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Improving continuity of patient care across sectors: Study protocol of the process evaluation of a quasi-experimental multi-centre study regarding an admission and discharge model in Germany (VESPEERA)

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Abstract

Introduction: Hospital stays are critical events as they often disrupt continuity of care. The aim of the VESPEERA programme is the development, implementation and evaluation of a structured admission and discharge program in general practices and hospitals. This process evaluation aims to describe and explore the implementation of the VESPEERA programme. The evaluation concerns the intervention fidelity, reach in targeted populations, perceived effects, working mechanisms, feasibility, determinants for implementation, including contextual factors, and associations with the outcomes evaluation.

Methods and analysis: The process evaluation is linked to the VESPEERA outcomes evaluation, which has a quasi-experimental multi-centre design with four study arms and is conducted in hospitals and general practices Germany. The VESPEERA programme comprises several components: an assessment before admission, an admission letter, a telephonic discharge conversation between hospital and general practice before discharge, discharge information for patients, structured planning of

follow-up care after discharge in the general practice and a telephone monitoring for patients with a risk of rehospitalisation.

The process evaluation has a mixed-methods design, incorporating interviews (patients and both care providers who do and do not participate in the VESPEERA programme, total n=75), questionnaires (patients and care providers who participate in the VESPEERA programme, total n=475), implementation plans of hospitals, data documented in general practices, claims-based data and hospital process data.

Data analysis is descriptive and explorative. Qualitative data will be transcribed and analysed using framework analysis based on the Consolidated Framework for Implementation Research. Associations between the outcomes of the program and measures in the process evaluation will be explored in regression models.

Ethics and dissemination: Ethics approval has been obtained by the ethics committee of the Medical Faculty Heidelberg prior to the start of the study (S-352/2018). Results will be disseminated through a final report to the funding agency, articles in peer-reviewed journals, and conferences.

Trial Registration: DRKS00015183 on DRKS / Universal Trial Number (UTN): U1111-1218-0992

Key Words: process evaluation, implementation science, intervention fidelity, CFIR, barriers, facilitators, admission management, discharge management, continuity of care

Strengths and limitations of this study:

- The process evaluation will help to interpret the findings of the outcomes evaluation of a hospital admission and discharge program.

- The perspectives of a broad range of stakeholders are considered, including care providers, patients and other stakeholders.
- This mixed-methods process evaluation addresses a broad range of aspects, which are associated with implementation and outcomes of the VESPEERA programme.
- Linkage of interview and questionnaire data with data sources of the outcome evaluation is not possible at individual level.

Introduction

Insufficient communication between hospitals and physicians in the outpatient sector may jeopardize the recovery process, lead to avoidable rehospitalisations[1, 2] and induce adverse events.[3] These outcomes also affect health related patient satisfaction and healthcare costs.[4] The legislator in Germany responded to this care problem by obligating hospitals to offer discharge management measures to all patients ("*Rahmenvertrag über ein Entlassmanagement beim Übergang in die Versorgung nach Krankenhausbehandlung nach § 39 Abs. 1 S.9 SGB V*"). The VESPEERA programme aims to support the implementation of this regulation. It develops, implements and evaluates a structured hospital admission and discharge program between general practices and hospitals to avoid interruptions in the admission and discharge process. The interventions and the outcomes evaluation are described elsewhere.[5] Subsequently, we first summarize the patient-directed interventions in the VESPEERA programme, the implementation strategies, and the outcomes evaluation. Then we elaborate on the process evaluation in the remaining of this paper.

VESPEERA programme

Legislation in Germany is focused on hospital discharge and does not address admission management. The VESPEERA programme supports the implementation of structured discharge management and adds admission management procedures, further outpatient care after discharge and some other interventions. The VESPEERA programme consists of several intervention components before, during and after a hospital stay in general practices and hospitals concerning admission and discharge. Before hospital admission, the general practitioner (GP) will conduct an assessment with the patient in order to generate an admission letter for the hospital, providing

medical and social information on the patient. Intervention components in the hospital include a telephonic discharge conversation for defined high-risk patients between the hospital and the general practice as well as a patient discharge information. After discharge, another assessment will be conducted in the general practice to facilitate planning of follow-up treatment and to identify patients with an increased risk for rehospitalisation based on the HOSPITAL Score (a score to determine risk of 30-day rehospitalisation[6]). These patients will be enrolled in a three-month telephone monitoring. Table 1 gives an overview on the intervention components and study arms.

Table 1: **VESPEERA intervention components for all study arms**

Interventions		*Study arm 1:* **planned** admission into a **participating** hospital	*Study arm 2:* **planned** admission into a **non-participating** hospital	*Study arm 3:* unplanned admission into a **participating** hospital	*Study arm 4:* unplanned admission into a **non-participating** hospital	*Study arm 5:* **control group**, not participating in VESPEERA
General practice	**Interventions in the general practice before admission:** (A) assessment for admission (B) admission letter and patient brochure	X	X			
Hospital	**Interventions in the hospital:** (C) telephonic discharge conversation (D) determination of HOSPITAL Score and patient discharge information	X				

General practice	**Interventions in the general practice after discharge:** (E) assessment for planning of follow-up treatment (F) telephone monitoring, depending on the risk for rehospitalisation	X	X	X	X	

Implementation strategies

Several strategies were applied to support the implementation of structured hospital admission and discharge management. The strategies are named according to the ERIC compilation by Powell et al.[7] and are reported using the recommendations by Proctor et al.[8] are as following:

First, the record system is changed by enhancing the PraCMan-Cockpit, software that is routinely used in Baden-Wuerttemberg within the PracMan case management programme.[9] The resulting CareCockpit includes the additional VESPEERA module, which assists general practices with organising patient information, conducting the assessments and care planning, generating the admission letter and other documents, and administrating telephone calls within the telephone monitoring. The CareCockpit is software that works independently from the practice information system and is used by the Care Assistant in General Practice (*Versorgungsassistentin in der Hausarztpraxis*, VERAH) and the GP. Furthermore, the CareCockpit works as an electronical case report form for data analysis within the outcomes evaluation.

Second, train-the-trainer strategies are used in order to instruct GPs and VERAHs in software utilisation and study processes. Trainers are teams of two (GP and VERAH)

who are experienced in training the PraCMan-Cockpit and who were instructed in handling the CareCockpit by the study central office. GPs and VERAHs who are interested in participating in the VESPEERA programme sign up for a one-time 2.5 hour training. GPs and VERAHs learn the handling of the software in a role-play format.

Third, in order to support GPs and VERAHs with implementation of all intervention components, educational materials are developed. Investigator site files are provided after participation in the training by the study central office. Investigator site files contain instructions and background information on the following: obtaining informed consent by patients, installation of the CareCockpit-software, an overview on frequently asked questions concerning the handling of the software, conduction of the intervention components, and conduction of the patient survey. Furthermore, general practices are continuously provided with instructional video tutorials on handling the software by the study central office. Along with the trainings, educational materials are expected to increase intervention fidelity.

Fourth, formal commitments are obtained by participating hospitals. Adaptability is promoted in order to facilitate the integration of study components into clinical processes. Therefore, each hospital will provide information on how they will ensure the identification of study patients, the use of the admission letter, the execution of the telephonic discharge conversation, the dissemination of the patient discharge information and the transmission data to calculate the HOSPITAL Score. These formal commitments are obtained within four weeks after signing the participation agreement. Thereby, intervention fidelity as well as acceptance and attractiveness of the VESPEERA programme are expected to increase.

Fifth, both participating general practices and hospitals are provided ongoing consultation with the study central office and other consortium partners to support implementation. General practices and hospitals are repeatedly called by employees of the study central office and asked for the status of implementation and any problems that arise within the implementation process. General practices are offered refreshers on topics of the training, such as the procedure for obtaining informed consent by patients, handling of the software, and instruction of the intervention components. Thereby, intervention fidelity is expected to increase.

Sixth, consensus discussions with representatives of all stakeholders, thus physicians, GPs, patients, sickness funds and researchers, have been conducted. All intervention components were thoroughly discussed in the developmental period concerning the relevance of items, wording of items and design of documents, such as the patient discharge information. By involving users in the development of the intervention, acceptance and attractiveness of the programme are expected to increase.

Sixth, hospitals and general practices are provided feedback in the form of three benchmarking reports in September 2018, June 2019 and December 2019. The feedback reports are based on structured, quantified data-sources (claims data, patient data from the CareCockpit, and patient survey data), and are aggregated on a hospital or general practice level. These will be discussed in three moderated feedback meetings during the intervention period with care providers, where options for potential improvement will be developed. Feedback meetings are planned for September 2018, September 2019 and March 2020. Feedback meetings are moderated by the study central office with support by the other project partners. Care providers will have an active role in the meetings in a workshop format and

report their perspective and experiences. Audit and feedback is a strategy to improve professional practice, which has mixed and overall moderate impacts on professional performance.[10, 11] In this context, feedback provided is expected to enhance intervention fidelity.

Additionally, hospitals and general practices will receive fee-for-service for conducting patient-related care services as well as lump sum reimbursement for study organisation and participation in workshops and feedback meetings. General practices can invoice the care services as part of their usual invoice process, which is carried out at the end of each quarter year. Hospitals invoice the sickness fund 'Allgemeine Ortskrankenkasse' (AOK) Baden-Wurttemberg at the end of each quarter year. Lump sums are paid after participating in the feedback meetings. Fee-for-service gives an incentive to provide the different interventions components and thereby is expected to increase intervention fidelity.[12]

VESPEERA outcomes evaluation

The VESPEERA programme is "expected to reduce the number of avoidable rehospitalisations and emergency care contacts, to improve patient safety and patient involvement, to reduce overuse, underuse and misuse of health care, to improve the continuity of care and to improve interprofessional and cross-sectoral communication between patients, hospitals, general practices and the sickness fund 'Allgemeine Ortskrankenkasse (AOK) Baden-Wurttemberg'".[5]

The intervention is evaluated in a quantitative outcomes evaluation with a quasi-experimental design. The primary outcome is the number of rehospitalisations due to the same indication (three-digit ICD-10-GM code) within a time frame of three months (90 days) to the outpatient sector. The following indicators have been defined as secondary outcomes: rehospitalisation due to the same indication within

30 days; hospitalisations due to ambulatory care-sensitive conditions; delayed prescription of medication and medical products/ devices and referral to other health practitioner/s after discharge; utilisation of emergency or rescue services within three months; average care cost per year and patient participating in the VESPEERA programme.

Using AOK claims data, patient data from the CareCockpit, and data collected in a questionnaire-based patient survey, a difference-in-difference model is applied for the primary analysis. The change of the primary outcome (before vs. after the intervention) of each intervention group will be pairwise compared to the control group. A detailed description of the outcomes evaluation can be found in the corresponding study protocol.[5]

VESPEERA process evaluation

The VESPEERA programme is a complex intervention which intends to impact on a range of outcomes. The impact on outcomes depends not only on the effectiveness of planned interventions, but also on the degree of implementation of these interventions, the reach in relevant healthcare providers and patient populations, and the moderating impacts of the organisational and societal context in which the interventions are applied. As described by the Medical Research Council, complex interventions are characterized by multiple, mutually interacting intervention components; multiple targeted groups of individuals and organisations; multiple outcomes and mediating factors; high impact of the organisational and societal context on outcomes; and a "degree of flexibility or tailoring of the interventions".[13] These features largely apply to VESPEERA. A large number of interventions are applied; various organisations in different care sectors are involved, each with structural conditions specific to the sector (e.g. remuneration systems). The

effects of the interventions cover a range of domains.[5] Furthermore, hospitals are involved in the implementation within their organisation to tailor it to their local processes and structures.

We planned a process evaluation to provide insight into how well the intervention was implemented, why it did or did not work (i.e. did or did not have an effect on outcomes),[13-15] what context factors had an influence on the implementation and outcomes, and thereby allow to improve "transferability of potentially effective programs to other settings".[16] Investigation of implementation outcomes such as reach (whether the targeted population participated as intended/ the degree to which the targeted population participated) or intervention fidelity (whether the intervention was delivered as planned) can help to better understand the results of the outcomes evaluation.[17]

Objectives

The multifaceted VESPEERA programme contains a selection of recommended practices in patient care as well as a set of strategies to implement these. This process evaluation aims to examine the intervention fidelity, reach in targeted populations, perceived effects, working mechanisms, feasibility, and determinants for implementation, including contextual factors, as well as associations with the outcomes evaluation, so that programme outcomes can be better interpreted. The specific research questions are listed in Table 2.

Figure 1 shows the hypothesized working mechanisms of the VESPEERA programme and the primary areas of interest of the outcomes and the process evaluation, respectively. The planned procedures for the process evaluation will be described in detail below.

< Insert Figure 1 here >

Table 2: **Research question, outcomes and data sources**

Research Question	**Outcomes / Indicators**	**Data sources**
REACH AND INTERVENTION FIDELITY Was the intervention implemented as planned ("intervention fidelity") in targeted populations (''reach'')?	Proportion and description of patients who participated in VESPEERA compared to all targeted persons who meet the inclusion criteria	Data set consisting of CareCockpit-data, claims-based data and hospital process data
To what extent have the planned components been offered to care providers and patients? To what extent have these been utilised by care providers and patients? What was the adherence concerning the recommended practices of hospital admission and discharge. Has the targeted patient population been reached?	Proportion of persons enrolled in the general practitioner centered-care programme (HZV) who -have been admitted to a participating hospital by a participating practice, -for whom a new patient account has been created in the Care Cockpit and -for whom a complete admission letter including a medication plan was generated and was given to the patient to take along, compared to all participating HZV-insured persons in participating practices with planned hospital admissions	Data set consisting of CareCockpit-data, claims-based data and hospital process data

	Proportion of participating patients who -have been discharged from a participating hospital to their GP -for whom at the time of discharge the HOSPITAL Score has been determined compared to all participating patients who have been discharged from a participating hospital	Data set consisting of CareCockpit-data, claims-based data and hospital process data
	Proportion of participating patients for whom the assessment for planning of follow-up treatment has been conducted compared to all participating patients	Data set consisting of CareCockpit-data, claims-based data and hospital process data
	Proportion of participating patients who have been enrolled in the follow-up telephone monitoring due to an intermediate or high risk for rehospitalisation and for whom at least two phone calls have been conducted within the given timeframe of three months, per all participating patients	Data set consisting of CareCockpit-data, claims-based data and hospital process data

	The degree to which the intervention components in hospitals have been implemented and offered as compared to the intention	Hospital process data survey; Hospital Implementation plans; Questionnaires: staff from participating hospitals
PERCEIVED EFFECTS Which results, from the view point of care providers and patients, were: Achieved as intended? Not achieved although intended? Achieved although not intended (positive or negative)?	Open-ended question As support: 2a) and 2b): name outcomes of the outcome evaluation 2c): name domains of possible results	Qualitative survey: all participating care providers, patients Questionnaires: all participating care providers, patients
WORKING MECHANISMS Which components and aspects of the intervention programme contributed to achieving the results from the view point of care providers?	open-ended question as support: name intervention components (4-8 max., only those concerning the person being interviewed)	qualitative survey: all participating care providers Questionnaires: all participating care providers

FEASIBILITY What were acceptability and attractiveness of the programme from the point of view of care providers?	Open-ended questions	qualitative survey: all participating care providers Questionnaires: all participating care providers
CONTEXTUAL FACTORS a) What are determinants for implementing the program? b) Which contextual factors on system, hospital and practice level influenced the adoption of intervention components and outcomes of the program? c) Which practices concerning admission and discharge management have been implemented in non-participating hospitals during the intervention period (for example	Open-ended question in qualitative survey, structured questions in questionnaires As support: 5a): name domains, especially concerning behavioral factors (such as knowledge, attitude, self-efficacy, routine, desire/ will, skills/ capability; using the CFIR[18] 5b): name domains of contextual factors using frameworks (to be chosen when designing the questionnaires) 5c) :Open-ended question As support: Name components of admission and discharge management	qualitative survey: all participating care providers Questionnaires: all participating care providers qualitative survey: non-participating hospitals, management staff from non-participating hospitals

in consequence of the "Rahmenvertrag über ein Entlassmanagement nach Krankenhausbehandlung")?		
DOSE-RESPONSE ASSOCIATIONS Which associations exist between the outcomes (as disclosed by the outcomes evaluation) and findings of the process evaluation?		Data set consisting of CareCockpit-data, claims-based data and hospital process data

Methods of process evaluation

Study design

The process evaluation has an observational mixed-methods design, incorporating qualitative data from interviews and implementation plans with a description of the implementation in participating hospitals as well as quantitative data from questionnaires that are filled in for each patient in hospital, surveys and data collected through the CareCockpit software in general practices. This process evaluation is part of the VESPEERA study that lasts from October 2017 until March 2021. The planned time frame for the process evaluation started in July 2018; evaluations will be complete by the end of October 2020.

Study setting

The VESPEERA programme is implemented in 25 hospital departments and 115 general practices in a defined region in southern Germany. The process evaluation is carried out by the Department of General Practice and Health Services Research at the Heidelberg University Hospital.

Eligibility criteria

Patients who take part and gave their informed consent to the VESPEERA study participation and outcomes evaluation can participate in the process evaluation. GPs and VERAHs who participate in the VESPEERA study can participate in the process evaluation. Hospital staff from participating hospitals has to work in one of the departments selected for VESPEERA implementation OR have to be involved in the implementation process of the VESPEERA intervention components on a higher hierarchical level. Physicians, nursing staff and hospital management from non-participating hospitals as well as GPs and VERAHs from non-participating general

practices are included if they can provide insight into admission and discharge processes.

Above that, all participants have to be 18 years and older, have written and spoken German language skills and have to be able to give their informed consent into study participation in the process evaluation. Persons who are unable to give their consent are excluded from study participation.

Outcomes of the process evaluation

Table 2 gives an overview on the research questions phrased, outcomes and data sources used.

Data sources

The process evaluation uses data from a mix of sources.

Interviews

Qualitative interviews will be conducted with nursing staff, physicians and management staff from participating and non-participating hospitals, GPs and VERAHs from participating and non-participating general practices as well as participating patients after hospital stay. The interview guide addresses the intervention fidelity, intended and unplanned effects, and factors influencing implementation (barriers, facilitators, contextual factors) as well as acceptance and attractiveness of the intervention.

Questionnaires

Additionally, quantitative data result from structured surveys with participating general practitioners, VERAHs, physicians, nursing staff, management staff, and patients after a hospital stay. The questionnaire will be designed based on the results

of the qualitative interviews as well as other studies on process evaluations and will be piloted before use. This pseudonymised questionnaire will not contain any data that allows identification of participants' identity. Concepts addressed in the questionnaires will be, amongst others, reach (see Objective 1), unintended effects (see Objective 2), added value (see Objective 3), and barriers and facilitators for implementation (see Objective 4).

Hospital Process Data Survey

As part of the VESPEERA programme, hospitals are asked to collect the HOSPITAL Score for patients to determine their risk of rehospitalisation. This questionnaire is expanded by questions used for the process evaluation. These include sociodemographic questions and questions on processes that are part of the study interventions that are implemented within hospitals (identification of VESPEERA patients, utilisation of the VESPEERA admission letter, telephonic discharge conversation with the general practice).

Hospital Implementation Plans

In order to facilitate the integration of study components into clinical processes, different approaches are suitable for different hospitals. Therefore, each hospital will provide information on how they will ensure the identification of study patients, the use of the admission letter, the execution of the telephonic discharge conversation, the dissemination of the patient discharge information and determination of the HOSPITAL Score.

Patient data

For the outcomes evaluation, patient data from the CareCockpit is linked with claims-based data from AOK Baden-Wurttemberg and data from the hospital process data survey. This data set will be provided for the process evaluation. These data provide information on the study arm that the patient belongs to as well as patient characteristics, the pseudonym generated in the CareCockpit for data linkage, diagnoses, the medical question for admission, information on previous antibiotic prescriptions, living situation, long-term care related items (such as scales for activities of daily living and instrumental activities of daily living), medical information (such as pain, wounds, alarming symptoms for medical emergencies, PHQ-2 instrument for mental disorders screening), compliance to medicinal therapy, the items of the HOSPITAL Score as well as process data (provision of information to patients, information on whether any follow-up care has been initiated and successfully executed).

Sample size

The sample for the qualitative study is planned to reach saturation of data; the planned numbers are expected to be sufficient. The study sample for interviews on a hospital level consists of management staff, physicians and nursing staff and will be stratified by region and hospital size. On a practice level, GPs, VERAHs and patients, will be recruited from participating practices, stratified by practice size, region and gender. Additionally, staff from non-participating hospitals and general practices will be interviewed. This is important as interventions on a systems level can influence the effects of the evaluated care model. Table 3 gives an overview on the planned sample size for interviews.

Table 3**: Planned sample size for interviews**

		Planned number of participants (n)
Hospitals	Nursing Staff	10
	Management Staff	10
	Physicians	10
Non-participating hospitals	Nursing Staff	5
	Management Staff	5
	Physicians	5
General Practices	General Practitioners	10
	VERAHs	10
Non-participating general practices	General Practitioners	10
	VERAHs	10
Patients	Patient	10
Total number		**75**

The sample for the quantitative survey study comprises of all participating practices and hospitals (full study population) and a sample of n=200 patients for explorative data analysis (see Table 4). The sample size of patients was restricted out of feasibility reasons.

Table 4: **Planned sample size for questionnaires**

		Planned number of participants (n)
Hospitals	Nursing Staff	25
	Management Staff	25
	Physicians	25
General Practices	General Practitioners	100
	VERAHs	100
Patients	Patient	200
Total number		**475**

Recruitment

Within the process evaluation, participants will be recruited for interviews and written surveys.

Recruitment for qualitative interviews

Personnel from non-participating hospitals will be recruited by contacting the hospital management. A purposeful sample of hospitals will be selected, amongst others based on region, top-level versus basic care and previous interest to participate in VESPEERA. GPs and VERAHs from non-participating general practices will be recruited based on a list of all GPs who participate in GP-based care outside of the intervention region. A purposeful sample will be selected based on region, practice size and gender. Eligible patients will be contacted by the general practices, as they are not known to the study central office.

By using a response coupon eligible interview participants from all stakeholder groups can declare their interest in participating in an interview. They will then be contacted by the study central office, be provided with an information letter and the written consent form.

Recruitment for the survey

Personnel from participating hospitals will be recruited by the contact person at the hospitals. The contact persons will be provided with information letters, written informed consent forms and the paper-based questionnaires and will be asked to hand it out to eligible personnel as defined by the study central office. All participating general practices will be sent the information letters, informed consent forms and paper-based questionnaires for GPs and VERAHs and will be asked to fill it in. Patients will be recruited by the general practices, as they are not known to the

study central office. GPs will be provided with information letters, informed consent forms and paper-based questionnaires and will be asked to hand it out to eligible patients.

Data collection and management

Interviews

Interviews will be conducted as face-to-face or telephone interviews by researchers of the study central office. Interviews will last 30 minutes maximum and will be conducted using a semi-structured interview guide. In exceptional cases, for instance if problems within the recruitment process arise, written qualitative interviews consisting of open-end questions might be used. All interviews will be audio-recorded, transcribed verbatim and stored on a secured server of the study central office. Transcripts will contain pseudonymized data only.

Questionnaires

Paper-based questionnaires are mailed to physicians, VERAHs, nursing staff and management staff from participating hospitals, GPs and patients. The filled in questionnaires will be sent by mail using an enclosed post-paid envelope to the study central office, where they will be scanned and digitally stored on a secured server. Reminders for data collection of both interviews and questionnaires will be sent out to all potential participants one to two times via fax, mail or post.

Hospital Process Data Survey

Hospitals fill in the hospital process data survey on the conduction all intervention components for each case at the time of the patients' discharge, using the form they use to collect data for the HOSPITAL score used in the VESPEERA study.

The hospitals can either integrate the questionnaire into their hospital information system as an electronic questionnaire (transfer to the aQua-Institute via secure file transfer protocol (SFTP) servers) or fill in paper-based questionnaires that are sent to the aQua-Institute via mail using enclosed post-paid envelopes.

Hospital Implementation Plans

Participating hospitals will hand in a description of their individual implementation plan to the study central office.

Patient data

During the intervention period, patient data from the CareCockpit is continuously collected for the purpose of data analysis. Data from the CareCockpit is transferred along with claims-based data each quarter year.

Data analysis

Data analysis for the process evaluation is descriptive and explorative. Qualitative data will be transcribed according to established standards and will be analysed with regard to the research questions with framework analysis using the software MAXQDA.[19] The framework used for data analysis is the Consolidated Framework for Implementation Research (CFIR).[18] The CFIR was chosen as it is a comprehensive framework that takes into account many of the aspects that need to be considered when evaluating the implementation of a complex intervention in healthcare organisations.

Quantitative survey data and the indicators for the intervention fidelity will be analysed descriptively. Correlations between the outcomes of the process evaluation and the outcomes evaluation will further be analysed using multilevel regression models.

Patient and public involvement

Patients were actively involved in the conduction of all intervention components, as described in the 'Implementation Strategies' section. With the 'Gesundheitstreffpunkt Mannheim e.V.' as consortium partner, an organisation representing patient interests is involved in all stages of the study (funding application, design of the study, conduction of intervention components, interpretation of results, dissemination of results).

Discussion

This process evaluation aims to provide insight into the implementation process of the VESPEERA programme in the participating general practices and hospital departments as well as the determinants influencing the degree of implementation. The results will contribute to adjusting the VESPEERA programme after the completion of all evaluations for a possible implementation into routine care. By relying on the GP as a gatekeeper to further health care and by proposing communication structures, the VESPEERA programme is expected to improve continuity of care.

Continuity of care is a complex concept with no clear definition.[20] However, recurring components of continuity of care include the first contact with a primary care provider, i.e. gatekeeping, information continuity ("the capacity of that information to travel with the patient and throughout the health system, between providers and over time"[21]) and longitudinal care provider continuity.[2, 20] By improving continuity of care patient outcomes are supposedly improved. In a systematic review, Huntley et al. found that continuity of care, i.e. seeing the same GP, reduced utilisation of emergency departments and emergency hospital admissions.[22] Furthermore, in another systematic review by an Loenen et al. the authors showed that aspects of primary care such as a gatekeeping role and

provider continuity are associated with a lower risk of avoidable hospitalisations due to ambulant care sensitive conditions.[2]

Huntley et al.[22] und van Loenen et al.[2] included mostly observational studies in their reviews on the effects of organisational features of primary care on hospitalisations and emergency care use. With a quasi-experimental approach and a thorough process evaluation, the VESPEERA programme is expected to contribute to the literature on the effects of continuity of care and care coordination on several patient outcomes.

Within this process evaluation, perspectives of a broad range of stakeholders are considered. Furthermore, interviews allow for gaining in-depth understanding of experiences with the VESPEERA programme and communication processes, whereas questionnaires allow for a higher sample size. Thereby, this serves to understand the broad implementation of a complex intervention.

However, no linkage between interview and questionnaire data with data sources of the outcome evaluation is intended. The intervention fidelity and barriers and facilitators to implementing the intervention therefore cannot be linked with patient-individual outcomes.

Ethics, data protection and security, and dissemination

The study protocol has been submitted to and approved by the ethics committee of the Medical Faculty Heidelberg. A data protection concept is part of the VESPEERA contractual agreement between consortium partners and has been approved by a data security officer. The regulations of the European General Data Protection Regulation are met.

Dissemination of the results of this study is planned through the final report to the funding agency, articles in peer-reviewed journals as well as relevant national, and if relevant, international conferences.

Trial Status: The study protocol on hand is the protocol version 1.1 from June 18th 2018. Recruitment for interviews started on September 3rd 2018 and will approx. be completed by the end of May 2019.

List of Abbreviations

AOK	Allgemeine Ortskrankenkasse, large German sickness fund
CFIR	Consolidated Framework for Implementation Research
GP	general practitioner
HZV	general practitioner centered-care programme (Hausarztzentrierte Versorgung)
PraCMan	general practice-based case management programme (Hausarztpraxis-basiertes Case Management)
SFTP	Secure File Transfer Protocol
VERAH	Care Assistant in General Practice (Versorgungsassistentin in der Hausarztpraxis)

VESPEERA Improving continuity of patient care across sectors: A quasi-experimental multi-centre study regarding an admission and discharge model in Germany

Declarations

Ethics approval and consent to participate: The study protocol has been submitted to and approved by the ethics committee of the Medical Faculty Heidelberg prior to the start of the study (S-352/2018).

Patient consent for publication: Not applicable.

Data sharing: Access to data and materials can be requested from the data owners.

Competing interests: The authors declare that they have no competing interest. Joachim Szecsenyi holds stocks of the aQua-Institute.

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Authors contributions: JF, AK and MW drafted the original manuscript. All authors contributed to the design of the study, data collection and read and approved the final manuscript.

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Additional files: SPIRIT Checklist, World Health Organization Trial Registration Data Set, Figure 1

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Figure Legends

Figure 1: **Logic model of the working mechanisms in the VESPEERA programme**

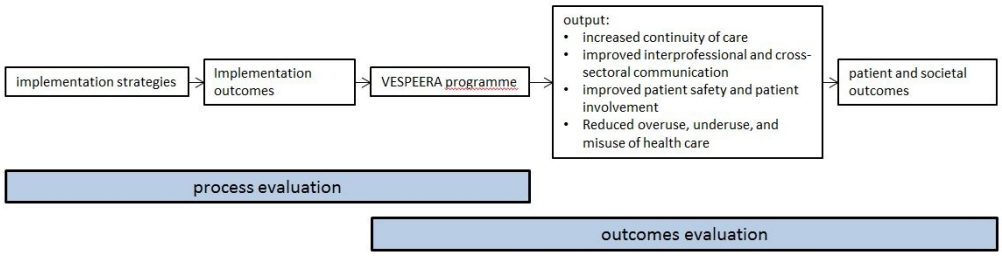

Figure 1: Logic model of the working mechanisms in the VESPEERA programme

302x77mm (96 x 96 DPI)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1 (Title)
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	4 (Trial Registration)
	2b	All items from the World Health Organization Trial Registration Data Set	Additional files
Protocol version	3	Date and version identifier	24 (Trial Status)
Funding	4	Sources and types of financial, material, and other support	26 (Declarations)
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1-2, 26 (Declarations)
	5b	Name and contact information for the trial sponsor	26 (Declarations)
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	26 (Declarations)

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	26 (Declarations)
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-6 (Background), 10-11 (VESPEERA process evaluation)
	6b	Explanation for choice of comparators	n.a.
Objectives	7	Specific objectives or hypotheses	11 (Objectives)
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, noninferiority, exploratory)	16 (Methods)
Methods: Participants, interventions, and outcomes			
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	10 (Study setting)
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)	16-17 (Study setting/ eligibility criteria)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	n.a
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	n.a.

	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	n.a.
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n.a.
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-15 (Table 2)
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)	16 (Study design)
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	19-20 (Sample Size)
Recruitment	15	20-21	16-17(Recruitment)
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n.a.
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n.a.
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n.a
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n.a.

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n.a.
Methods: Data collection, management, and analysis			
Data collection methods	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, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	21-22 (Data collection and management)
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_____
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	21-22(Data collection and management)
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	22(Data Analysis)
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	22 (Data Analysis)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	n.a.
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n.a.
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n.a.
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n.a.

Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n.a.
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	24 (Ethics, data protection and dissemination)
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	n.a.
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	16-17(Recruitment)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n.a.
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	21-22(Data collection and management)
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	26 (Declarations)
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	21-22 (Data collection and management)
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n.a.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	24 (Ethics, data protection and dissemination)

	31b	Authorship eligibility guidelines and any intended use of professional writers	n.a.
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n.a.
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	-
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n.a.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Improving continuity of patient care across sectors: Study protocol of the process evaluation of a quasi-experimental multi-centre study regarding an admission and discharge model in Germany (VESPEERA)

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Primary Subject Heading:	Health services research
Secondary Subject Heading:	General practice / Family practice
Keywords:	process evaluation, CFIR, determinants for implementation, admission management, discharge management, continuity of care

Title: Improving continuity of patient care across sectors: Study protocol of the process evaluation of a quasi-experimental multi-centre study regarding an admission and discharge model in Germany (VESPEERA)

Authors: Forstner, Johanna; Kunz, Aline; Straßner, Cornelia; Uhlmann, Lorenz; Kuemmel, Stephanie; Szecsenyi, Joachim; Wensing, Michel

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Abstract

Introduction: Hospital stays are critical events as they often disrupt continuity of care. This process evaluation aims to describe and explore the implementation of the VESPEERA programme. The evaluation concerns the intervention fidelity, reach in targeted populations, perceived effects, working mechanisms, feasibility, determinants for implementation, including contextual factors, and associations with the outcomes evaluation. The aim of the VESPEERA programme is the development, implementation and evaluation of a structured admission and discharge program in general practices and hospitals.

Methods and analysis: The process evaluation is linked to the VESPEERA outcomes evaluation, which has a quasi-experimental multi-centre design with four study arms and is conducted in hospitals and general practices in Germany. The VESPEERA programme comprises several components: an assessment before admission, an admission letter, a telephonic discharge conversation between hospital and general practice before discharge, discharge information for patients, structured planning of follow-up care after discharge in the general practice and a telephone monitoring for patients with a risk of rehospitalisation.

The process evaluation has a mixed-methods design, incorporating interviews (patients, both care providers who do and do not participate in the VESPEERA programme, total n=75), questionnaires (patients and care providers who participate

in the VESPEERA programme, total n=475), implementation plans of hospitals, data documented in general practices, claims-based data and hospital process data.

Data analysis is descriptive and explorative. Qualitative data will be transcribed and analysed using framework analysis based on the Consolidated Framework for Implementation Research. Associations between the outcomes of the program and measures in the process evaluation will be explored in regression models.

Ethics and dissemination: Ethics approval has been obtained by the ethics committee of the Medical Faculty Heidelberg prior to the start of the study (S-352/2018). Results will be disseminated through a final report to the funding agency, articles in peer-reviewed journals, and conferences.

Trial Registration: DRKS00015183 on DRKS / Universal Trial Number (UTN): U1111-1218-0992

Key Words: process evaluation, implementation science, intervention fidelity, CFIR, barriers, facilitators, admission management, discharge management, continuity of care

Strengths and limitations of this study:

- The process evaluation will help to interpret the findings of the outcomes evaluation of a hospital admission and discharge program.
- The perspectives of a broad range of stakeholders are considered, including care providers, patients and other stakeholders.
- This mixed-methods process evaluation addresses a broad range of aspects, which are associated with implementation and outcomes of the VESPEERA programme.

- Linkage of interview and questionnaire data with data sources of the outcome evaluation is not possible at individual level.

Introduction

Insufficient communication between hospitals and physicians in the outpatient sector may jeopardize the recovery process, lead to avoidable rehospitalisations[1, 2] and induce adverse events.[3] These outcomes also affect health related patient satisfaction and healthcare costs.[4] The legislator in Germany responded to this care problem by obligating hospitals to offer discharge management measures to all patients ("*Rahmenvertrag über ein Entlassmanagement beim Übergang in die Versorgung nach Krankenhausbehandlung nach § 39 Abs. 1 S.9 SGB V*"). The VESPEERA programme aims to support the implementation of this regulation. It develops, implements, and evaluates a structured hospital admission and discharge program between general practices and hospitals to avoid interruptions in the hospital admission and discharge process. An overview on the intervention components and the outcomes evaluation is given down below and are described in detail elsewhere.[5] Subsequently, we first summarize the patient-directed interventions in the VESPEERA programme, the VESPEERA outcomes evaluation, and the implementation strategies. Then we elaborate on the process evaluation in the remaining of this paper.

VESPEERA programme

Legislation in Germany is focused on hospital discharge and does not address admission management. The VESPEERA programme supports the implementation of structured discharge management and, amongst others, adds admission management procedures and further outpatient care after discharge in general practices . If admitted to the hospital electively, the general practitioner (GP) will conduct an assessment with the patient in order to generate an admission letter for

the hospital, providing medical and social information on the patient before hospital admission. Intervention components in the hospital include a telephonic discharge conversation for defined high-risk patients between the hospital and the general practice as well as a patient discharge information. After discharge, another assessment will be conducted in the general practice to facilitate planning of follow-up care (such as medication plans, referrals to specialists, prescriptions for medication and medical products and devices) and to identify patients with an increased risk for rehospitalisation based on the HOSPITAL Score (a score to determine risk of 30-day rehospitalisation[6]). These patients will be enrolled in a three-month telephone monitoring. Patients who had an emergency admission will receive the assessment for planning of follow-up care and, if eligible, the telephone monitoring. Table 1 gives an overview on the intervention components and study arms.

Table 1: **VESPEERA intervention components for all study arms**

Interventions		*Study arm 1:* **planned** admission into a **participating** hospital	*Study arm 2:* **planned** admission into a **non-participating** hospital	*Study arm 3:* unplanned admission into a **participating** hospital	*Study arm 4:* unplanned admission into a **non-participating** hospital	*Study arm 5:* **control group**, not participating in VESPEERA
General practice	**Interventions in the general practice before admission:** (A) assessment for admission (B) admission letter and patient brochure	X	X			

Hospital	**Interventions in the hospital:** (C) telephonic discharge conversation (D) determination of HOSPITAL Score and patient discharge information	X				
General practice	**Interventions in the general practice after discharge:** (E) assessment for planning of follow-up care (F) telephone monitoring, depending on the risk for rehospitalisation	X	X	X	X	

VESPEERA outcomes evaluation

The VESPEERA programme is "expected to reduce the number of avoidable rehospitalisations and emergency care contacts, to improve patient safety and patient involvement, to reduce overuse, underuse and misuse of health care, to improve the continuity of care and to improve interprofessional and cross-sectoral communication between patients, hospitals, general practices and the sickness fund 'Allgemeine Ortskrankenkasse (AOK) Baden-Wurttemberg'".[5]

The intervention is evaluated in a quantitative outcomes evaluation with a quasi-experimental design. The primary outcome is the number of rehospitalisations due to the same indication (three-digit ICD-10-GM code) within a time frame of three months (90 days) to the outpatient sector. The following indicators have been defined as secondary outcomes: rehospitalisation due to the same indication within 30 days; hospitalisations due to ambulatory care-sensitive conditions; delayed prescription of

medication and medical products/ devices and referral to other health practitioner/s after discharge; utilisation of emergency or rescue services within three months; average care cost per year and patient participating in the VESPEERA programme.

Using AOK claims data, patient data from the CareCockpit, and data collected in a questionnaire-based patient survey, a difference-in-difference model is applied for the primary analysis. The change of the primary outcome (before vs. after the intervention) of each intervention group will be pairwise compared to the control group. A detailed description of the outcomes evaluation can be found in the corresponding study protocol.[5]

Implementation strategies

Several strategies were applied to support the implementation of structured hospital admission and discharge management. The strategies are named according to the ERIC compilation by Powell et al.[7] and are reported using the recommendations by Proctor et al.[8] are as following:

First, consensus discussions with representatives of all stakeholders, thus physicians, GPs, patients, sickness funds and researchers, have been conducted. All intervention components were thoroughly discussed in the developmental period concerning the relevance of items, wording of items and design of documents, such as the patient discharge information. By involving users in the development of the intervention, acceptance and attractiveness of the programme are expected to increase.

Second, formal commitments are obtained by participating hospitals. Adaptability is promoted in order to facilitate the integration of study components into clinical processes. Therefore, each hospital will provide information on how they will ensure

the identification of study patients, the use of the admission letter, the execution of the telephonic discharge conversation, the dissemination of the patient discharge information and the transmission data to calculate the HOSPITAL Score. These formal commitments are obtained within four weeks after signing the participation agreement. Thereby, intervention fidelity as well as acceptance and attractiveness of the VESPEERA programme are expected to increase.

Third, the record system is changed by enhancing the PraCMan-Cockpit, software that is routinely used in Baden-Wuerttemberg within the PracMan case management programme.[9] The resulting CareCockpit includes the additional VESPEERA module, which assists general practices with organising patient information, conducting the assessments and care planning, generating the admission letter and other documents, and administrating telephone calls within the telephone monitoring. The CareCockpit is software that works independently from the practice information system and is used by the Care Assistant in General Practice (*Versorgungsassistentin in der Hausarztpraxis*, VERAH) and the GP. Furthermore, the CareCockpit works as an electronical case report form for data analysis within the outcomes evaluation.

Fourth, train-the-trainer strategies are used in order to instruct GPs and VERAHs in software utilisation and study processes. Trainers are teams of two (GP and VERAH) who are experienced in training the PraCMan-Cockpit and who were instructed in handling the CareCockpit by the study central office. GPs and VERAHs who are interested in participating in the VESPEERA programme sign up for a one-time 2.5 hour training. GPs and VERAHs learn the handling of the software in a role-play format.

Fifth, in order to support GPs and VERAHs with implementation of all intervention components, educational materials are developed. Investigator site files are provided after participation in the training by the study central office. Investigator site files

contain instructions and background information on the following: obtaining informed consent by patients, installation of the CareCockpit-software, an overview on frequently asked questions concerning the handling of the software, conduction of the intervention components, and conduction of the patient survey. Furthermore, general practices are continuously provided with instructional video tutorials on handling the software by the study central office. Along with the trainings, educational materials are expected to increase intervention fidelity.

Sixth, both participating general practices and hospitals are provided ongoing consultation with the study central office and other consortium partners to support implementation. General practices and hospitals are repeatedly called by employees of the study central office and asked for the status of implementation and any problems that arise within the implementation process. General practices are offered refreshers on topics of the training, such as the procedure for obtaining informed consent by patients, handling of the software, and instruction of the intervention components. Thereby, intervention fidelity is expected to increase.

Seventh, hospitals and general practices are provided feedback in the form of three benchmarking reports in September 2018, June 2019 and December 2019. The feedback reports are based on structured, quantified data-sources (claims data, patient data from the CareCockpit, and patient survey data), and are aggregated on a hospital or general practice level. These will be discussed in three moderated feedback meetings during the intervention period with care providers, where options for potential improvement will be developed. Feedback meetings are planned for September 2018, September 2019 and March 2020. Feedback meetings are moderated by the study central office with support by the other project partners. Care providers will have an active role in the meetings in a workshop format and report their perspective and experiences. Audit and feedback is a strategy to improve

professional practice, which has mixed and overall moderate impacts on professional performance.[10, 11] In this context, feedback provided is expected to enhance intervention fidelity.

Additionally, hospitals and general practices will receive fee-for-service for conducting patient-related care services as well as lump sum reimbursement for study organisation and participation in workshops and feedback meetings. General practices can invoice the care services as part of their usual invoice process, which is carried out at the end of each quarter year. Hospitals invoice the sickness fund 'Allgemeine Ortskrankenkasse' (AOK) Baden-Wurttemberg at the end of each quarter year. Lump sums are paid after participating in the feedback meetings. Fee-for-service gives an incentive to provide the different interventions components and thereby is expected to increase intervention fidelity.[12]

VESPEERA process evaluation

The VESPEERA programme is a complex intervention which intends to impact on a range of outcomes. The impact on outcomes depends not only on the effectiveness of planned interventions, but also on the degree of implementation of these interventions, the reach in relevant healthcare providers and patient populations, and the moderating impacts of the organisational and societal context in which the interventions are applied. As described by the Medical Research Council, complex interventions are characterized by multiple, mutually interacting intervention components; multiple targeted groups of individuals and organisations; multiple outcomes and mediating factors; high impact of the organisational and societal context on outcomes; and a "degree of flexibility or tailoring of the interventions".[13] These features largely apply to VESPEERA. A large number of interventions are applied; various organisations in different care sectors are involved, each with structural

conditions specific to the sector (e.g. remuneration systems). The effects of the interventions cover a range of domains.[5] Furthermore, hospitals are involved in the implementation within their organisation to tailor it to their local processes and structures.

We planned a process evaluation to provide insight into how well the intervention was implemented, why it did or did not work (i.e. did or did not have an effect on outcomes),[13-15] what context factors had an influence on the implementation and outcomes, and thereby allow to improve "transferability of potentially effective programs to other settings".[16] Investigation of implementation outcomes such as reach (whether the targeted population participated as intended/ the degree to which the targeted population participated) or intervention fidelity (whether the intervention was delivered as planned) can help to better understand the results of the outcomes evaluation.[17]

Objectives

This process evaluation aims to examine the intervention fidelity, reach in targeted populations, perceived effects, working mechanisms, feasibility, and determinants for implementation, including contextual factors, as well as associations with the outcomes evaluation, so that programme outcomes can be better interpreted. The research questions that are of interest within this process evaluation are illustrated in table 2.

Table 2: Research questions

1. REACH AND INTERVENTION FIDELITY
a) Was the intervention implemented as planned ("intervention fidelity") in targeted populations (''reach'')?

b) To what extent have the planned components been offered to care providers and patients? c) To what extent have these been utilised by care providers and patients? d) What was the adherence concerning the recommended practices of hospital admission and discharge? e) Has the targeted patient population been reached?
2. PERCEIVED EFFECTS:
Which results, from the view point of care providers and patients, were: a) Achieved as intended? b) Not achieved although intended? c) Achieved although not intended (positive or negative)?
3. WORKING MECHANISMS:
Which components and aspects of the intervention programme contributed to achieving the results from the view point of care providers?
4. FEASIBILITY:
What were acceptability and attractiveness of the programme from the point of view of care providers?
5. CONTEXTUAL FACTORS
a) What are determinants for implementing the program? b) Which contextual factors on system, hospital and practice level influenced the adoption of intervention components and outcomes of the programme? c) Which practices concerning admission and discharge management have been implemented in non-participating hospitals during the intervention period (for example in consequence of the new regulation on hospital discharge management)?
6. DOSE-RESPONSE ASSOCIATIONS:
Which associations exist between the outcomes (as disclosed by the outcomes evaluation) and findings of the process evaluation?

Figure 1 shows the hypothesized working mechanisms of the VESPEERA programme and the primary areas of interest of the outcomes and the process evaluation, respectively. The planned procedures for the process evaluation will be described in detail below.

< Insert Figure 1 here >

Methods of process evaluation

Study design

The process evaluation has an observational mixed-methods design, incorporating qualitative data from interviews and implementation plans with a description of the

implementation in participating hospitals as well as quantitative data from questionnaires that are filled in for each patient in hospital, surveys and data collected through the CareCockpit software in general practices. This process evaluation is part of the VESPEERA study that lasts from October 2017 until March 2021. The planned time frame for the process evaluation started in July 2018; evaluations will be complete by the end of March 2021.

Study setting

The VESPEERA programme is implemented in 25 hospital departments and 115 general practices in a defined region in southern Germany. The process evaluation is carried out by the Department of General Practice and Health Services Research at the Heidelberg University Hospital.

Eligibility criteria

Patients who take part and gave their informed consent to the VESPEERA study participation and outcomes evaluation can participate in the process evaluation. GPs and VERAHs who participate in the VESPEERA study can participate in the process evaluation. Hospital staff from participating hospitals has to work in one of the departments selected for VESPEERA implementation OR have to be involved in the implementation process of the VESPEERA intervention components on a higher hierarchical level (such as hospital management). Physicians, nursing staff and hospital management from non-participating hospitals as well as GPs and VERAHs from non-participating general practices are included if they can provide insight into their regular admission and discharge processes and the implementation of the new legislation on hospital discharge management.

Above that, all participants have to be 18 years and older, have written and spoken German language skills and have to be able to give their informed consent into study participation in the process evaluation. Persons who are unable to give their consent are excluded from study participation.

Outcomes of the process evaluation and data sources

The process evaluation uses data from a mix of sources, which in the following are described in detail (an overview on the research questions phrased, outcomes and data sources used can be found as a supplementary file).

Interviews

Qualitative interviews will be conducted with nursing staff, physicians and management staff from participating and non-participating hospitals, GPs and VERAHs from participating and non-participating general practices as well as participating patients after hospital stay. The interview guide addresses the intervention fidelity, perceived effects, and factors influencing implementation (barriers, facilitators, contextual factors) as well as acceptance and attractiveness of the intervention.

Questionnaires

Additionally, quantitative data result from structured surveys with participating general practitioners, VERAHs, physicians, nursing staff, management staff, and patients after a hospital stay. The questionnaire will be designed based on the results of the qualitative interviews as well as other studies on process evaluations and will be piloted before use. This pseudonymised questionnaire will not contain any data that allows identification of participants' identity. Concepts addressed in the questionnaires will be, amongst others, reach (see research question 1), unintended effects (see research

question 2), added value (see research question 3), and barriers and facilitators for implementation (see research question 5).

Hospital Process Data Survey

As part of the VESPEERA programme, hospitals are asked to collect the HOSPITAL Score for patients to determine their risk of rehospitalisation. This questionnaire is expanded by questions used for the process evaluation. These include sociodemographic questions and questions on processes that are part of the study interventions that are implemented within hospitals (identification of VESPEERA patients, utilisation of the VESPEERA admission letter, telephonic discharge conversation with the general practice). Data from the hospital process data survey will be used to analyse intervention fidelity for intervention components within hospitals.

Hospital Implementation Plans

In order to facilitate the integration of study components into clinical processes, different approaches are suitable for different hospitals. Therefore, each hospital will provide information on how they will ensure the identification of study patients, the use of the admission letter, the execution of the telephonic discharge conversation, the dissemination of the patient discharge information and determination of the HOSPITAL Score. Hospital implementation plans will be used to analyse intervention fidelity for intervention components within hospitals.

Patient data

For the outcomes evaluation, patient data from the CareCockpit is linked with claims-based data from AOK Baden-Wurttemberg and data from the hospital process data survey. This data set will be provided for the process evaluation. These data provide information on the study arm that the patient belongs to as well as patient

characteristics, the pseudonym generated in the CareCockpit for data linkage, diagnoses, the medical question for admission, information on previous antibiotic prescriptions, living situation, long-term care related items (such as scales for activities of daily living and instrumental activities of daily living), medical information (such as pain, wounds, alarming symptoms for medical emergencies, PHQ-2 instrument for mental disorders screening), compliance to medicinal therapy, the items of the HOSPITAL Score as well as process data (provision of information to patients, information on whether any follow-up care has been initiated and successfully executed). The patient data set will be used for the analysis of reach and intervention fidelity as well as dose-response associations. The following indicators are used as outcomes for the analysis of reach and intervention fidelity:

- Proportion and description of patients who participated in VESPEERA compared to all targeted persons who meet the inclusion criteria
- Proportion of persons enrolled in the general practitioner centered-care programme (HZV) who have been admitted to a participating hospital by a participating practice, for whom a new patient account has been created in the CareCockpit and for whom a complete admission letter including a medication plan was generated and was given to the patient to take along, compared to all participating HZV-insured persons in participating practices with planned hospital admissions.
- Proportion of participating patients who have been discharged from a participating hospital to their GP, for whom at the time of discharge the HOSPITAL Score has been determined, compared to all participating patients who have been discharged from a participating hospital.
- Proportion of participating patients for whom the assessment for planning of follow-up treatment has been conducted compared to all participating patients.
- Proportion of participating patients who have been enrolled in the follow-up telephone monitoring due to an intermediate or high risk for rehospitalisation and for whom at least two

phone calls have been conducted within the given timeframe of three months, per all participating patients.

- The degree to which the intervention components in hospitals have been implemented and offered as compared to the intention.

Sample size

The sample for the qualitative study is planned to reach saturation of data; the planned numbers are expected to be sufficient. The study sample for interviews on a hospital level consists of management staff, physicians and nursing staff and will be stratified by region and hospital size. On a practice level, GPs, VERAHs, and patients will be recruited from participating practices, stratified by practice size, region and gender. Additionally, staff from non-participating hospitals and general practices will be interviewed. This is important as interventions on a systems level can influence the effects of the evaluated care model. Table 3 gives an overview on the planned sample size for interviews.

Table 3: **Planned sample size for interviews**

		Planned number of participants (n)
Hospitals	Nursing Staff	10
	Management Staff	10
	Physicians	10
Non-participating hospitals	Nursing Staff	5
	Management Staff	5
	Physicians	5
General Practices	General Practitioners	10
	VERAHs	10
Non-participating general practices	General Practitioners	10
	VERAHs	10
Patients	Patient	10
Total number		**75**

The sample for the quantitative survey study comprises of all participating practices and hospitals (full study population) and a sample of n=200 patients for explorative data analysis (see Table 4). The sample size of patients was restricted out of feasibility reasons.

Table 4: **Planned sample size for questionnaires**

		Planned number of participants (n)
Hospitals	Nursing Staff	25
	Management Staff	25
	Physicians	25
General Practices	General Practitioners	100
	VERAHs	100
Patients	Patient	200
Total number		**475**

Recruitment

Within the process evaluation, participants will be recruited for interviews and written surveys.

Recruitment for qualitative interviews

Personnel from non-participating hospitals will be recruited by contacting the hospital management. A purposeful sample of hospitals will be selected, amongst others based on region, top-level versus basic care and previous interest to participate in VESPEERA. GPs and VERAHs from non-participating general practices will be recruited based on a list of all GPs who participate in GP-based care outside of the intervention region. A purposeful sample will be selected based on region, practice size and

gender. All participating general practices are asked to recruit eligible patients, as they are not known to the study central office.

By using a response coupon eligible interview participants from all stakeholder groups can declare their interest in participating in an interview. They will then be contacted by the study central office, be provided with an information letter and the written consent form.

Recruitment for the survey

Personnel from participating hospitals will be recruited by the contact person at the hospitals. The contact persons will be provided with information letters, written informed consent forms and the paper-based questionnaires and will be asked to hand it out to eligible personnel as defined by the study central office. All participating general practices will be sent the information letters, informed consent forms and paper-based questionnaires for GPs and VERAHs and will be asked to fill it in. Patients will be recruited by the general practices, as they are not known to the study central office. GPs will be provided with information letters, informed consent forms and paper-based questionnaires and will be asked to hand it out to eligible patients.

Data collection and management

Interviews

Interviews will be conducted as face-to-face or telephone interviews by researchers of the study central office. Interviews will last 30 minutes maximum and will be conducted using a semi-structured interview guide. In exceptional cases, for instance if problems within the recruitment process arise, written qualitative interviews consisting of open-end questions might be used. All interviews will be audio-recorded,

transcribed verbatim and stored on a secured server of the study central office. Transcripts will contain pseudonymized data only.

Questionnaires

Paper-based questionnaires are mailed to physicians, VERAHs, nursing staff and management staff from participating hospitals, GPs and patients. The filled in questionnaires will be sent by mail using an enclosed post-paid envelope to the study central office, where they will be scanned and digitally stored on a secured server. Reminders for data collection of both interviews and questionnaires will be sent out to all potential participants one to two times via fax, mail or post.

Hospital Process Data Survey

Hospitals fill in the hospital process data survey on the conduction of all intervention components for each case at the time of the patients' discharge, using the form they use to collect data for the HOSPITAL score used in the VESPEERA study.

The hospitals can either integrate the questionnaire into their hospital information system as an electronic questionnaire (transfer to the aQua-Institute via secure file transfer protocol (SFTP) servers) or fill in paper-based questionnaires that are sent to the aQua-Institute via mail using enclosed post-paid envelopes.

Hospital Implementation Plans

Participating hospitals will hand in a description of their individual implementation plan to the study central office.

Patient data

During the intervention period, patient data from the CareCockpit is continuously collected for the purpose of data analysis. Data from the CareCockpit is transferred along with claims-based data each quarter year.

Data analysis

Data analysis for the process evaluation is descriptive and explorative. Qualitative data will be transcribed according to established standards and will be analysed with regard to the research questions with framework analysis using the software MAXQDA.[18] The framework used for data analysis is the Consolidated Framework for Implementation Research (CFIR).[19] A deductive approach is chosen to assign paraphrases from the interviews to the themes and subthemes of the CFIR. Then, inductive coding within the CFIR themes is carried out and subthemes specific to the project are generated. The CFIR was chosen as it is a comprehensive framework that takes into account many of the aspects that need to be considered when evaluating the implementation of a complex intervention in healthcare organisations.

Quantitative survey data and the indicators for the intervention fidelity will be analysed descriptively. Correlations between the outcomes of the process evaluation and the outcomes evaluation will further be analysed using multilevel regression models. Using patient data, response (e.g. rehospitalisations within 30 days after discharge) will be related to dose of the implementation interventions (e.g. transmission of an admission letter to the hospital), taking clustering of patients in primary care practices into account. As the analysis is explorative, we refrain from a detailed pre-specified analysis plan.

Patient and public involvement

Patients were actively involved in the conduction of all intervention components, as described in the 'Implementation Strategies' section. With the 'Gesundheitstreffpunkt Mannheim e.V.' as consortium partner, an organisation representing patient interests is involved in all stages of the study (funding application, design of the study, conduction of intervention components, interpretation of results, dissemination of results).

Discussion

This process evaluation aims to provide insight into the implementation process of the VESPEERA programme in the participating general practices and hospital departments as well as the determinants influencing the degree of implementation. The results will contribute to adjusting the VESPEERA programme after the completion of all evaluations for a possible implementation into routine care. By relying on the GP as a gatekeeper to further health care and by proposing communication structures, the VESPEERA programme is expected to improve continuity of care.

Continuity of care is a complex concept with no clear definition.[20] However, recurring components of continuity of care include the first contact with a primary care provider, i.e. gatekeeping, information continuity ("the capacity of that information to travel with the patient and throughout the health system, between providers and over time"[21]) and longitudinal care provider continuity.[2, 20] By improving continuity of care patient outcomes are supposedly improved. In a systematic review, Huntley et al. found that continuity of care, i.e. seeing the same GP, reduced utilisation of emergency departments and emergency hospital admissions.[22] Furthermore, in another systematic review by an Loenen et al. the

authors showed that aspects of primary care such as a gatekeeping role and provider continuity are associated with a lower risk of avoidable hospitalisations due to ambulant care sensitive conditions.[2]

Huntley et al.[22] und van Loenen et al.[2] included mostly observational studies in their reviews on the effects of organisational features of primary care on hospitalisations and emergency care use. With a quasi-experimental approach and a thorough process evaluation, the VESPEERA programme is expected to contribute to the literature on the effects of continuity of care and care coordination on several patient outcomes.

Within this process evaluation, perspectives of a broad range of stakeholders are considered. Furthermore, interviews allow for gaining in-depth understanding of experiences with the VESPEERA programme and communication processes, whereas questionnaires allow for a higher sample size. Thereby, this serves to understand the broad implementation of a complex intervention.

However, no linkage between interview and questionnaire data with data sources of the outcome evaluation is intended. The intervention fidelity and barriers and facilitators to implementing the intervention therefore cannot be linked with patient-individual outcomes.

Ethics, data protection and security, and dissemination

The study protocol has been submitted to and approved by the ethics committee of the Medical Faculty Heidelberg. A data protection concept is part of the VESPEERA contractual agreement between consortium partners and has been approved by a

data security officer. The regulations of the European General Data Protection Regulation are met.

Dissemination of the results of this study is planned through the final report to the funding agency, articles in peer-reviewed journals as well as relevant national, and if relevant, international conferences.

Trial Status: The study protocol on hand is the protocol version 1.1 from June 18th 2018. Recruitment for interviews started on September 3rd 2018 and will approx. be completed by the end of May 2019.

List of Abbreviations

AOK	Allgemeine Ortskrankenkasse, large German sickness fund
CFIR	Consolidated Framework for Implementation Research
GP	general practitioner
HZV	general practitioner centered-care programme (Hausarztzentrierte Versorgung)
PraCMan	general practice-based case management programme (Hausarztpraxis-basiertes Case Management)
SFTP	Secure File Transfer Protocol

VERAH	Care Assistant in General Practice (Versorgungsassistentin in der Hausarztpraxis)
VESPEERA	Improving continuity of patient care across sectors: A quasi-experimental multi-centre study regarding an admission and discharge model in Germany

Declarations

Ethics approval and consent to participate: The study protocol has been submitted to and approved by the ethics committee of the Medical Faculty Heidelberg prior to the start of the study (S-352/2018).

Patient consent for publication: Not applicable.

Data sharing: Access to data and materials can be requested from the data owners.

Competing interests: The authors declare that they have no competing interest. Joachim Szecsenyi holds stocks of the aQua-Institute.

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Authors contributions: JF, AK and MW drafted the original manuscript. CS, MW, JF, AK, and SZ have planned the study, planned the data collection and have designed all instruments for data collection. LU provided statistical expertise. SK is involved in data collection of patient data. All authors read and approved the final manuscript.

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Additional files: SPIRIT Checklist, World Health Organization Trial Registration Data Set, Figure 1

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Figure Legends

Figure 1: **Logic model of the working mechanisms in the VESPEERA programme**

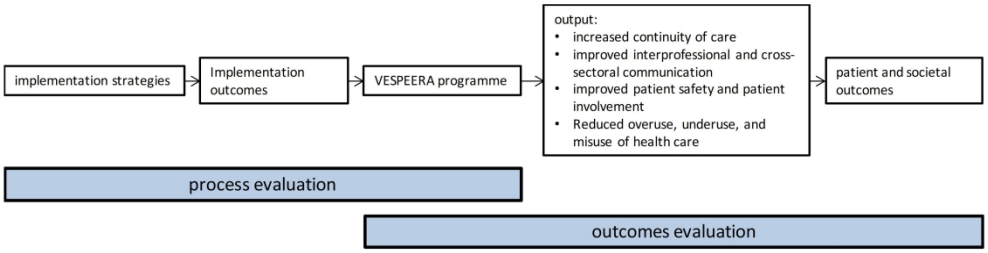

Figure 1: Logic model of the working mechanisms in the VESPEERA programme

1016x254mm (96 x 96 DPI)

Research Question	Outcomes / Indicators	Data sources
1. REACH AND INTERVENTION FIDELITY a) Was the intervention implemented as planned ("intervention fidelity") in targeted populations ("reach")? b) To what extent have the planned components been offered to care providers and patients? c) To what extent have these been utilised by care providers and patients? d) What was the adherence concerning the recommended practices of hospital admission and discharge. e) Has the targeted patient population been reached?	Proportion and description of patients who participated in VESPEERA compared to all targeted persons who meet the inclusion criteria	patient data
	Proportion of persons enrolled in the general practitioner centered-care programme (HZV) who -have been admitted to a participating hospital by a participating practice, -for whom a new patient account has been created in the Care Cockpit and -for whom a complete admission letter including a medication plan was generated and was given to the patient to take along, compared to all participating HZV-insured persons in participating practices with planned hospital admissions	patient data
	Proportion of participating patients who -have been discharged from a participating hospital to their GP -for whom at the time of discharge the HOSPITAL Score has been determined compared to all participating patients who have been discharged from a participating hospital	patient data

	Proportion of participating patients for whom the assessment for planning of follow-up care has been conducted compared to all participating patients	patient data
	Proportion of participating patients who have been enrolled in the follow-up telephone monitoring due to an intermediate or high risk for rehospitalisation and for whom at least two phone calls have been conducted within the given timeframe of three months, per all participating patients	patient data
	The degree to which the intervention components in hospitals have been implemented and offered as compared to the intention	Hospital process data survey; Hospital Implementation plans; Questionnaires: staff from participating hospitals
2. PERCEIVED EFFECTS Which results, from the view point of care providers and patients, were: a) Achieved as intended? b) Not achieved although intended? c) Achieved although not intended (positive or negative)?	Open-ended question As support: a) and b): name outcomes of the outcome evaluation c): name domains of possible results	interviews: all participating care providers*, patients Questionnaires: all participating care providers, patients

3. WORKING MECHANISMS Which components and aspects of the intervention programme contributed to achieving the results from the view point of care providers?	open-ended question as support: name intervention components (4-8 max., only those concerning the person being interviewed)	interviews: all participating care providers Questionnaires: all participating care providers
4. FEASIBILITY What were acceptability and attractiveness of the programme from the point of view of care providers?	Open-ended questions	interviews: all participating care providers Questionnaires: all participating care providers
5. CONTEXTUAL FACTORS a) What are determinants for implementing the program? b) Which contextual factors on system, hospital and practice level influenced the adoption of intervention components and outcomes of the program?	Open-ended question in interviews, structured questions in questionnaires As support: a): name domains, especially concerning behavioral factors (such as knowledge, attitude, self-efficacy, routine, desire/ will, skills/ capability; using the CFIR[18] b): name domains of contextual factors using frameworks (to be chosen when designing the questionnaires)	interviews: all participating care providers Questionnaires: all participating care providers

c) Which practices concerning admission and discharge management have been implemented in non-participating hospitals during the intervention period (for example in consequence of the new regulation on hospital discharge management as described in the introduction)?	c) :Open-ended question As support: Name components of admission and discharge management	interviews: non-participating hospitals, management staff from non-participating hospitals
6. DOSE-RESPONSE ASSOCIATIONS Which associations exist between the outcomes (as disclosed by the outcomes evaluation) and findings of the process evaluation?		patient data

* care providers include all staff from participating and non-participating hospitals and general practices as described in the 'eligibility criteria' section

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1 (Title)
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	4 (Trial Registration)
	2b	All items from the World Health Organization Trial Registration Data Set	Additional files
Protocol version	3	Date and version identifier	24 (Trial Status)
Funding	4	Sources and types of financial, material, and other support	26 (Declarations)
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1-2, 26 (Declarations)
	5b	Name and contact information for the trial sponsor	26 (Declarations)
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	26 (Declarations)

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	26 (Declarations)
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-6 (Background), 10-11 (VESPEERA process evaluation)
	6b	Explanation for choice of comparators	n.a.
Objectives	7	Specific objectives or hypotheses	11 (Objectives)
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, noninferiority, exploratory)	16 (Methods)
Methods: Participants, interventions, and outcomes			
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	10 (Study setting)
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)	16-17 (Study setting/ eligibility criteria)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	n.a
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	n.a.

	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	n.a.
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n.a.
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12-15 (Table 2)
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)	16 (Study design)
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	19-20 (Sample Size)
Recruitment	15	20-21	16-17(Recruitment)
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n.a.
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n.a.
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n.a
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n.a.

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n.a.
Methods: Data collection, management, and analysis			
Data collection methods	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, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	21-22 (Data collection and management)
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_____
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	21-22(Data collection and management)
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	22(Data Analysis)
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	22 (Data Analysis)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	n.a.
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n.a.
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n.a.
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n.a.

Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n.a.
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	24 (Ethics, data protection and dissemination)
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	n.a.
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	16-17(Recruitment)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n.a.
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	21-22(Data collection and management)
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	26 (Declarations)
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	21-22 (Data collection and management)
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n.a.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	24 (Ethics, data protection and dissemination)

	31b	Authorship eligibility guidelines and any intended use of professional writers	n.a.
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n.a.
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	-
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n.a.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.