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Home-based management of hypoxaemic COVID-19 patients: design of the Therapy@Home pilot study

Josi A Boeijen ,[1] Alma C van de Pol,[1] Rick T van Uum ,[1] Roderick P Venekamp ,[1] Karin Smit,[1] Karin A H Kaasjager,[2] Robert van den Broek,[3] Wilma Bijsterbosch,[3] Lisette Schoonhoven,[1] Frans H Rutten ,[1] Dorien L M Zwart[1]

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[1]Department of General Practice and Nursing Science, Julius Center for Health Sciences and Primary Care, Utrecht, Netherlands
[2]Department of Epidemiology and Health Economics, Julius Center for Health Sciences and Primary Care, Utrecht, Netherlands
[3]Department of Internal Medicine, University Medical Center Utrecht, Utrecht, Netherlands

Correspondence to
Ms Josi A Boeijen;
J.A.boeijen@umcutrecht.nl

ABSTRACT

Introduction During the COVID-19 pandemic, hospital capacity was strained. Home-based care could relieve the hospital care system and improve patient well-being if safely organised.

We designed an intervention embedded in a regional collaborative healthcare network for the home-based management of acutely ill COVID-19 patients requiring oxygen treatment. Here, we describe the design and pilot protocol for the evaluation of the feasibility of this complex intervention.

Methods and analysis Following a participatory action research approach, the intervention was designed in four consecutive steps: (1) literature review and establishment of an expert panel; (2) concept design of essential intervention building blocks (acute medical care, acute nursing care, remote monitoring, equipment and technology, organisation and logistics); (3) safety assessments (prospective risk analysis and a simulation patient evaluation) and (4) description of the design of the pilot (feasibility) study aimed at including approximately 15–30 patients, sufficient for fine-tuning for a large-scale randomised intervention.

Ethics and dissemination All patients will provide written, informed consent. The study was approved by the Medical Ethics Review Committee of the University Medical Center Utrecht, the Netherlands (protocol NL77421.041.21). The preparatory steps (1–4) needed to perform the pilot are executed and described in this paper. The findings of the pilot will be published in academic journals. If we consider the complex intervention feasible, we aim to continue with a large-scale randomised controlled study evaluating the clinical effectiveness, safety and implementation of the complex intervention.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ We describe five essential elements ('building blocks') that comprise complex interventions for home-based management of acutely ill COVID-19 patients.
⇒ These generic building blocks could also be applied to the development of home-based management for other acutely ill patients.
⇒ The design of the intervention was iteratively developed and extensively evaluated by a multidisciplinary expert panel.
⇒ Informed consent will be asked from acutely ill patients, which may lead to a high participation barrier.
⇒ The current study will give important information on the feasibility of the intervention implementation, but it will not yield data on the formal efficacy of the intervention.

INTRODUCTION

During the COVID-19 pandemic, hospital capacity was often strained by a high influx of critically ill COVID-19 patients.[1 2] To relieve pressure on hospitals, early discharge initiatives were successfully introduced to manage hypoxaemic COVID-19 patients at home with oxygen treatment after clinical improvement during hospital admission, under remote monitoring.[3–7] Ideally, future home-based management of COVID-19 patients is organised acutely, at the start of presentation, without initial hospital admission, directly from the emergency department (ED) or from home. Evidence for feasibility and safety of acute home-based management is, however, lacking.

If found to be feasible and safe, acute home-based management may improve patients' self-efficacy, recovery and mental well-being, notably in older adults at higher risk of delirium when hospitalised. The development and evaluation of acute home-based management have been prioritised by the Dutch Ministry of Health,[8] the Dutch College of General Practitioners[9] and the Dutch Society of Internal Medicine.[10]

Acute home-based medical management should be according to current practical guidelines, but it should also consist of the timely delivery of equipment, for example, an oxygen concentrator and a pulse oximeter, and an initial check by a healthcare

professional on the adequate use of such equipment by patients or relatives at home. Furthermore, adequate remote monitoring should be established in order to follow-up on the patient's health status during treatment. Remote monitoring entails periodical measurement of, for instance, peripheral oxygen saturation (SpO_2), heart rate and shortness of breath score for detecting deterioration in a timely manner.[11] If performed regularly, these spot-(self)measured health data should provide sufficient follow-up of the patient's oxygenation status and circulatory circumstances. The envisioned intervention for home-based management should be well coordinated, making sure that building blocks interact seamlessly, thus leading to safe, effective and patient-centred care. For this, the adaptive behaviour of healthcare workers from diverse disciplines is needed. All in all, such an interprofessional and multicomponent intervention qualifies as complex.[12] To be successfully implemented in general practice, the intervention should be feasible and as lean as possible.

The UK Medical Research Council (MRC) published guidance on developing complex interventions and created a framework that facilitates working towards an effective and implementable design.[13] Participatory action research (PAR) is a research method that fits this framework well. The PAR approach actively involves healthcare professionals and other stakeholders to design and implement complex interventions, considering local needs, barriers and facilitators. PAR has been widely used in the design of interventions that address complex and multifactorial healthcare problems,[14] such as antibiotic resistance and stewardship interventions,[15] and telemonitoring for chronic conditions,[16] but has not been explicitly used in the context of acute COVID-19 care.

In this paper, we describe the study design according to MRC guidance for developing and evaluating a home-based complex care intervention for acutely ill COVID-19 patients who require oxygen. We describe the essential elements—five 'building blocks'—that comprise the intervention, as well as the design of the pilot study used for evaluation. The feasibility data generated in this pilot can be used to set up and implement large-scale acute home-based management initiatives for critical episodes of COVID-19 or other acute respiratory tract infections requiring oxygen treatment, for example, a severe influenza infection or community-acquired pneumonia.

METHODS AND ANALYSIS

Framework

Guided by the MRC framework, we designed the intervention in four steps: (1) literature search plus evaluation of regional protocols with the assessment of knowledge gaps in clinical practice and the establishment of a multidisciplinary expert panel; (2) design of the intervention 'building blocks' through consensus meetings with the expert panel; (3) a prospective risk analysis and test case with a simulation patient and (4) design of the pilot study. During these successive steps, the PAR approach was followed, as further specified below.

PAR approach

PAR is a research process that requires the active involvement of different stakeholders. PAR aims to (1) trigger a change process for solving a practical problem, (2) be a learning process among those directly involved and (3) help further develop scientific knowledge. It simultaneously facilitates change in daily practice and contributes to the scientific debate. The PAR approach works through an iterative process of planning, action and reflection together with those who will experience the envisioned change intervention.[17] Plan-Do-Study-Act (PDSA) is the iterative problem-solving model that is used as a method to structure the research process throughout (online supplemental figure 1).

Step 1: literature search and establishment of the multidisciplinary expert panel

Literature search

We performed a literature search. We did not find studies evaluating the development and effect of acute (preadmission) home-based interventions for COVID-19 patients in acute respiratory distress. Several studies, however, reported positive experiences with home-based use of pulse oximeters in COVID-19 patients.[3 4 11 18–29]

The multidisciplinary expert panel

We established a multidisciplinary expert panel to deliver an intervention that is tailored to managing acute home-based care and to make sure the intervention can eventually be evaluated appropriately. This panel is involved in the design, development and evaluation of the intervention throughout all phases. Relevant stakeholders in the Utrecht region were approached by the research team and recruited for representation in the panel: general practitioners (GPs) from four regional primary care groups, pulmonologists and acute care internists from four hospitals in the region, home care nursing organisations and an office for nursing care mediation, a monitoring centre, a regional care coordination centre and a patient representative from the Utrecht Elderly Care Network (see online supplemental table 1 for a list of stakeholder organisations).

Step 2: defining the intervention building blocks

In this step, the home-based intervention was established. The expert panel defined five essential components ('building blocks') for acute care at home during weekly consensus meetings. Each ideated building block was then organised and protocolised, using existing regional care structures where possible and inventing new or redirected care paths where necessary. To endeavour equivalency to hospital care, the intervention design details a plan for (1) acute medical care, (2) acute nursing care, (3) remote monitoring, (4) equipment and technology and (5) organisation and logistics. The designed concept of each building block is shown in tables 1–3. Pilot-phase

Table 1 Concept and implementation of intervention building blocks 1 and 2: acute medical care and acute nursing care

Acute medical care	
Concept	**Implementation**
Supervising physician In the 'acute medical care' building block, agreements about which physician is responsible for the patient in the home setting should be formulated (eg, GP, pulmonologist or another physician). Ideally, GPs and hospital specialists should reach consensus on standard clinical practice to ensure widespread availability and uniformity of care.	**Supervising physician** Representatives of regional primary care groups and local hospitals reached consensus: medical care responsibility will be with the main, supervising physician who finally decides on initiating acute home-based management. This could be a hospital specialist or the patient's own GP, depending on the type of patient. See below.
Determination of the patient population Characteristics of the target patient population for home-based management should be formulated.	**Two types of patients are eligible** Non-frail patients who would normally be admitted to the COVID-19 ward after the initial evaluation in the ED. The supervising physician will be a hospital specialist (type one patient). Frail patients who do not want to go to hospital or for whom hospital admission and ED evaluation is considered not desirable. The supervising physician will be the patient's GP (type two patient).
Diagnostic guidance Diagnostic guidance should be given prior to the start of treatment. E.g. is ED diagnostic work-up desired or could diagnostic tests be performed in the home setting in a timely manner?	**Diagnostic guidance** ED diagnostic work-up prior to home-based management will be mandatory for type 1 patients and optional for type 2 patients.
Treatment options Treatment options should be protocolised, including an up-to-date recommended medication regimen, oxygen start and stop criteria, and oxygen titration protocols.	**Medication regimen** Medication regimen of dexamethasone (6 mg once daily for 10 days) and thrombosis prophylaxis is recommended for all patients. If motivated well, supervising physicians are allowed to deviate from the treatment protocol. Empirical use of antibiotics is not recommended. **Oxygen start and stop criteria** Oxygen treatment start and stop criteria and titration protocols are standardised. The standard target SpO_2 is ≥94%. Oxygen therapy can be reduced step-by-step with 1 L/min after the SpO_2 is stable for 24 hours. Home management can be stopped if a patient does not require medication and oxygen supplementation any longer and does not have any aberrations in their measurements for 48 hours. However, it is allowed to personalise individual care plans.
Glucose monitoring Recommendations for glucose monitoring in case of corticosteroid use should be specified.	**Glucose monitoring** For patients with a history of diabetes, glucose will be monitored at least once daily, starting on day 2 of treatment before the evening meal.
Clinical evaluation The necessity and frequency of in-person clinical evaluation (separate from remote monitoring) of each patient during the home-based intervention should be determined, as well as explicit actions and escalation pathways in case of clinical deterioration, and a plan for care post-recovery.	**Clinical evaluation** In person, clinical evaluation of the patient (in addition to remote monitoring) throughout the home-based intervention will be done by a specialised home nurse (see 'acute nursing care'). Post-recovery care will be at the discretion of the supervising physician.
Acute nursing care	
Concept	**Implementation**
Nursing care Essential patient assessments, instructions, and support usually provided by hospital ward nurses should be secured in a home-based adapted manner.	**Specialised home care nurse** Daily visit by a specialised home care nurse is scheduled on day 0, 1 and 2 (longer if considered needed). Problems and abnormal findings will be reported to the supervising physician, either directly or via the monitoring team.

Continued

Table 1 Continued

Acute nursing care	
Concept	**Implementation**
Tasks (1) Assessment of the home facilities and patient/carer self-management ability; (2) verification whether the course of disease is understood; (3) assessments of the patient's clinical condition; (4) verification of correct equipment use; (5) verification of correct medication use and adherence.	**Tasks** The protocolised tasks of the home care nurses include evaluation of patient's clinical status, verification of medication adherence and adequate equipment use. The daily checklist is specified in online supplemental table 2. The nurse can assist with glucose monitoring and subcutaneous injections of thrombosis prophylaxis as needed. They can support patient and carer and assess whether additional home facilities (ie, sanitary adjustments) are needed. The home care nurse will provide informal care givers and family members with general support during the home management as needed.

ED, emergency department; GP, general practitioner; SpO_2, peripheral oxygen saturation.

implementation strategies for each building block are shown alongside.

Step 3: safety assessments

After the initial intervention was established, we subjected the intervention design to two practical safety assessments: (1) a prospective risk analysis to identify weaknesses in the protocols and develop safety net strategies and (2) a test case with a simulation patient to trial the logistics of the complex intervention.

Prospective risk analysis

Prospective risk analysis enables evaluation, followed by improvement of the healthcare processes and may prevent incidents.[30] We subjected the intervention to a prospective risk analysis using the Health Failure Mode and Effect Analysis (HFMEA) method.[31] In this method, a multidisciplinary team describes a healthcare process in detail and identifies all possible failure modes. The potential severity of the consequences and estimated frequency for each failure mode are then assessed and scored on a scale from 1 to 5. After the identification of potential failure mode causes, actions and controls can be implemented to eliminate failure modes or mitigate their effects.[31 32] The prospective risk analysis aided in identifying protocol omissions and formulating explicit safety net strategies. A delay in the delivery of the oxygen concentrator, for example, was identified as a potential risk of the complex intervention. Possible causes identified included healthcare professionals' time constraints to organise delivery and a lack of clear agreements on responsibilities. To overcome the latter potential risk, all stakeholders agreed that the responsibility for oxygen delivery was with the Care Coordination Centre. We made a coordination protocol summarising the tasks needed to organise timely delivery and this was made available to Care Coordination Centre employees.

Test case with a simulation patient

We tested the logistics of the intervention with a simulation patient, a healthy 66-year-old woman not involved in the study and without work experience in healthcare. During the test case, all care providers were informed about the simulation setting, but the timing of the test was not announced beforehand. Logistics were trialled, and the encountered hurdles were discussed in the following expert panel meetings to mitigate the encountered problems. The test case showed that there was a lack of helicopter view over the logistics, partly due to communication delays. This was mitigated by the more active involvement of a 'first-day case manager' and explicit feedback loops between building blocks. Moreover, we encountered a lack of acute nursing care availability in the short term due to a lack of personnel, a problem that is difficult to mitigate for future scenarios. The simulation patient provided valuable feedback from a patient's perspective. She stressed that the information and instructions given to her were extensive and recommended repeated instruction, preferably with an informal caregiver present.

Step 4: feasibility pilot study protocol

In this upcoming step, the intervention and its feasibility will be piloted in 15–30 patients, while we will fine-tune the intervention further, aiming to learn from each patient's trajectory using a PAR approach. Here, we outline the design of the pilot phase.

Setting

An observational pilot study in the province of Utrecht (1.3 million inhabitants) was executed between November 2021 and December 2023.

Inclusion and exclusion criteria

Two different categories of patients can participate in the study: type 1—nonfrail patients in respiratory distress who would normally be admitted to the COVID-19 ward (not the intensive care unit) for oxygen support and type 2—frail COVID-19 patients in respiratory distress for whom hospital admission is not desirable due to anticipated treatment limitations, as a result of, for example, frailty, terminal phase care or patients' preferences. Inclusion

Table 2 Concept and implementation of intervention building blocks 3 and 4: remote monitoring and equipment and technology

Remote monitoring	
Concept	**Implementation**
Monitoring plan Remote patient monitoring allows healthcare providers to monitor symptom progression and clinical deterioration at home. This remote monitoring should be executed within the limits of a pre-defined monitoring plan. In reaction to monitoring parameters, care plans can be adapted to cope with the change in the patient's condition.	**Monitoring plan** Key elements of the monitoring plan and an example of the monitoring protocol are described below. **Monitoring protocol example** If a patient reports an SpO_2 1–2% below the target SpO_2 (usually 94%), the monitoring centre will advise to increase oxygen treatment with 1 L/min and repeat measurement after 5 min. **Deviations from the monitoring protocol** The supervising physician will be contacted in case of deviations from the standard monitoring protocol. For questions or deterioration during the evening and night, patients/carers can contact regular acute care facilities, that is, the out-of-hours primary care facility.
Vital parameters The key parameter is the patient's SpO_2 measured with a medically validated pulse-oximeter. Additional parameters are heart rate, respiratory rate, temperature, shortness of breath, cough and general well-being scales. **Pulse oximeters** Pulse oximetry has been used successfully in the home setting.[3–6 22] Assessment of respiratory rate by patients or care givers may be unreliable because awareness of assessment often inadvertently changes the respiratory rate.[35 36] Moreover, there is large observer variability. Devices for measuring respiratory rate are available but not validated for use in the home context.[37]	**Vital parameters** Three times daily the patient registers the SpO_2 (after 5 min of rest), heart rate, temperature, and he/she fills out the visual analogue scale for shortness of beath. The general well-being and visual analogue scale for cough is filled out once daily (see online supplemental table 3). **Communication with monitoring staff** The monitoring staff checks the parameters and scores during office hours, either by the app or by twice daily telephone contact in case of diary use. All patients are called at least once daily for a check-up and to communicate, if needed, any changes in treatment, for example, up or down titration of oxygen or changes in medication use.
Remote monitoring facility A remote monitoring facility includes staff that can 'coordinate' the monitoring, which entails both checking and communicating about the collected health status data with the patients, supervising physicians, and other healthcare personnel.	**Remote monitoring facility** Remote monitoring will be provided by the Medical Control Centre (MCC), located in the University Medical Centre Utrecht, serving all patients in the vicinity of all four regional hospitals. Monitoring staff includes students from (bio-)medical training programmes, supervised by both specialised nurses and trained GPs affiliated with the research team. Office hours: 9AM to 5PM, 7 days a week. Patients are instructed to contact regular acute care facilities, that is, the out-of-hours primary care facility, in case of urgent medical problems or questions, or when SpO2 deteriorates below 90% in the evening and night.
Digital vs analogue monitoring Data exchange in remote monitoring can be organised digitally, for example, via an app, or through diary keeping with follow-up by phone, or a combination of both methods. Digital monitoring requires adequate patient/carer skills and availability of devices which may fail to cater to elderly patients. Follow-up by phone is more time intensive for monitoring personnel.	**Digital vs analogue monitoring** Patients can choose to register their parameters and scores in a written diary or in an app (Luscii Healthtech BV, Amsterdam, the Netherlands).
Equipment and technology	
Concept	**Implementation**
Timely oxygen equipment delivery Home-based acute care requires timely equipment delivery. Oxygen support system such as an oxygen concentrator should be delivered at home shortly after ED visit, if applicable.	**Timely oxygen equipment delivery** For oxygen therapy at home, an oxygen concentrator (DeVilbiss Healthcare LLC, CE-certified; supplied by a company for home delivery of medical equipment) and standard nasal cannula will be delivered to the patient's home within 4 hours after requisition. The oxygen concentrator supplies a maximum of 4–6 litres of oxygen per minute.

Continued

Table 2 Continued

Equipment and technology	
Concept	**Implementation**
Monitoring equipment Validated pulse oximeters should be at the patient's disposal for measurement of SpO_2 and pulse rate. Other equipment that should be considered: thermometer (ear of rectal), a temporary height-adjustable bed, or other amendments to the home setting (eg, sanitary adjustments). Equipment used should be validated for medical use. Non-validated pulse oximeters do not perform adequately at lower SpO_2, e.g. below SpO_2 94%.[38–40]	**Monitoring equipment** To self-measure SpO_2, patients will be provided with one of two types of pulse oximeters: Nonin type 3230 (CE-certified, Nonin Medical Inc) or the iHealth air pulse (CE-certified, iHealthlabs Europe). Both pulse oximeters are validated for medical use according to the Food and Drug Administration (FDA) and follow International Organisation for Standardisation (ISO) guidelines. To self-measure temperature, patients will receive ear thermometers (ThermoScan 3, IRT 3030, Braun).

ED, emergency department; GP, general practitioner; SpO_2, peripheral oxygen saturation.

and exclusion criteria are described in online supplemental table 4.

Intervention description

The intervention is described in detail in tables 1–3 (implementation).

Data collection

Evaluation cycles: short and large

In PDSA cycles, data gathered during the pilot study will be iteratively collected, analysed and discussed by the expert panel and adjustments will be implemented in the intervention and/or amendments will be made to the research protocol of the pilot study. There is a short-cycle evaluation in which the expert panel will convene every 1–2 weeks to evaluate the care trajectories of already included patients. In addition, the research team will evaluate the intervention in a larger evaluation cycle, every 6–8 weeks, to assess the predefined outcome measures; the 'key elements' are summarised in box 1. These key elements were defined by the expert panel prior to the initiation of the pilot study as crucial steps in the intervention in the pilot phase and for future implementation in a larger randomised controlled trial (RCT).

Other data collected

We will collect data on patient characteristics, disease course (days alive out of hospital) and healthcare use

Table 3 Concept and implementation of intervention building block 5: organisation and logistics

Organisation and logistics	
Concept	**Implementation**
Coordination Arranging acute care in the home setting is a medical as well as a logistic endeavour, especially on the first day the home-based management starts. Coordination between building blocks should go smoothly. Administrative and logistical support may be required.	**Coordination** An overview of the building blocks is given in figure 1. Organisation of acute home care is coordinated and facilitated by a regionally available Care Coordination Centre (CCC). This centre is dedicated to organising emergency care along the whole acute care pathway, starting in the home setting. This centre will be responsible for contacting and connecting the building blocks.
Patient transport If necessary, patient transport should be arranged, conceivably with oxygen support during transport (this could be in the patient's private vehicle, assisted by care givers, or through ambulance care).	**Patient transport** Patient transport via ambulance from the ED to the home will be arranged, if necessary, by the Care Coordinating Centre or ED personnel. If the patient does not acutely require oxygen treatment, patients and carers will travel in their private vehicle.
Patient instruction Agreements should be made on who provides the patient with adequate and repeated instruction on medication and equipment use, monitoring requirements, and who to contact in case of questions or emergencies.	**Patient instruction** Repeated instruction on monitoring and understanding what to do with measurements is provided both by the home care nurse and monitoring staff.
Patient support The complete journey to establishment of acute home management can be initially overwhelming for the acutely ill patients and their family. Patient support or a 'case manager', other than the treating physicians or emergency care nurses, that keeps a bird's eye view over the intervention logistics and progression on the first day could be considered.	**Patient support** Patients receive instruction and support from a research assistant on the first day. The research assistant will provide the patient and family with the initial instructions and monitors the progression of the logistics on the first day of home management.

ED, emergency department.

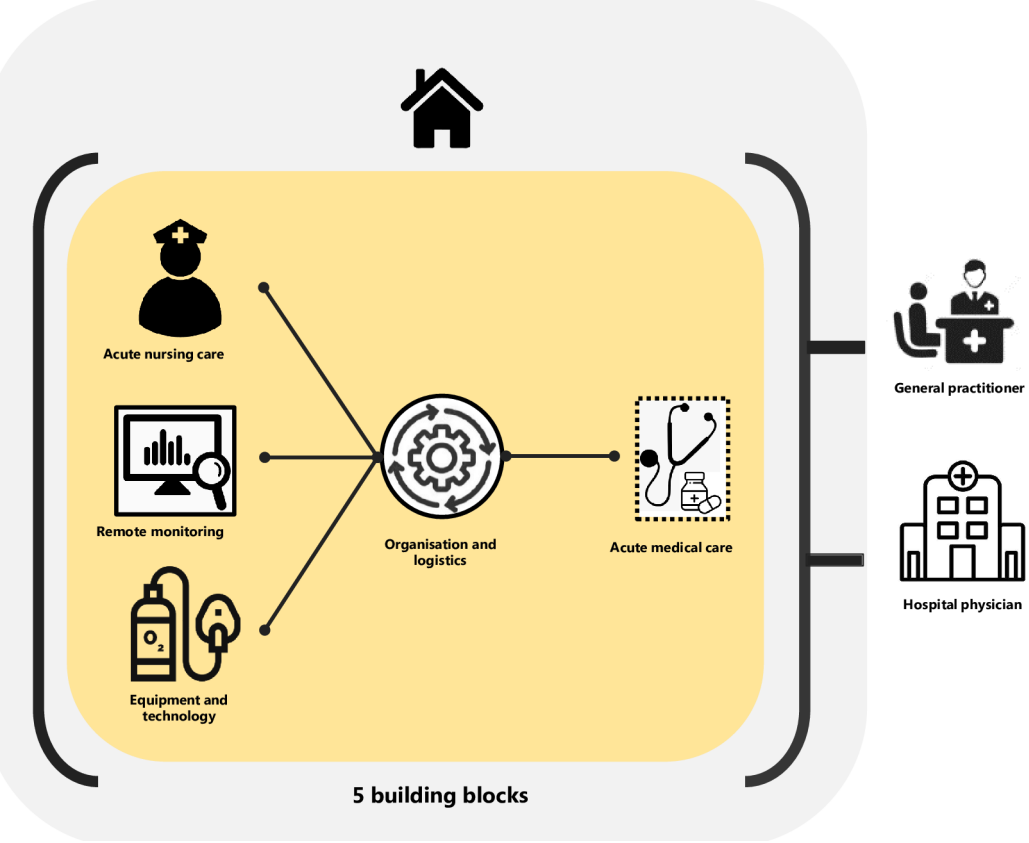

Figure 1 Five building blocks for acute home management: (1) acute medical care (supervised by a general practitioner or hospital physician), (2) acute nursing care, (3) remote monitoring, (4) equipment and technology and (5) organisation and logistics.

Box 1 'Key elements' (outcome measures) of the intervention which are assessed to help define successful implementation.

Key element	Assessment norms
Does the patient or caregiver manage the *self-measurements* adequately?	Successful if at least 75% of measurements is completed on days 0–2.
Is it clear to all involved parties who the main *supervising physician* is at the start of home management?	Yes/No (assessed during the evaluation cycle)
Does the patient have enough opportunity to ask *questions*?	Yes/No (assessed during the interview)
Is *contact established* between (1) patient and monitoring centre and (2) monitoring centre and the supervising physician?	Yes/No
Did *remote monitoring* go according to plan? Defined as: three measurements per day and a telephonic follow-up at least once per day.	Successful if at least 95% contact moments were completed as planned on days 0–2.
Does communication via the *app* work as intended?	Yes/No
Are the *medical decisions* of the patient management according to protocol?	Yes/No
Is the communication between the patient's *general practitioner* and other professionals involved considered adequate?	Yes/No (assessed during evaluation cycle)
Is the *oxygen concentrator* delivered on time (<4 hours) at the right location?	Yes/No
Is the *acute nursing care* organised on days 0, 1 and 2?	Yes/No
Are *serious adverse events*, if applicable, attributed to the course of the disease or to specific elements in the procedure?	Yes/No

through a combination of inclusion forms, GP and hospital medical file extractions and patient monitoring diaries. We will follow up with patients for 30 days. We use WHODAS 2.0 patient questionnaires to facilitate future RCT development. The coordinating researcher will contact patients on days 2 and 30 to fill out the questionnaires. Lastly, we will collect qualitative data using semistructured interviews. We will separately interview involved GPs and participants with their informal caregivers. Key topics of these interviews will be (1) the feeling of safety, (2) the experienced advantages and disadvantages (or perceived risks) of home management and (3) recommendations for improving the intervention. Of note, in this pilot study, we will not assess the clinical effectiveness of the piloted intervention.

Data analysis

During and after the completion of the pilot phase, we will assess the completion of the key elements for each patient and, if not, the reasons for noncompletion. This facilitates further tailoring of the intervention and designing a final intervention that may be evaluated in a larger real-world setting. Furthermore, we will register patients' healthcare use for the benefit of a health technology assessment to estimate the potential financial impact and advantage of the home management intervention. This assessment will provide a basis to facilitate a broader discussion for future implementation (ie, with healthcare insurance companies and policymakers). Lastly, qualitative data from the interviews will be coded and then analysed thematically.

Sample size calculation

In this pilot, a formal sample size calculation is not indicated. Fifteen to a maximum of 30 patients are expected to be sufficient for data saturation to go through the evaluation cycles to fine-tune the intervention and evaluate whether the intervention is suitable for use on a larger scale.

Patient and public involvement

Patient representatives are involved in all stages of our pilot. A patient representative from the Utrecht Elderly Care Network helped with designing, formalising and continuously evaluating the intervention and was a participant in the multidisciplinary expert panel. We had a simulation patient as a test case to trial the intervention logistics (and hence safety) prior to the inception of the pilot. Furthermore, the experience of patients participating in the pilot will be used in the iterative PAR approach to further develop the intervention. For this, we will use patients' experiences as collected from both questionnaires and qualitative interviews.

ETHICS AND DISSEMINATION

This study will be conducted according to the principles of the Declaration of Helsinki (10th version)[33] and the Dutch Conduct Code of Health Research.[34] The Medical Ethics Review Committee of the University Medical Center Utrecht, the Netherlands, approved the study (protocol NL77421.041.21) according to the Medical Research Involving Human Subjects Act (WMO) and will monitor any amendments made. We have registered the pilot in the Dutch Trial Register (LTR) under number 22 655 (https://www.onderzoekmetmensen.nl/en/trial/22655). The Dutch Trial Register (LTR) is the official data provider of the International Clinical Trial Registry Platform. Patients will be informed about the study through their GP. If they are interested, the coordinating researcher will visit the patient at home and obtain written informed consent. Study results will be published in international peer-reviewed medical journals and will be used to design a larger RCT to properly assess the effectiveness and safety of this complex home-based care intervention.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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ORCID iDs
Josi A Boeijen http://orcid.org/0000-0002-6259-4364
Rick T van Uum http://orcid.org/0000-0001-9415-4286
Roderick P Venekamp http://orcid.org/0000-0002-1446-9614
Frans H Rutten http://orcid.org/0000-0002-5052-7332

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