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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-027847
Article Type:	Protocol
Date Submitted by the Author:	10-Nov-2018
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Keywords:	health care, fragile, elderly

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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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Word Count. 4709

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

For peer review only

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 people¹. 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 health², 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 concept⁶. 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 needs⁷. 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 controls⁸.

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

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

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16 A pilot study (not published) showed that 60% of the target population had at least one
17 hospitalisation during a 12-month period. The hypothesis is that this figure will be reduced by
18 20% in the intervention group in this study. A sample size calculation based on this
19 reduction, a power of 0.8 and a significance level of 0.05 led to a minimum of 270
20 participants per group. Considering the frail and elderly population, we estimate a 40% drop-
21 out rate and we have therefore increased the sample size to 378 per group. Since we are
22 using a pragmatic clinical trial design, featuring heterogeneity within both the participating
23 population and the participating healthcare centres, this reduces the likelihood of detecting
24 meaningful changes; therefore, it is reasonable to double the number of participants per
25 group, giving a final number of 800 included individuals per group.
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31 **Prediction of patient cases**

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33 The prediction model is described elsewhere (manuscript submitted). In short, the data was
34 obtained between November 2015 and October 2016 from the computerised information
35 system of the County Council of Östergötland, where statistics for all the healthcare in the
36 county is stored. For example, for the whole population there are records of: number of visits
37 to primary or hospital care, number of days in hospital, diagnostic codes for each visit, etc.
38 We used an in-ward hospital stay between November 2016 and January 2017 as the
39 dependent variable. The prediction variables are based on a previous study⁴, including
40 number of GP visits and International Classification of Diseases, 10th Revision, (ICD-10)
41 codes, use of assistive technology, emergency room (ER) visits, age and gender. The aim is
42 to identify participants aged 75 or older who are likely to be hospitalised during the next three
43 months. Risk scores were calculated for all individuals using logistic regression. Individuals
44 were ranked according to the risk scores (for hospital care), from high to low. A cut-off value
45 was chosen so that 800 individuals from the participating healthcare centres with the highest
46 scores were selected for proactive intervention for a period of two years. The same cut-off
47 value was then used to choose individuals from the control healthcare centres.
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54 **Evaluation form.**

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56 A four-page evaluation form has been developed and is used to standardise the evaluation of
57 each individual (the Primary Care Assessment Tool for the Elderly- PASTEL). The goal is to
58 create a time-efficient, easy-to-use tool for a doctor-nurse team. It is intended to be used by
59 primary care nurses and doctors with different levels of experience. The PASTEL form is
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3 based on the holistic approach of Comprehensive Geriatric Assessment (CGA) ⁶ and
4 includes different aspects of health and function that are often of importance to the older
5 patient. It also includes the Clinical Frailty Scale ⁹.
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9 The form contains three parts. The first consists of an interview guide with mostly multiple-
10 choice questions and a self-rating of health. The second part is a checklist for a brief physical
11 examination and laboratory testing, a medication review and questions about the individual's
12 opinion about their present and future needs for care. The third part is used for a team
13 meeting to make a common estimation of frailty and to decide on the need for further
14 investigation and actions to support the elderly person.
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18 19 20 **Intervention**

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

44 Primary outcome measures are: healthcare cost, number of hospital care episodes, hospital
45 care days and mortality. Secondary outcomes are: number of outpatient visits, cost of social
46 care and informal care, number of drugs, number of prescribed drugs not recommended for
47 the elderly, health-related quality of life (HRQoL), cost-effectiveness, sense of security and
48 functional ability.
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51 Data on healthcare consumption will be obtained from the administrative healthcare
52 database and data on healthcare costs from the cost-per-patient database. Cost for social
53 care and informal care will be estimated by number of contacts multiplied by a defined unit
54 cost. Use of medications at the group level will be studied by extracting group data from the
55 National Medication Database, before, during and after the study.
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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-VAS¹¹ for health-related quality of life (HRQoL) estimates, activities of daily living/functions by the ADL Staircase¹² and RAND-36 for self-reported functional health¹³. A measure for sense of security in care is also used (SECP)¹⁴. The dizziness handicap inventory is used to detect

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3 the presence of a risk of falls ¹⁵ and its related health consequences. A visual analogue scale
4 (0–100 mm) and a pain-drawing instrument is used to evaluate pain experience ¹⁶.
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8 *Interviews from the patient's perspective.* In one sub-project, we focus on how frail older
9 people experience care services if included in the intervention. Twenty semi-structured
10 interviews with elderly patients will be conducted. A selection of elderly patients will be made,
11 and this selection will include patients who have experiences of the intervention. Interviews
12 are intended to provide access to the feelings, thoughts and experiences of patients. The
13 starting point is that the interview is a knowledge-producing activity, and it is during the
14 interview and in the interaction with the individual and the researcher that knowledge is
15 produced ¹⁷. Another sub-project aims to investigate how the elderly experience their
16 everyday lives and the opportunities for rehabilitation from an availability and participation
17 perspective. Do the elderly receive the rehabilitation they consider themselves to need? A
18 qualitative study with a strategic selection of approximately 20 participants from the
19 intervention group will be conducted.
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26 *Qualitative studies of selected parts of the healthcare system.* A qualitative approach
27 (shadowing) ¹⁸ is used to study the working conditions for nurses in primary care in relation to
28 challenges in their professional responsibility connected to their work. The proposed sub-
29 project addresses key issues in order to obtain knowledge about how competence levels and
30 the distribution of tasks match the needs of frail older people living at home. The ongoing
31 development in the field of the care of older people can be studied through the concept of
32 task-shifting ¹⁹. Questions of task shifting are implicit in discussions concerning the
33 relationship between general competence and specialist competence within professional
34 groups or the resource deficit in relation to ageing populations. The main aim is therefore to
35 explore and characterise task-shifting processes in practices, competencies, responsibilities
36 and roles from the perspective of registered nurses working within the main project. A
37 second aim is to explore the challenges of handling drugs and the pharmaceutical
38 preparations related to nurse practices in home care, and how these challenges are
39 processed.
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44 *Implementation studies.* In order to meet the future challenges posed by an ageing
45 population, it is not only important to develop and evaluate new care models, but also to
46 ensure that these models are implemented successfully by organisations providing care.
47 Three separate studies investigate the implementation of the new work routines for improved
48 care among the frail elderly.
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51 To study the implementation of the model, the project will use a framework that specifies four
52 types (or domains) of determinants, which function as barriers and/or facilitators for
53 successful implementation. Research in implementation science has established that
54 successful implementation depends on an interplay between these determinants: (1) the
55 effectiveness of the strategies chosen to support the implementation; (2) the characteristics
56 of the new practices (routines, methods, etc.) being implemented; (3) beliefs, attitudes and
57 motivations among the front-line implementers; and (4) the context of the implementation.
58 The framework will provide a basic structure of interviews which will be carried out with
59 representatives of different levels of the healthcare system: from political leadership and
60 primary-care management to practitioners on the front line of primary care. Study I focuses

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3 on the role of professionals in implementing the new work routines, including adopting a
4 holistic approach to care. This study also investigates readiness to change at both an
5 individual level (e.g. resources, attitudes) and an organisational level (e.g. system that
6 support change).
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8 Study II. Preliminary results from Study I indicate that successful collaboration between
9 primary care providers and the municipalities is essential in achieving proactive care and
10 implementing the new work routines. Indeed, most care of the frail elderly occurs outside of a
11 primary care setting. The second study therefore investigates these conditions or
12 collaborations via interviews with managers representing both organisations. A concept
13 mapping approach will be used to identify and quantify the factors affecting implementation.
14 Interviews will be audio-recorded and transcribed verbatim.
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16 Finally, a third study will focus on investigating the governance mechanisms that influence
17 the present situation as well as the uptake of new models through policy-making and
18 implementation. Despite good intentions and various policies, Swedish elderly care has not
19 undergone any extensive change; thus, the same challenges and development needs are
20 being discussed today as 20 years ago.
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22 For this reason, this sub-project will investigate the mechanisms that facilitate or impede
23 evidence-based policy-making and implementation from the political level to the regional
24 level in elderly care. Questions that will be studied are: What influences policy-making and
25 implementation at different levels? What are the strategies for policy implementation? How is
26 policy implementation monitored and evaluated at different levels? Three levels of policy-
27 making and implementation will be studied. Level 1: politicians and Ministry of Health and
28 Social Affairs. Level 2: state agencies and authorities at national level, i.e. NBHW
29 (Socialstyrelsen) and the Swedish Association of Local Authorities and Regions. Level 3:
30 politicians, executive boards and managers at county council and regional level. Interviews
31 will be audio-recorded and transcribed verbatim.
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39 **Statistical analysis for sub-studies**

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

53 An overview is presented in Fig. 1. The project started with the development of the case-
54 finding algorithm (manuscript in progress) in 2017. Based on this model, the case-finding
55 process was undertaken at the beginning of March 2017.
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58 Selected patients were presented to each healthcare centre for the start of the intervention
59 programme in April 2017. A run-in period of April–December 2017 was used, during which
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3 healthcare centres were informed about and introduced to the new work model, and patients
4 were subsequently enrolled onto the programme. All selected high-risk patients will have
5 received an initial healthcare and/or social care plan. More than 90% of the selected patients
6 were included by the end of December 2017. The intervention/follow-up period is planned to
7 last for two years, until the end of 2019 (Fig 1).
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10 An initial questionnaire was sent to all selected patients in the intervention and control
11 healthcare centres during May–June 2017. The questionnaire will also be distributed to
12 enrolled participants in years 2 and 3. Interviews with professionals in participating primary
13 care health centres and communities were performed during June–September 2017.
14 Interviews with elderly participants in order to capture the patient’s perspective on the study
15 were performed during December 2017–July 2018. Interviews with elderly participants in
16 order to capture the patient’s perspective on rehabilitation will take place during November
17 2018–February 2019. Interviews with high-level decision-makers and politicians were
18 conducted during January–September 2018.
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21 A first preliminary outcome analysis after 13 months of intervention will be performed in
22 January 2019. The intervention and collection of healthcare data ends on 31 December
23 2019. The analysis of primary and secondary outcome measures starts in 2020. The
24 scientific writing-up and participation in academic conferences has already started for some
25 of the sub-projects. The writing period for the intervention study begins in spring 2020.
26 Dialogue with owners/stakeholders at a political level takes place every six months during the
27 course of the project.
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30 Possible evidence for changes in elderly care across the whole County of Östergötland will
31 be available in autumn 2020, when the implementation process of the new care model can
32 be broadened. Members of the research group are participating in workshops at a national
33 level concerning healthcare development.
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39 Figure 1. Overview of the project over time.

40 Figure 2. Overview of the intervention.
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45 **Ethics and dissemination**

46 This study was subject to ethical evaluation and approved by the regional ethical review
47 board in Linköping (Dnr 2016/347-31). They judged all aspects of the study including design
48 and safety. By adding an academic study to an ongoing change in the healthcare process for
49 the elderly, we do not per se include or exclude treatment possibilities for individuals or
50 groups of individuals. The study itself is “inert” within the healthcare system. Therefore, we
51 do not see that the use of aggregated patient data from the healthcare system can be of any
52 harm to the participants. On the contrary, we find strong ethical motives for the study, which
53 is an academic attempt to detect the real-world effectiveness of a politically determined
54 intervention into a large patient group. The patients who responded to the questionnaire did
55 so using an informed consent.
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3 The data will be presented in scientific journals and communicated at scientific meetings
4 during the period 2018–2022. The outcome data of the study will be presented to the
5 healthcare provider (County Council of Östergötland) for a discussion on the evidence
6 relating to future care models for elderly persons. The data will also be used by healthcare
7 managers and decision-makers for the development of future care models.
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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, alternative⁸. 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 persons⁷ 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

1
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3 Johan Lyth analysis, scientific writing
4

5 Malin Wass, project-coordinator, scientific writing
6

7 Agneta Andersson: co-investigator, analysis, scientific writing
8
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10 11 12 13 **Funding statement** 14

15 This work was supported by the County Council of Östergötland and Linköping University
16 from the strategic research fund for 'Health Care and Welfare' [Grant number 2016186-14].
17 Contact person is Dean Johan Söderholm, Deans office, Medical Faculty, Linköping
18 University. This funding source had no role in the design of this study and will not have any
19 role during its execution, analyses, interpretation of the data, or decision to submit results.
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22 Competing interests: None.
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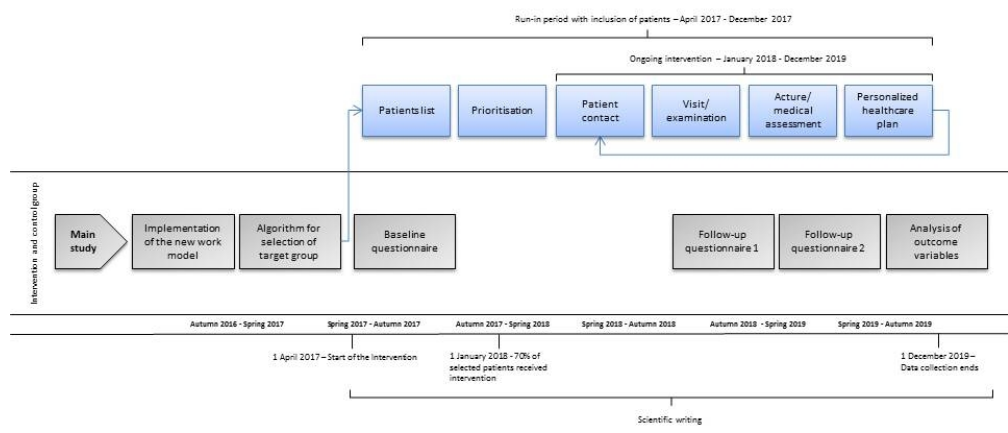


Figure 1. Overview of the project over time.

254x190mm (96 x 96 DPI)

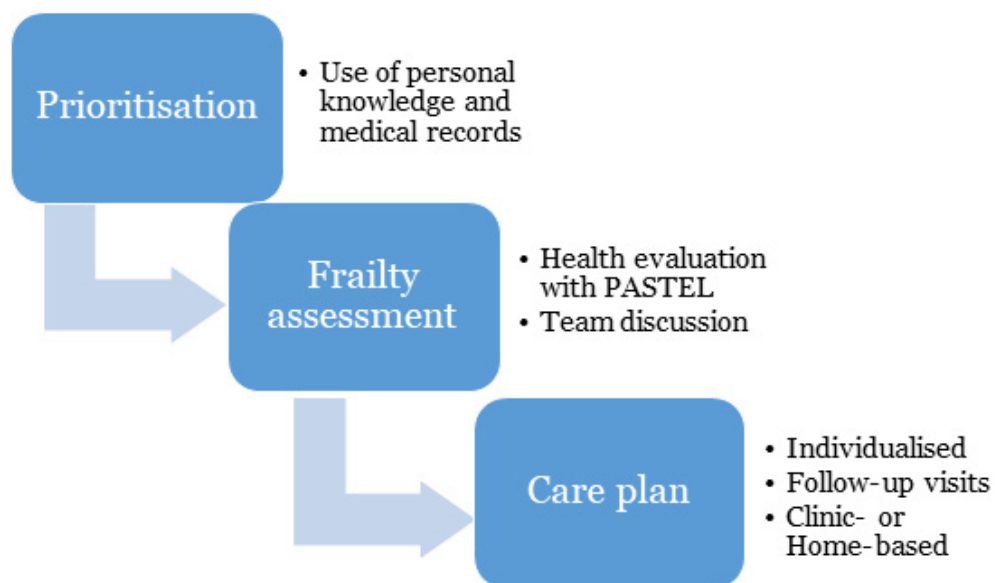


Figure 2. Overview of the intervention.

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.

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

1	Trial registration:	#2b	All items from the World Health Organization Trial	n/a
2				
3	data set		Registration Data Set	
4				
5				
6	Protocol version	#3	Date and version identifier	n/a
7				
8				
9	Funding	#4	Sources and types of financial, material, and other support	15
10				
11				
12	Roles and	#5a	Names, affiliations, and roles of protocol contributors	1, 14
13				
14	responsibilities:			
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16	contributorship			
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20	Roles and	#5b	Name and contact information for the trial sponsor	15
21				
22	responsibilities:			
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24	sponsor contact			
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26	information			
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30	Roles and	#5c	Role of study sponsor and funders, if any, in study design;	15
31				
32	responsibilities:		collection, management, analysis, and interpretation of	
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34	sponsor and funder		data; writing of the report; and the decision to submit the	
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42	Roles and	#5d	Composition, roles, and responsibilities of the coordinating	14
43				
44	responsibilities:		centre, steering committee, endpoint adjudication	
45				
46	committees		committee, data management team, and other individuals or	
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54	Background and	#6a	Description of research question and justification for	4-5
55				
56	rationale		undertaking the trial, including summary of relevant studies	
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		(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:	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug adherence and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	n/a
Interventions:	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
concomitant care			
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

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	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
18 19 20 21 22 23 24 25 26 27	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
28 29 30 31 32 33 34	Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
35 36 37 38 39 40 41 42	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
43 44 45 46 47 48 49	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
50 51 52 53 54 55 56 57 58 59 60	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

1		questionnaires, laboratory tests) along with their reliability	
2		and validity, if known. Reference to where data collection	
3		forms can be found, if not in the protocol	
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8	Data collection plan:	#18b Plans to promote participant retention and complete follow-	n/a
9	retention	up, including list of any outcome data to be collected for	
10		participants who discontinue or deviate from intervention	
11		protocols	
12			
13	Data management	#19 Plans for data entry, coding, security, and storage, including	8
14		any related processes to promote data quality (eg, double	
15		data entry; range checks for data values). Reference to	
16		where details of data management procedures can be	
17		found, if not in the protocol	
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20	Statistics: outcomes	#20a Statistical methods for analysing primary and secondary	8
21		outcomes. Reference to where other details of the statistical	
22		analysis plan can be found, if not in the protocol	
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30	Statistics: additional	#20b Methods for any additional analyses (eg, subgroup and	n/a
31	analyses	adjusted analyses)	
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34	Statistics: analysis	#20c Definition of analysis population relating to protocol non-	n/a
35	population and	adherence (eg, as randomised analysis), and any statistical	
36	missing data	methods to handle missing data (eg, multiple imputation)	
37			
38	Data monitoring:	#21a Composition of data monitoring committee (DMC); summary	8
39	formal committee	of its role and reporting structure; statement of whether it is	
40		independent from the sponsor and competing interests; and	
41		reference to where further details about its charter can be	
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1		found, if not in the protocol. Alternatively, an explanation of	
2		why a DMC is not needed	
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6	Data monitoring:	#21b Description of any interim analyses and stopping guidelines,	12
7			
8	interim analysis	including who will have access to these interim results and	
9		make the final decision to terminate the trial	
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13	Harms	#22 Plans for collecting, assessing, reporting, and managing	n/a
14			
15		solicited and spontaneously reported adverse events and	
16			
17		other unintended effects of trial interventions or trial conduct	
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21	Auditing	#23 Frequency and procedures for auditing trial conduct, if any,	8
22			
23		and whether the process will be independent from	
24			
25		investigators and the sponsor	
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29	Research ethics	#24 Plans for seeking research ethics committee / institutional	12
30			
31	approval	review board (REC / IRB) approval	
32			
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34	Protocol	#25 Plans for communicating important protocol modifications	n/a
35			
36	amendments	(eg, changes to eligibility criteria, outcomes, analyses) to	
37			
38		relevant parties (eg, investigators, REC / IRBs, trial	
39			
40		participants, trial registries, journals, regulators)	
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44	Consent or assent	#26a Who will obtain informed consent or assent from potential	12
45			
46		trial participants or authorised surrogates, and how (see	
47			
48		Item 32)	
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51	Consent or assent:	#26b Additional consent provisions for collection and use of	12
52			
53	ancillary studies	participant data and biological specimens in ancillary	
54			
55		studies, if applicable	
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1	Confidentiality	#27	How personal information about potential and enrolled	n/a
2			participants will be collected, shared, and maintained in	
3			order to protect confidentiality before, during, and after the	
4			trial	
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11	Declaration of	#28	Financial and other competing interests for principal	15
12	interests		investigators for the overall trial and each study site	
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16	Data access	#29	Statement of who will have access to the final trial dataset,	8
17			and disclosure of contractual agreements that limit such	
18			access for investigators	
19				
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24	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial care, and for	n/a
25	trial care		compensation to those who suffer harm from trial	
26			participation	
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31	Dissemination policy:	#31a	Plans for investigators and sponsor to communicate trial	12-13
32	trial results		results to participants, healthcare professionals, the public,	
33			and other relevant groups (eg, via publication, reporting in	
34			results databases, or other data sharing arrangements),	
35			including any publication restrictions	
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44	Dissemination policy:	#31b	Authorship eligibility guidelines and any intended use of	n/a
45	authorship		professional writers	
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49	Dissemination policy:	#31c	Plans, if any, for granting public access to the full protocol,	n/a
50	reproducible		participant-level dataset, and statistical code	
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54	research			
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57	Informed consent	#32	Model consent form and other related documentation given	n/a
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1 materials to participants and authorised surrogates
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4 Biological specimens [#33](#) Plans for collection, laboratory evaluation, and storage of n/a
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6 biological specimens for genetic or molecular analysis in the
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8 current trial and for future use in ancillary studies, if
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10 applicable
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13 The SPIRIT checklist is distributed under the terms of the Creative Commons Attribution License CC-
14 BY-ND 3.0. This checklist can be completed online using <https://www.goodreports.org/>, a tool made
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16 by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-027847.R1
Article Type:	Protocol
Date Submitted by the Author:	26-Feb-2019
Complete List of Authors:	Marcusson, Jan; Clinical & Experimental Medicine, Geriatrics Nord, Magnus; Department of Medical and Health Sciences, Family Medicine Johansson, Maria; Clinical & Experimental Medicine, Geriatrics Alwin, Jenny; Department of Medical and Health Sciences, Health Care Analysis Levin, Lars-Åke; Department of Medical and Health Sciences, Health Care Analysis Dannapfel, Petra; Clinical & Experimental Medicine, Geriatrics Thomas, Kristin; Department of Medicine and Health Sciences, Linköping University Poksinska, Bozena Bonnie; Linköpings universitet, Management and Engineering Sverker, Annette; Department of Medicine and Health Sciences, Linköping University, Rehabilitation Medicine Olaison, Anna; Social and Welfare Studies Cedersund, Elisabet; Social and Welfare Studies, Ageing and Social Change Kelfve, Susanne; Social and Welfare Studies Motel-Klingebiel, Andreas; Social and Welfare Studies Hellström, Ingrid; Department of Social and Welfare Studies, Faculty of Health Sciences, Linköping University Kullberg, Agneta; Social and Welfare Studies Böttiger, Ylva; Department of Medicine and Health Sciences, Linköping University, Clinical Pharmacology Dong, Huan-Ji; Department of Medicine and Health Sciences, Linköping University Peolsson, Anneli; Department of Medicine and Health Sciences, Linköping University, Physiotherapy Wass, Malin; Research and Development Unit in Region Östergötland Lyth, Johan; Research and Development Unit in Region Östergötland Andersson, Agneta; Research and Development Unit in Region Östergötland
Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Geriatric medicine, Medical management
Keywords:	health care, elderly, frail

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SCHOLARONE™
Manuscripts

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

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Word Count. 4838

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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

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3 77 • The developed clinical evaluation and management model integrates primary care
4 78 with community care and social services
5 79 • The project also focuses on the perspectives of the patients, the professionals in the
6 80 healthcare system and the governance mechanisms, which may explain the
7 81 perceived shortcomings of today's healthcare for the elderly
8 82 • A fairly long run-in period due to clinical realities and organisational inertia in the
9 83 healthcare system as well as a long intervention period of two years are clinical
10 84 necessities, but this increases the risk of non-controlled influences on the project
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85 INTRODUCTION

86 The healthcare situation of the elderly is a challenge for healthcare systems in many
87 countries, and healthcare providers struggle to meet the needs of a growing number of older
88 people ¹. In Sweden, the largest consumers of medical services (60%) are persons 80 years
89 and older (15% of the population), a group that is predicted to increase by 50% over the next
90 15 years. Several studies report that a majority of the aged population is satisfied with their
91 health ², manage life at home and consider themselves healthy ^{3 4}. Only a minority of the
92 aged population is in need of hospital care. In most cases, the healthcare system does not
93 distinguish between different groups among the heterogeneous old-age population; instead,
94 both hospital and primary care are organised using a passive and reactive (acting when
95 symptoms or problems occur) approach. There have been many attempts to define and
96 measure frailty among the elderly in order to detect persons with significant care needs
97 (e.g.⁵). However, “frailty” is difficult to define as a medical condition and there is no
98 consensus on the operational definition of the concept ⁶. Three major frailty models have been
99 suggested: physical frailty model, deficit accumulation model of frailty, and the biopsychosocial or
100 multidimensional model ⁷. Furthermore, evaluation using clinical instruments requires and
101 trained staff for each individual evaluation, which is not easily applied within a broader clinical
102 context that lacks a primary geriatric perspective (e.g. primary care and acute ward
103 disciplines).

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

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

129 **METHOD AND ANALYSIS**

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

135 Insert figure 1 here. Overview of the project over time

137 **Patient involvement**

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

144 **Intervention study of proactive care for older persons in primary 145 care**

146 **Primary scientific question**

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

151 **Design, randomisation and setting**

152 This intervention study is designed to follow a shift in the paradigm of elderly care that had
153 already been decided by the care providers. This led us to use a study design that enables
154 us to detect the real-world effectiveness of the intervention in a broad patient group in a real,
155 non-selected clinical context with clinically meaningful outcome parameters. Consequently,
156 our design follows a selected pragmatic clinical trial model, in which defined primary care
157 health centres using the new work routines constitute our intervention group and the
158 remaining centres are used as controls⁹.

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

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3 167 risk scores (for hospitalisation) are predicted in healthcare centres with similar characteristics
4 168 to the intervention centres, but they receive care as usual, and these centres are not made
5 169 aware of the control patients. There is no randomisation at the patient level, but the case-
6 170 finding algorithm was used in the selection and the patients with the highest risk scores were
7 171 included until the preferred number of patients was reached. There was no randomisation of
8 172 healthcare centres; these were provided by the healthcare sponsor (County Council of
9 173 Östergötland). The control healthcare centres were matched in terms of location (city,
10 174 countryside), size and socio-economic distribution. A pre-study analysis of the primary
11 175 outcome measures of the two patient groups revealed no significant differences between
12 176 them.

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15 179 **Sample size**

16 180 A pilot study (not published) showed that 60% of the target population had at least one
17 181 hospitalisation during a 12-month period. The hypothesis is that this figure will be reduced by
18 182 20% in the intervention group in this study. A sample size calculation based on this
19 183 reduction, a power of 0.8 and a significance level of 0.05 led to a minimum of 270
20 184 participants per group. Considering the frail and elderly population, we estimate a 40% drop-
21 185 out rate and we have therefore increased the sample size to 378 per group. Since we are
22 186 using a pragmatic clinical trial design, featuring heterogeneity within both the participating
23 187 population and the participating healthcare centres, this reduces the likelihood of detecting
24 188 meaningful changes; therefore, it is reasonable to double the number of participants per
25 189 group, giving a final number of 800 included individuals per group.

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27 191 **Prediction of patient cases**

28 192 The prediction model is described elsewhere (manuscript submitted). In short, the data was
29 193 obtained between November 2015 and October 2016 from the computerised information
30 194 system of the County Council of Östergötland, where statistics for all the healthcare in the
31 195 county is stored. For example, for the whole population there are records of: number of visits
32 196 to primary or hospital care, number of days in hospital, diagnostic codes for each visit, etc.
33 197 We used an in-ward hospital stay between November 2016 and January 2017 as the
34 198 dependent variable. The prediction variables are based on a previous study⁴, including
35 199 number of GP visits and International Classification of Diseases, 10th Revision, (ICD-10)
36 200 codes, use of assistive technology, emergency room (ER) visits, age and gender. The aim is
37 201 to identify participants aged 75 or older who are likely to be hospitalised during the next three
38 202 months. Risk scores were calculated for all individuals using logistic regression. Individuals
39 203 were ranked according to the risk scores (for hospital care), from high to low. A cut-off value
40 204 was chosen so that 800 individuals from the participating healthcare centres with the highest
41 205 scores were selected for proactive intervention for a period of two years. The same cut-off
42 206 value was then used to choose individuals from the control healthcare centres.

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44 208 **Evaluation form.**

209 A four-page evaluation form has been developed and is used to standardise the evaluation of
210 each individual (the Primary Care Assessment Tool for the Elderly- PASTEL). The goal is to
211 create a time-efficient, easy-to-use tool for a doctor-nurse team. It is intended to be used by
212 primary care nurses and doctors with different levels of experience. The PASTEL form is
213 based on the holistic approach of Comprehensive Geriatric Assessment (CGA) ⁶, which can
214 be regarded as combination of diagnostic and therapeutic processes where problems are
215 identified and managed. The assessments cover medical, psychiatric, functional, and social
216 domains required to enable a multifaceted therapeutic plan.
217 It also includes the Clinical Frailty Scale¹⁰.

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

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227 **Intervention**

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

236 Insert figure 2 here. Overview of the intervention

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

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246 **Outcome measures for intervention**

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

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3 250 the elderly, health-related quality of life (HRQoL), cost-effectiveness, sense of security and
4 251 functional ability.

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6 252 Data on healthcare consumption will be obtained from the administrative healthcare
7 253 database and data on healthcare costs from the cost-per-patient database. Costs for social
8 254 care and informal care are collected from the "Questionnaire for the patient's perspective and
9 255 in-depth patient data" (see below) and will be estimated by number of contacts multiplied by
10 256 a defined unit cost. Use of medications at the group level will be studied by extracting group
11 257 data from the National Medication Database, before, during and after the study.
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14 15 259 **Statistical analysis for intervention study**

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17 260 Primary and secondary outcome measures for intervention vs control population will consist
18 261 of analyses for completed year 1 and 2 respectively, using the intention to treat (ITT) and last
19 262 observation carried forward (LOCF) method. Differences in means and proportions between
20 263 groups will be analysed using a t-test. Differences in categorical data will be analysed using
21 264 a Chi-squared test. If the baseline mean risk score differs between the intervention and
22 265 control groups, primary outcomes adjusted for risk score will be analysed using linear or
23 266 logistic regression.

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29 30 269 **Monitoring**

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32 270 Every six months, each primary care centre is monitored by the project group, providing
33 271 opportunities for dialogue and problem solving. Every six months, or earlier when needed,
34 272 each primary care centre reviews the patients included in the study and actions are
35 273 considered depending on the results of the review. Every six months, the primary care teams
36 274 gather for a network meeting to discuss common issues and share experiences.

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40 41 276 **Data management**

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43 277 No biomaterials are included in the study. All patient data will be processed lawfully
44 278 according to the General Data Protection Regulation (GDPR). The data file used for the
45 279 prediction model, for the intervention group and the control group was retrieved from Region
46 280 Östergötland's administrative databases. The data file that will be used for analysis in both
47 281 the main study and the sub-studies contains personal data from Region Östergötland's
48 282 administrative databases as well as data reported by the patient. The file will only be
49 283 available to the overall project manager and individuals responsible for each sub-project, i.e.
50 284 the co-authors of this paper. The file will be stored in databases with a high level of security
51 285 at Region Östergötland and Linköping University and also protected by personal passwords.
52 286 Questions regarding data are replied to through the corresponding author upon request. We
53 287 used the SPIRIT reporting guidelines ¹¹.

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290 **Sub-studies on different perspectives of elderly care, from patient** 291 **to professionals and governance to societal aspects.**

292 **Scientific questions**

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

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

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

327 **Methods for sub-studies**

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

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3 339 assessment of social-structure and life-course information at baseline and referenced with
4 340 nationally representative life-course data on health, occupation and family from Statistics
5 341 Sweden (SCB) and the National Board of Health and Welfare (Socialstyrelsen). Measures in
6 342 the questionnaire include the EQ-5D-3L and EQ-VAS ¹² for health-related quality of life
7 343 (HRQoL) estimates, activities of daily living/functions by the ADL Staircase ¹³ and RAND-36
8 344 for self-reported functional health ¹⁴. A measure for sense of security in care is also used
9 345 (SECP) ¹⁵. The dizziness handicap inventory is used to detect the presence of a risk of falls
10 346 ¹⁶ and its related health consequences. A visual analogue scale (0–100 mm) and a pain-
11 347 drawing instrument is used to evaluate pain experience ¹⁷.

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17 349 *Interviews from the patient's perspective.* In one sub-project, we focus on how frail older
18 350 people experience care services if included in the intervention. Twenty semi-structured
19 351 interviews with elderly patients will be conducted. A selection of elderly patients will be made,
20 352 and this selection will include patients who have experiences of the intervention. Interviews
21 353 are intended to provide access to the feelings, thoughts and experiences of patients. The
22 354 starting point is that the interview is a knowledge-producing activity, and it is during the
23 355 interview and in the interaction with the individual and the researcher that knowledge is
24 356 produced ¹⁸. Another sub-project aims to investigate how the elderly experience their
25 357 everyday lives and the opportunities for rehabilitation from an availability and participation
26 358 perspective. Do the elderly receive the rehabilitation they consider themselves to need? A
27 359 qualitative study with a strategic selection of approximately 20 participants from the
28 360 intervention group will be conducted.

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34 362 *Qualitative studies of selected parts of the healthcare system.* A qualitative approach
35 363 (shadowing) ¹⁹ is used to study the working conditions for nurses in primary care in relation to
36 364 challenges in their professional responsibility connected to their work. The proposed sub-
37 365 project addresses key issues in order to obtain knowledge about how competence levels and
38 366 the distribution of tasks match the needs of frail older people living at home. The ongoing
39 367 development in the field of the care of older people can be studied through the concept of
40 368 task-shifting ²⁰. Questions of task shifting are implicit in discussions concerning the
41 369 relationship between general competence and specialist competence within professional
42 370 groups or the resource deficit in relation to ageing populations. The main aim is therefore to
43 371 explore and characterise task-shifting processes in practices, competencies, responsibilities
44 372 and roles from the perspective of registered nurses working within the main project. A
45 373 second aim is to explore the challenges of handling drugs and the pharmaceutical
46 374 preparations related to nurse practices in home care, and how these challenges are
47 375 processed.

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52 376 *Implementation studies.* In order to meet the future challenges posed by an ageing
53 377 population, it is not only important to develop and evaluate new care models, but also to
54 378 ensure that these models are implemented successfully by organisations providing care.
55 379 Three separate studies investigate the implementation of the new work routines for improved
56 380 care among the frail elderly.

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59 381 To study the implementation of the model, the project will use a framework that specifies four
60 382 types (or domains) of determinants, which function as barriers and/or facilitators for

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3 383 successful implementation. Research in implementation science has established that
4 384 successful implementation depends on an interplay between these determinants: (1) the
5 385 effectiveness of the strategies chosen to support the implementation; (2) the characteristics
6 386 of the new practices (routines, methods, etc.) being implemented; (3) beliefs, attitudes and
7 387 motivations among the front-line implementers; and (4) the context of the implementation.
8 388 The framework will provide a basic structure of interviews which will be carried out with
9 389 representatives of different levels of the healthcare system: from political leadership and
10 390 primary-care management to practitioners on the front line of primary care. Study I focuses
11 391 on the role of professionals in implementing the new work routines, including adopting a
12 392 holistic approach to care. This study also investigates readiness to change at both an
13 393 individual level (e.g. resources, attitudes) and an organisational level (e.g. system that
14 394 support change).
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16 396 Study II. Preliminary results from Study I indicate that successful collaboration between
17 397 primary care providers and the municipalities is essential in achieving proactive care and
18 398 implementing the new work routines. Indeed, most care of the frail elderly occurs outside of a
19 399 primary care setting. The second study therefore investigates these conditions or
20 400 collaborations via interviews with managers representing both organisations. A concept
21 401 mapping approach will be used to identify and quantify the factors affecting implementation.
22 402 Interviews will be audio-recorded and transcribed verbatim.
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24 404 Finally, a third study will focus on investigating the governance mechanisms that influence
25 405 the present situation as well as the uptake of new models through policy-making and
26 406 implementation. Despite good intentions and various policies, Swedish elderly care has not
27 407 undergone any extensive change; thus, the same challenges and development needs are
28 408 being discussed today as 20 years ago.
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30 410 For this reason, this sub-project will investigate the mechanisms that facilitate or impede
31 411 evidence-based policy-making and implementation from the political level to the regional
32 412 level in elderly care. Questions that will be studied are: What influences policy-making and
33 413 implementation at different levels? What are the strategies for policy implementation? How is
34 414 policy implementation monitored and evaluated at different levels? Three levels of policy-
35 415 making and implementation will be studied. Level 1: politicians and Ministry of Health and
36 416 Social Affairs. Level 2: state agencies and authorities at national level, i.e. NBHW
37 417 (Socialstyrelsen) and the Swedish Association of Local Authorities and Regions. Level 3:
38 418 politicians, executive boards and managers at county council and regional level. Interviews
39 419 will be audio-recorded and transcribed verbatim.
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41 421 *Cost-effectiveness.* A cost-effectiveness analysis will also be performed. The primary
42 422 outcome in the analysis is the incremental cost-effectiveness ratio (ICER): cost/quality
43 423 adjusted life year (QALY). The QALY-weights for the analysis will be derived from the EQ-
44 424 5D-3L, and the QALYs will be calculated by multiplying the QALY-weight with time. The
45 425 analysis will have a societal perspective meaning that all relevant costs will be included in the
46 426 analysis. Health care utilization and costs will be retrieved from administrative databases.
47 427 Information on social care and informal care will be retrieved from the questionnaire. The
48 428 cost-effectiveness analysis will be performed with a short-term perspective (within trial), and
49 429 also with a life-time perspective applying health economic decision modelling.
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53 433 **Statistical analysis for sub-studies**

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3 434 The outcomes of the sub-studies are: number of outpatient visits, cost of social and informal
4 435 care, number of drugs, number of prescribed drugs not recommended for the elderly, health-
5 436 related quality of life (HRQoL), cost-effectiveness, sense of security and functional ability.
6 437 The measures will be analysed for years 1 and 2 respectively using the intention to treat
7 438 (ITT) and last observation carried forward (LOCF) method. Differences between groups will
8 439 be analysed using a t-test. We intend to estimate the cost-effectiveness in terms of
9 440 cost/QALY (quality-adjusted life years) from a lifetime perspective using simulation models.
10 441 The QALY weights will be obtained from the EQ-5D-3L.

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15 443 **Time plan**

17 444 An overview is presented in Fig. 1. The project started with the development of the case-
18 445 finding algorithm (manuscript in progress) in 2017. Based on this model, the case-finding
19 446 process was undertaken at the beginning of March 2017. Selected patients were presented
20 447 to each healthcare centre for the start of the intervention programme in April 2017. A run-in
21 448 period of April–December 2017 was used, during which healthcare centres were informed
22 449 about and introduced to the new work model, and patients were subsequently enrolled onto
23 450 the programme. All selected high-risk patients will have received an initial healthcare and/or
24 451 social care plan. More than 90% of the selected patients were included by the end of
25 452 December 2017. The intervention/follow-up period is planned to last for two years, until the
26 453 end of 2019 (Fig 1).

27 454 An initial questionnaire was sent to all selected patients in the intervention and control
28 455 healthcare centres during May–June 2017. The questionnaire will also be distributed to
29 456 enrolled participants in years 2 and 3. Interviews with professionals in participating primary
30 457 care health centres and communities were performed during June–September 2017.
31 458 Interviews with elderly participants in order to capture the patient's perspective on the study
32 459 were performed during December 2017–July 2018. Interviews with elderly participants in
33 460 order to capture the patient's perspective on rehabilitation will take place during November
34 461 2018–February 2019. Interviews with high-level decision-makers and politicians were
35 462 conducted during January–September 2018.

36 463 A first preliminary outcome analysis after 13 months of intervention will be performed in
37 464 2019. The intervention and collection of healthcare data ends on 31 December 2019. The
38 465 analysis of primary and secondary outcome measures starts in 2020. The scientific writing-
39 466 up and participation in academic conferences has already started for some of the sub-
40 467 projects. The writing period for the intervention study begins in spring 2020. Dialogue with
41 468 owners/stakeholders at a political level takes place every six months during the course of the
42 469 project.

43 470 Possible evidence for changes in elderly care across the whole County of Östergötland will
44 471 be available in autumn 2020, when the implementation process of the new care model can
45 472 be broadened. Members of the research group are participating in workshops at a national
46 473 level concerning healthcare development.

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3 476 **Ethics and dissemination**
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5 477 This study was subject to ethical evaluation and approved by the regional ethical review
6 478 board in Linköping (Dnr 2016/347-31). They judged all aspects of the study including design
7 479 and safety. By adding an academic study to an ongoing change in the healthcare process for
8 480 the elderly, we do not per se include or exclude treatment possibilities for individuals or
9 481 groups of individuals. The study itself is “inert” within the healthcare system. Therefore, we
10 482 do not see that the use of aggregated patient data from the healthcare system can be of any
11 483 harm to the participants. On the contrary, we find strong ethical motives for the study, which
12 484 is an academic attempt to detect the real-world effectiveness of a politically determined
13 485 intervention into a large patient group. The patients who responded to the questionnaire did
14 486 so using an informed consent.
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18 487 The data will be presented in scientific journals and communicated at scientific meetings
19 488 during the period 2018–2022. The outcome data of the study will be presented to the
20 489 healthcare provider (County Council of Östergötland) for a discussion on the evidence
21 490 relating to future care models for elderly persons. The data will also be used by healthcare
22 491 managers and decision-makers for the development of future care models.
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493 **DISCUSSION**

494 Clinical trials on complex healthcare processes are rare and difficult to design with adequate
495 scientific quality. On the other hand, delimited clinical trials may also only be valid within an
496 academic setting and the outcome difficult to reproduce in clinical reality. In order to
497 counteract the scientific challenges facing trials in complex clinical settings and processes,
498 the use of a pragmatic clinical trial design is one, or perhaps the only, alternative⁹. In terms
499 of the primary context of elderly care, this study is intended to find answers to basic scientific
500 questions about the future healthcare of the elderly.

501 One challenge for the study was to find older patients in need of healthcare, hopefully before
502 escalating needs would develop. Managing thousands of patients during this screening for
503 possible illness may be impossible in healthcare using face-to-face methods. Statistical
504 models for case findings have recently proven valid and are recommended in the clinical
505 healthcare of old persons⁸ so this *modus operandi* was used in this study.

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

510

511 **Authors contributions**

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

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

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

519 Ylva Böttiger: design, analysis, scientific writing

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

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

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

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

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

1
2
3 529 Susanne Kelfve, Andreas Motel-Klingebiel: design of postal questionnaire, analysis of well-
4 530 being, network support, satisfaction and social inequality based on questionnaire and registry
5 531 data, scientific writing

6
7 532 Ingrid Hellström, Agneta Kullberg: design and analysis of professional perspective, scientific
8 533 writing

9
10 534 Johan Lyth analysis, scientific writing

11
12 535 Malin Wass, project-coordinator, scientific writing

13
14 536 Agneta Andersson: co-investigator, analysis, scientific writing

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21 539 **Funding statement**

22
23 540 This work was supported by the County Council of Östergötland and Linköping University
24 541 from the strategic research fund for 'Health Care and Welfare' [Grant number 2016186-14].
25 542 Contact person is Dean Johan Söderholm, Deans office, Medical Faculty, Linköping
26 543 University. This funding source had no role in the design of this study and will not have any
27 544 role during its execution, analyses, interpretation of the data, or decision to submit results.

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29 545 Competing interests: None.

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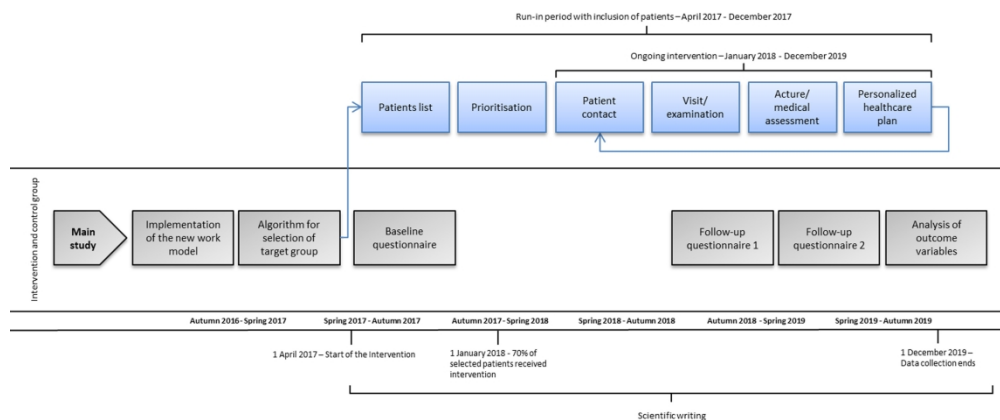
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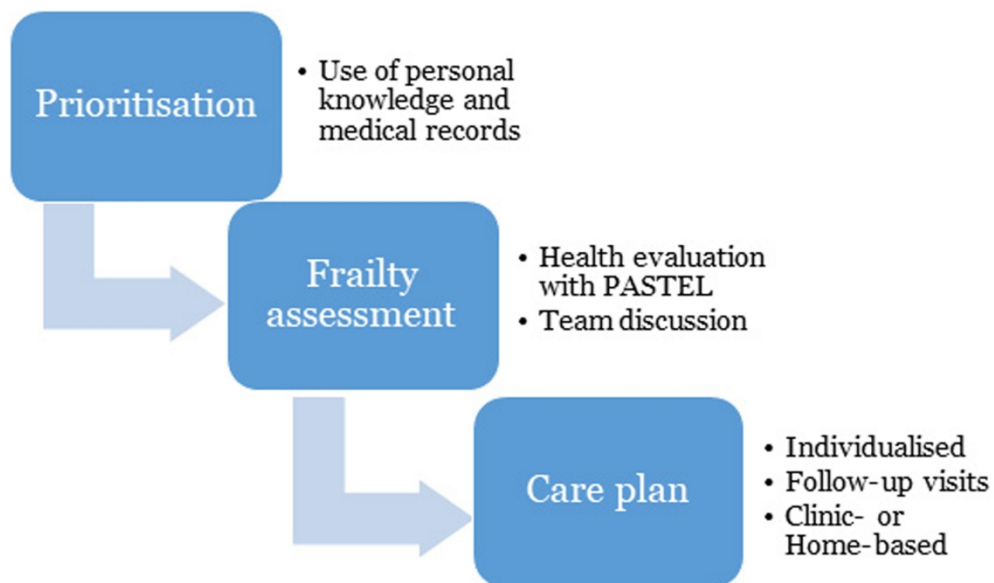
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Reporting checklist for protocol of a clinical trial.

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

1	Trial registration:	#2b	All items from the World Health Organization Trial	n/a
2				
3	data set		Registration Data Set	
4				
5				
6	Protocol version	#3	Date and version identifier	n/a
7				
8				
9	Funding	#4	Sources and types of financial, material, and other support	15
10				
11				
12	Roles and	#5a	Names, affiliations, and roles of protocol contributors	1, 14
13				
14	responsibilities:			
15				
16	contributorship			
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20	Roles and	#5b	Name and contact information for the trial sponsor	15
21				
22	responsibilities:			
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24	sponsor contact			
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26	information			
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29				
30	Roles and	#5c	Role of study sponsor and funders, if any, in study design;	15
31				
32	responsibilities:		collection, management, analysis, and interpretation of	
33				
34	sponsor and funder		data; writing of the report; and the decision to submit the	
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42	Roles and	#5d	Composition, roles, and responsibilities of the coordinating	14
43				
44	responsibilities:		centre, steering committee, endpoint adjudication	
45				
46	committees		committee, data management team, and other individuals or	
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54	Background and	#6a	Description of research question and justification for	4-5
55				
56	rationale		undertaking the trial, including summary of relevant studies	
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		(published and unpublished) examining benefits and harms	
		for each intervention	
6	Background and	#6b Explanation for choice of comparators	5-6
7			
8	rationale: choice of		
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10	comparators		
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13	Objectives	#7 Specific objectives or hypotheses	5
14			
15			
16	Trial design	#8 Description of trial design including type of trial (eg, parallel	5
17		group, crossover, factorial, single group), allocation ratio,	
18		and framework (eg, superiority, equivalence, non-inferiority,	
19		exploratory)	
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26	Study setting	#9 Description of study settings (eg, community clinic,	5
27		academic hospital) and list of countries where data will be	
28		collected. Reference to where list of study sites can be	
29		obtained	
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36	Eligibility criteria	#10 Inclusion and exclusion criteria for participants. If applicable,	6
37		eligibility criteria for study centres and individuals who will	
38		perform the interventions (eg, surgeons, psychotherapists)	
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44	Interventions:	#11a Interventions for each group with sufficient detail to allow	7
45		replication, including how and when they will be	
46	description	administered	
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51	Interventions:	#11b Criteria for discontinuing or modifying allocated	n/a
52		interventions for a given trial participant (eg, drug dose	
53	modifications	change in response to harms, participant request, or	
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		improving / worsening disease)	
Interventions:	#11c	Strategies to improve adherence to intervention protocols,	n/a
adherence		and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	
Interventions:	#11d	Relevant concomitant care and interventions that are	n/a
concomitant care		permitted or prohibited during the trial	
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

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	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
18 19 20 21 22 23 24 25 26 27	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
28 29 30 31 32 33 34	Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
35 36 37 38 39 40 41 42	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
43 44 45 46 47 48 49	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
50 51 52 53 54 55 56 57 58 59 60	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

1		questionnaires, laboratory tests) along with their reliability	
2		and validity, if known. Reference to where data collection	
3		forms can be found, if not in the protocol	
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8	Data collection plan:	#18b Plans to promote participant retention and complete follow-	n/a
9	retention	up, including list of any outcome data to be collected for	
10		participants who discontinue or deviate from intervention	
11		protocols	
12			
13	Data management	#19 Plans for data entry, coding, security, and storage, including	8
14		any related processes to promote data quality (eg, double	
15		data entry; range checks for data values). Reference to	
16		where details of data management procedures can be	
17		found, if not in the protocol	
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19			
20	Statistics: outcomes	#20a Statistical methods for analysing primary and secondary	8
21		outcomes. Reference to where other details of the statistical	
22		analysis plan can be found, if not in the protocol	
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30	Statistics: additional	#20b Methods for any additional analyses (eg, subgroup and	n/a
31	analyses	adjusted analyses)	
32			
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34	Statistics: analysis	#20c Definition of analysis population relating to protocol non-	n/a
35	population and	adherence (eg, as randomised analysis), and any statistical	
36	missing data	methods to handle missing data (eg, multiple imputation)	
37			
38	Data monitoring:	#21a Composition of data monitoring committee (DMC); summary	8
39	formal committee	of its role and reporting structure; statement of whether it is	
40		independent from the sponsor and competing interests; and	
41		reference to where further details about its charter can be	
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1		found, if not in the protocol. Alternatively, an explanation of	
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3		why a DMC is not needed	
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6	Data monitoring:	#21b Description of any interim analyses and stopping guidelines,	12
7			
8	interim analysis	including who will have access to these interim results and	
9		make the final decision to terminate the trial	
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13	Harms	#22 Plans for collecting, assessing, reporting, and managing	n/a
14			
15		solicited and spontaneously reported adverse events and	
16			
17		other unintended effects of trial interventions or trial conduct	
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21	Auditing	#23 Frequency and procedures for auditing trial conduct, if any,	8
22			
23		and whether the process will be independent from	
24			
25		investigators and the sponsor	
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29	Research ethics	#24 Plans for seeking research ethics committee / institutional	12
30			
31	approval	review board (REC / IRB) approval	
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34	Protocol	#25 Plans for communicating important protocol modifications	n/a
35			
36	amendments	(eg, changes to eligibility criteria, outcomes, analyses) to	
37			
38		relevant parties (eg, investigators, REC / IRBs, trial	
39			
40		participants, trial registries, journals, regulators)	
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44	Consent or assent	#26a Who will obtain informed consent or assent from potential	12
45			
46		trial participants or authorised surrogates, and how (see	
47			
48		Item 32)	
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51	Consent or assent:	#26b Additional consent provisions for collection and use of	12
52			
53	ancillary studies	participant data and biological specimens in ancillary	
54			
55		studies, if applicable	
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1	Confidentiality	#27	How personal information about potential and enrolled	n/a
2			participants will be collected, shared, and maintained in	
3			order to protect confidentiality before, during, and after the	
4			trial	
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11	Declaration of	#28	Financial and other competing interests for principal	15
12	interests		investigators for the overall trial and each study site	
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16	Data access	#29	Statement of who will have access to the final trial dataset,	8
17			and disclosure of contractual agreements that limit such	
18			access for investigators	
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24	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial care, and for	n/a
25	trial care		compensation to those who suffer harm from trial	
26			participation	
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31	Dissemination policy:	#31a	Plans for investigators and sponsor to communicate trial	12-13
32	trial results		results to participants, healthcare professionals, the public,	
33			and other relevant groups (eg, via publication, reporting in	
34			results databases, or other data sharing arrangements),	
35			including any publication restrictions	
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44	Dissemination policy:	#31b	Authorship eligibility guidelines and any intended use of	n/a
45	authorship		professional writers	
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49	Dissemination policy:	#31c	Plans, if any, for granting public access to the full protocol,	n/a
50	reproducible		participant-level dataset, and statistical code	
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54	research			
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57	Informed consent	#32	Model consent form and other related documentation given	n/a
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1 materials to participants and authorised surrogates
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4 Biological specimens [#33](#) Plans for collection, laboratory evaluation, and storage of n/a
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6 biological specimens for genetic or molecular analysis in the
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8 current trial and for future use in ancillary studies, if
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10 applicable
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