responsible for each sub-project, i.e. the co-authors of this paper. The file will be stored in databases with a high level of security at Region Östergötland and Linköping University and also protected by personal passwords. Questions regarding data are replied to through the corresponding author upon request. We used the SPIRIT reporting guidelines [11].

Sub-studies on different perspectives of elderly care, from patient to professionals and governance to societal aspects.

Scientific questions

What are the experiences of the previous and new healthcare model for older people from a wider individual, social, professional and societal perspective? What are the governance mechanisms that may facilitate or act as barriers to the development of healthcare for older people? What is the cost-effectiveness of the intervention in comparison to care as usual?

Based on these overall questions, there are four main research perspectives with specific research questions:

1. *The perspective of the older patients and their families:* How does the change in healthcare provision towards proactive primary elderly care impact upon individual participation and subjective well-being as well as objective indicators of quality of life beyond health? How does the change in healthcare provision towards proactive primary elderly care shape the receipt of informal help and support from spouses, offspring and the wider network? These research questions are studied through a questionnaire from the patient's perspective and interviews from the patient's perspective.
2. *The professional perspective on the healthcare system:* How does the change in healthcare provision towards proactive primary elderly care change the satisfaction and support of the professionals within the healthcare system? The methods used are qualitative studies of selected parts of the healthcare system, and implementation studies (see below). An implementation study explores the organisational readiness to implement the new work routines in primary care. Investigating organisational readiness can provide knowledge about early factors that are important for implementation.
3. *The governance perspective:* What are the mechanisms and explanations for today's elderly care, from the political level down to operative healthcare management? The methods used are implementation studies using semi-structured interviews.
4. *Cost-effectiveness:* What is the cost-effectiveness of the intervention compared to usual care? Data will be collected through questionnaires concerning patient health related outcomes and from administrative registries of health care consumption and costs.

Methods for sub-studies

Questionnaire for the patient's perspective and in-depth patient data. We will study how the change in healthcare provision impacts upon individual well-being, the support they receive from their private networks of families and friends and their satisfaction with and the support of the healthcare system. A longitudinal study design enables us to follow changes over time. Moreover, we will analyse whether the focusing of care contributes to the life-course accumulation of (dis)advantage in old age and how this contributes to social inequality dynamics. The longitudinal patient questionnaire study collects data on three occasionsover a period of 36 months: baseline before intervention, after completed year 1 and 2, respectively. The information from the questionnaires will be combined with a registry-based

assessment of social-structure and life-course information at baseline and referenced with nationally representative life-course data on health, occupation and family from Statistics Sweden (SCB) and the National Board of Health and Welfare (Socialstyrelsen). Measures in the questionnaire include the EQ-5D-3L and EQ-VAS [12] for health-related quality of life (HRQoL) estimates, activities of daily living/functions by the ADL Staircase [13] and RAND-36 for self-reported functional health [14]. A measure for sense of security in care is also used (SECP) [15]. The dizziness handicap inventory is used to detect the presence of a risk of falls [16] and its related health consequences. A visual analogue scale (0–100 mm) and a pain-drawing instrument is used to evaluate pain experience [17].

Interviews from the patient's perspective. In one sub-project, we focus on how frail older people experience care services if included in the intervention. Twenty semi-structured interviews with elderly patients will be conducted. A selection of elderly patients will be made, and this selection will include patients who have experiences of the intervention. Interviews are intended to provide access to the feelings, thoughts and experiences of patients. The starting point is that the interview is a knowledge-producing activity, and it is during the interview and in the interaction with the individual and the researcher that knowledge is produced [18]. Another sub-project aims to investigate how the elderly experience their everyday lives and the opportunities for rehabilitation from an availability and participation perspective. Do the elderly receive the rehabilitation they consider themselves to need? A qualitative study with a strategic selection of approximately 20 participants from the intervention group will be conducted.

Qualitative studies of selected parts of the healthcare system. A qualitative approach (shadowing) [19] is used to study the working conditions for nurses in primary care in relation to challenges in their professional responsibility connected to their work. The proposed sub-project addresses key issues in order to obtain knowledge about how competence levels and the distribution of tasks match the needs of frail older people living at home. The ongoing development in the field of the care of older people can be studied through the concept of task-shifting [20]. Questions of task shifting are implicit in discussions concerning the relationship between general competence and specialist competence within professional groups or the resource deficit in relation to ageing populations. The main aim is therefore to explore and characterise task-shifting processes in practices, competencies, responsibilities and roles from the perspective of registered nurses working within the main project. A second aim is to explore the challenges of handling drugs and the pharmaceutical preparations related to nurse practices in home care, and how these challenges are processed.

Implementation studies. In order to meet the future challenges posed by an ageing population, it is not only important to develop and evaluate new care models, but also to ensure that these models are implemented successfully by organisations providing care. Three separate studies investigate the implementation of the new work routines for improved care among the frail elderly.

To study the implementation of the model, the project will use a framework that specifies four types (or domains) of determinants, which function as barriers and/or facilitators for

successful implementation. Research in implementation science has established that successful implementation depends on an interplay between these determinants: (1) the effectiveness of the strategies chosen to support the implementation; (2) the characteristics of the new practices (routines, methods, etc.) being implemented; (3) beliefs, attitudes and motivations among the front-line implementers; and (4) the context of the implementation. The framework will provide a basic structure of interviews which will be carried out with representatives of different levels of the healthcare system: from political leadership and primary-care management to practitioners on the front line of primary care. Study I focuses on the role of professionals in implementing the new work routines, including adopting a holistic approach to care. This study also investigates readiness to change at both an individual level (e.g. resources, attitudes) and an organisational level (e.g. system that support change).

Study II. Preliminary results from Study I indicate that successful collaboration between primary care providers and the municipalities is essential in achieving proactive care and implementing the new work routines. Indeed, most care of the frail elderly occurs outside of a primary care setting. The second study therefore investigates these conditions or collaborations via interviews with managers representing both organisations. A concept mapping approach will be used to identify and quantify the factors affecting implementation. Interviews will be audio-recorded and transcribed verbatim.

Finally, a third study will focus on investigating the governance mechanisms that influence the present situation as well as the uptake of new models through policy-making and implementation. Despite good intentions and various policies, Swedish elderly care has not undergone any extensive change; thus, the same challenges and development needs are being discussed today as 20 years ago.

For this reason, this sub-project will investigate the mechanisms that facilitate or impede evidence-based policy-making and implementation from the political level to the regional level in elderly care. Questions that will be studied are: What influences policy-making and implementation at different levels? What are the strategies for policy implementation? How is policy implementation monitored and evaluated at different levels? Three levels of policy-making and implementation will be studied. Level 1: politicians and Ministry of Health and Social Affairs. Level 2: state agencies and authorities at national level, i.e. NBHW (Socialstyrelsen) and the Swedish Association of Local Authorities and Regions. Level 3: politicians, executive boards and managers at county council and regional level. Interviews will be audio-recorded and transcribed verbatim.

Cost-effectiveness. A cost-effectiveness analysis will also be performed. The primary outcome in the analysis is the incremental cost-effectiveness ratio (ICER): cost/quality adjusted life year (QALY). The QALY-weights for the analysis will be derived from the EQ-5D-3L, and the QALYs will be calculated by multiplying the QALY-weight with time. The analysis will have a societal perspective meaning that all relevant costs will be included in the analysis. Health care utilization and costs will be retrieved from administrative databases. Information on social care and informal care will be retrieved from the questionnaire. The cost-effectiveness analysis will be performed with a short-term perspective (within trial), and also with a life-time perspective applying health economic decision modelling.

Statistical analysis for sub-studies

The outcomes of the sub-studies are: number of outpatient visits, cost of social and informal care, number of drugs, number of prescribed drugs not recommended for the elderly, health-related quality of life (HRQoL), cost-effectiveness, sense of security and functional ability. The measures will be analysed for years 1 and 2 respectively using the intention to treat (ITT) and last observation carried forward (LOCF) method. Differences between groups will be analysed using a t-test. We intend to estimate the cost-effectiveness in terms of cost/QALY (quality-adjusted life years) from a lifetime perspective using simulation models. The QALY weights will be obtained from the EQ-5D-3L.

Time plan

An overview is presented in Fig. 1. The project started with the development of the case-finding algorithm (manuscript in progress) in 2017. Based on this model, the case-finding process was undertaken at the beginning of March 2017. Selected patients were presented to each healthcare centre for the start of the intervention programme in April 2017. A run-in period of April–December 2017 was used, during which healthcare centres were informed about and introduced to the new work model, and patients were subsequently enrolled onto the programme. All selected high-risk patients will have received an initial healthcare and/or social care plan. More than 90% of the selected patients were included by the end of December 2017. The intervention/follow-up period is planned to last for two years, until the end of 2019 (Fig 1).

An initial questionnaire was sent to all selected patients in the intervention and control healthcare centres during May–June 2017. The questionnaire will also be distributed to enrolled participants in years 2 and 3. Interviews with professionals in participating primary care health centres and communities were performed during June–September 2017. Interviews with elderly participants in order to capture the patient's perspective on the study were performed during December 2017–July 2018. Interviews with elderly participants in order to capture the patient's perspective on rehabilitation will take place during November 2018–February 2019. Interviews with high-level decision-makers and politicians were conducted during January–September 2018.

A first preliminary outcome analysis after 13 months of intervention will be performed in 2019. The intervention and collection of healthcare data ends on 31 December 2019. The analysis of primary and secondary outcome measures starts in 2020. The scientific writing-up and participation in academic conferences has already started for some of the sub-projects. The writing period for the intervention study begins in spring 2020. Dialogue with owners/stakeholders at a political level takes place every six months during the course of the project.

Possible evidence for changes in elderly care across the whole County of Östergötland will be available in autumn 2020, when the implementation process of the new care model can be broadened. Members of the research group are participating in workshops at a national level concerning healthcare development.

Ethics and dissemination

This study was subject to ethical evaluation and approved by the regional ethical review board in Linköping (Dnr 2016/347-31). They judged all aspects of the study including design and safety. By adding an academic study to an ongoing change in the healthcare process for the elderly, we do not per se include or exclude treatment possibilities for individuals or groups of individuals. The study itself is “inert” within the healthcare system. Therefore, we do not see that the use of aggregated patient data from the healthcare system can be of any harm to the participants. On the contrary, we find strong ethical motives for the study, which is an academic attempt to detect the real-world effectiveness of a politically determined intervention into a large patient group. The patients who responded to the questionnaire did so using an informed consent.

The data will be presented in scientific journals and communicated at scientific meetings during the period 2018–2022. The outcome data of the study will be presented to the healthcare provider (County Council of Östergötland) for a discussion on the evidence relating to future care models for elderly persons. The data will also be used by healthcare managers and decision-makers for the development of future care models.

DISCUSSION

Clinical trials on complex healthcare processes are rare and difficult to design with adequate scientific quality. On the other hand, delimited clinical trials may also only be valid within an academic setting and the outcome difficult to reproduce in clinical reality. In order to counteract the scientific challenges facing trials in complex clinical settings and processes, the use of a pragmatic clinical trial design is one, or perhaps the only, alternative [9]. In terms of the primary context of elderly care, this study is intended to find answers to basic scientific questions about the future healthcare of the elderly.

One challenge for the study was to find older patients in need of healthcare, hopefully before escalating needs would develop. Managing thousands of patients during this screening for possible illness may be impossible in healthcare using face-to-face methods. Statistical models for case findings have recently proven valid and are recommended in the clinical healthcare of old persons [8] so this *modus operandi* was used in this study.

There is a great need for improved healthcare for the elderly and a simultaneous knowledge gap regarding scientific data on what care models to use in the future. This study aims to fill some of that gap and may hopefully generate some clinically meaningful data that can be used for the future development of healthcare for older persons.

Authors contributions

All authors have made substantial contributions to the conception or design of the work, or the acquisition, analysis or interpretation of data. They have participated in the drafting the work or revising it critically for important intellectual content. The gave final approval of the version published.

Jan Marcusson: principal investigator, design, analysis and scientific writing.

Magnus Nord: clinical project leader, design, clinical site visits, data collection, analysis, scientific writing

Ylva Böttiger: design, analysis, scientific writing

Huan-Ji Dong: design and analysis of prediction model. Scientific writing.

Maria Johansson, Anneli Peolsson: clinicians and scientists responsible for rehabilitation, design of the postal questionnaire, data collection, analysis, scientific writing

Jenny Alwin, Lars-Åke Levin: design and health economic analysis, design of the postal questionnaire, data collection, analysis, scientific writing

Petra Dannapfel, Kristin Thomas, Bonnie Poksinska, design and analysis of implementation studies, data collection, analysis, scientific writing

Annette Sverker, Anna Olaison, Elisabet Cedersund, design of interviews and analysis of the patient's perspective, scientific writing

Susanne Kelfve, Andreas Motel-Klingebiel: design of postal questionnaire, analysis of well-being, network support, satisfaction and social inequality based on questionnaire and registry data, scientific writing

Ingrid Hellström, Agneta Kullberg: design and analysis of professional perspective, scientific writing

Johan Lyth analysis, scientific writing

Malin Wass, project-coordinator, scientific writing

Agneta Andersson: co-investigator, analysis, scientific writing

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Competing interests: None.

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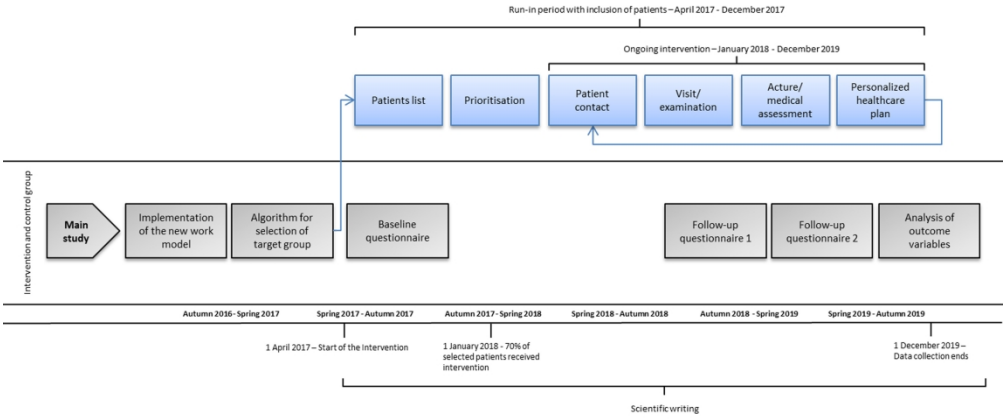

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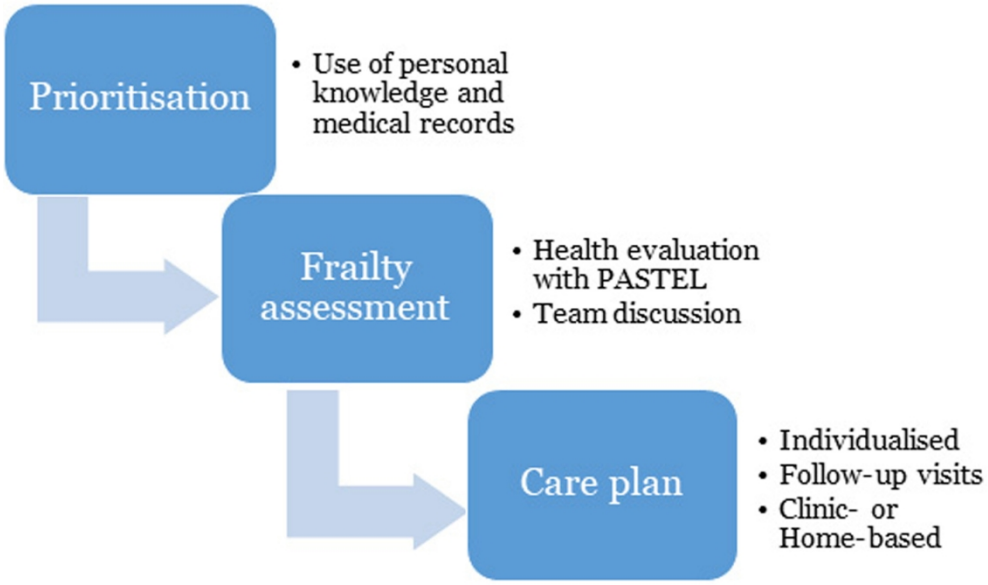

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2

Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	n/a
Funding	#4	Sources and types of financial, material, and other support	15
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 14
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	15
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	15
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	14
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies	4-5

		(published and unpublished) examining benefits and harms for each intervention	
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	5-6
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or	n/a

		improving / worsening disease)	
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	n/a
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	7
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11-12
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	n/a

Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg,	8

		questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	8
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	8
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	n/a
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	n/a
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be	8

		found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	12
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	8
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	12
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	12
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	12

Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	n/a
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	15
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	8
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	12-13
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Informed consent	#32	Model consent form and other related documentation given	n/a

materials		to participants and authorised surrogates	
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a