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Hospital at home – a study to reduce rehospitalizations

Submission date 28/01/2023	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/04/2023	**Overall study status** Ongoing	
Last Edited 29/11/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The aim of the Hospital@Home study is to reduce the rehospitalization rate in in-hospital patients on a medical ward at high risk of rehospitalization. The intervention consists of a targeted multidisciplinary intervention over 5 days after hospital discharge and aims to ensure an optimal transition from hospital to ambulatory care. The primary objective is to reduce the rate of unplanned rehospitalisation in the aforementioned patient group by 25%.

Who can participate?
Hospital inpatients at high risk of rehospitalization scheduled for discharge to their home

What does the study involve?
In addition to the standard-of-care counseling prior to hospital discharge, patients in the intervention group will be contacted by telephone daily for 5 days, starting on the day after hospital discharge. They will be asked about their general well-being, need for support in their daily care, and their adherence to prescribed medications. If a home visit is deemed necessary before discharge or on one of the daily phone calls, the visit will be carried out by a member of the study team. Members of the Hospital@Home study team will coordinate the discharge management prior to discharge, such as ensuring that all the necessary paperwork is present, organizing and coordinating post-discharge outpatient care, organizing any necessary material and medication and follow-up appointments with primary care physicians.

What are the possible benefits and risks of participating?
Participants could potentially receive a direct benefit from participation if they receive additional care from the Hospital@Home team. The goal of the intervention is to improve patient care in the home environment by coordinating the various inpatient and outpatient services involved, thus reducing unplanned readmissions and increasing patient satisfaction with the discharge procedure. No risks are expected.

Where is the study run from?
Cantonal Hospital of Baden, Canton Aargau (Switzerland)

When is the study starting and how long is it expected to run for?
November 2021 to January 2026

Who is funding the study?
1. Department of Health, Canton of Aargau (Switzerland)
2. Stiftung Kardio (Switzerland)

Who is the main contact?
Prof. Dr. med. M. Wertli, maria.wertli@ksb.ch

Contact information

Type(s)
Principal Investigator

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Prof Maria Wertli

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SNCTP000005155, BASEC2022-01040

Study information

Scientific Title
Hospital@Home: Improving discharge management and reducing the risk of rehospitalizations in multimorbid Patients

Acronym
H@H

Study objectives

Current study hypothesis as of 29/10/2024:

We hypothesize that through a targeted multidisciplinary intervention, the risk of rehospitalization within 30 days in high-risk patients can be reduced by at least 25%. Such a reduction would result in substantial individual and societal benefits.

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Previous study hypothesis:
It is hypothesized that through a targeted multidisciplinary intervention over 5 days after hospital discharge, the risk of rehospitalization within 30 days in high-risk patients can be reduced by at least 25%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/09/2022, Ethikkommission Nordwest- und Zentralschweiz EKNZ (Hebelstrasse, 53 4056, Basel, Switzerland; +41 (0)61 268 13 50; eknz@bs.ch); ref: 2022-01040

Study design
Pragmatic single-center randomized open-label superiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Rrisk for unplanned rehospitalizations in multimorbid patients discharged from the hospital

Interventions
Current interventions as of 29/10/2024:

The multimodal intervention includes several transitional care components per discharge phase: pre-discharge, bridging, and post-discharge interventions.

Pre-discharge interventions
Patients will receive individualized discharge management by an APN of the Hospital@Home team in addition to standard-of-care counseling. For each patient, the APN will instruct self-

management, conduct medication reconciliation and review, assess the needs for post-discharge care coordination, improve the discharge summary and care plan, and involve the family as needed.

Bridging interventions
Bridging interventions such as coordination and planning of outpatient follow-up appointments with primary care physicians or community nurses and availability of material and medication upon discharge (coordination with pharmacies) are used as needed. In addition to patient education, communication with the outpatient healthcare team (primary care physicians, specialists, and community nurses) and family members ensures that patients are aware of appointments and changes to their care plan. A scheduled home visit can also serve as a bridging intervention to directly hand over patients to the community nurses (e.g., for patients with intravenous therapy or supply and/or drainage systems).

Post-discharge intervention
Patients will receive structured telephone follow-up daily for 5 days (weekdays only) following the discharge. The telephone calls will focus on the following aspects:
• Assessment of symptoms and vital signs, general well-being, and organizational issues;
• Potentially adjustments to medications based on the treatment plan;
• Medication adherence, structured needs assessment to organize missing medications or material (e.g. wound dressings), identification of the need for home visits and follow-up visits;
• Counseling on health-related issues, patient and family education;
• Organizing and coordinating additional follow-up visits with primary care physicians and specialists;
• Organizing and coordinating care with community nurses (if necessary)
During the first 5-days post-discharge, the Hospital@Home team may conduct home visits, if needed. Home visits are performed by APN and/or a physician and are aimed at avoiding the need for rehospitalization by early treatment adjustments. Patients in the intervention group will be able to call a hotline to contact the Hospital@Home team during workdays to ask questions or to receive help.

Control procedures
Patients assigned to the control arm will receive the current standard-of-care counselling before hospital discharge. The nurse care manager team will provide a summary of discharge recommendations and organize outpatient care. In each patient the responsible resident physician will review the discharge medication, conduct a medication reconciliation, and explain the updated medication

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Previous interventions:

Patients with a BARRS-Score ≥5 will be randomised after providing written informed consent. The researchers will use blinded group allocation by randomizing patients into an intervention and a control group using the study software RedCap. A randomization list will be generated by a statistician otherwise not involved in the study. The randomization will be stratified based on the presence/absence of active cancer and/or heart insufficiency.

Patients will be randomly assigned into two parallel groups:
1. Intervention: The Hospital@Home care team will follow up patients for 5 days
2. Control group: usual discharge without follow-up

Patients in the intervention arm will – in addition to the standard-of-care counseling prior to hospital discharge – receive a multidisciplinary, coordinated 5-day care at their home, starting on the day after discharge. Members of the Hospital@Home study team will coordinate the discharge management prior to discharge, such as ensuring that all the necessary paperwork is present, organizing and coordinating post-discharge outpatient care, organizing any necessary material and medication and follow-up appointments with primary care physicians.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 29/10/2024:

The primary outcome is the rate of first unplanned rehospitalizations within 30 days after discharge from the index admission. An unplanned rehospitalization is defined as an unscheduled admission to any hospital and any division within 30 days after discharge.

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Previous primary outcome measure:

The rate of unplanned rehospitalizations in the high-risk group (BARRS score ≥5) at 30 days after discharge. Planned (elective) rehospitalizations will not be counted as events. This information is collected by a phone call at 30 days after discharge.

Secondary outcome measures
Current secondary outcome measures as of 29/10/2024:

1. The rate of unplanned rehospitalizations in the high-risk group (BARRS score ≥ 5) 18 days after discharge.
2. Change in quality of life between discharge and 30 days after discharge, using the EQ5D-5L
3. Quality of life after 30 days, using the EQ5D-5L
4. Death within 30 days
5. Health care use (e.g., physicians' visits, emergency department visits) within 30 days
6. Patient satisfaction with the discharge management at 30 days, using a clinic-specific questionnaire (TEA)

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Previous secondary outcome measures:

1. The rate of unplanned rehospitalizations in the high-risk group (BARRS score ≥5) 18 days after discharge. This information is collected by a phone call 30 days after discharge
2. Quality of life measured by EQ-5D questionnaire at discharge and 30 days after discharge
3. Patient satisfaction with discharge management, as measured by the Transition Evaluation Assessment Tool (TEA) at 5 days after discharge

Overall study start date
21/11/2021

Completion date

31/01/2027

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 25/11/2024:
Patients ≥18 years old with a high risk (estimated risk ≥20%) for unplanned rehospitalization who consent to participate are included in this RCT, if they meet the following inclusion criteria:
1. Hospital inpatients with a high risk (estimated risk ≥20%) for unplanned rehospitalization (BARRS-Score of ≥5 points) who are scheduled for discharge to their home
2. Patient and/or proxy must be able to give written informed consent
3. Patient and/or proxy must be able to communicate in German

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Previous participant inclusion criteria as of 29/10/2024 to 25/11/2024:
1. Hospital inpatients with a high risk (estimated risk ≥20%) for unplanned rehospitalization (BARRS-Score of ≥5 points) scheduled for discharge to their home
2. Patient must be able to give written informed consent

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Previous participant inclusion criteria:
1. Hospital inpatients with a BARRS-Score of ≥5 points scheduled for discharge to their home
2. Patient must be able to communicate in the German language
3. Patient must be able to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The sample size is 681 patients in each arm. Assuming a 20% drop-out rate, the final target sample size will be 1704 patients (852 in each group).

Key exclusion criteria
Current participant exclusion criteria as of 25/11/2024:
Patients are excluded if they meet the following criteria:
1. Discharge to other institutions (e.g., rehabilitation facilities, nursing homes);
2. Patients or proxy that are not able to understand the trial (e.g., cognitive impairment, language barrier);
3. Anticipated death within 30 days of the trial period;
4. Planned hospitalization within the next 30 days;

5. Unacceptable distance for home visits (>20 km away from the hospital);
6. Prior participation in the current trial (electronic health record will be labeled).

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Previous participant exclusion criteria as of 29/10/2024 to 25/11/2024:
1. Discharge to other institutions (e.g., rehabilitation facilities, nursing homes);
2. Patients that are not able to understand the trial (e.g., cognitive impairment, language barrier);
3. Anticipated death within 30 days of the trial period;
4. Planned hospitalization within the next 30 days;
5. Unacceptable distance for home visits (>20 km away from the hospital);
6. Prior participation in the current trial (electronic health record will be labelled).

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Previous exclusion criteria:
1. Patients discharged to other institutions, including rehabilitation facilities, nursing homes
2. Inability/unwillingness to give informed consent, e.g. due to cognitive impairment or language barrier
3. Patients who are scheduled for a planned hospitalization within the next 30 days
4. Patients who live more than 20 km away from the hospital
5. Previous participation in the trial

Date of first enrolment
04/05/2023

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Switzerland

Study participating centre
CTU Cantonal Hospital of Baden, Canton Aargau
Kantonsspital Baden AG
Im Ergel 1
Baden AG
Switzerland
5404

Sponsor information

Organisation
Kantonsspital Baden

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.kantonsspitalbaden.ch/

ROR
https://ror.org/034e48p94

Funder(s)

Funder type
Charity

Funder Name
Stiftung Kardio

Funder Name
Department of Health, Canton of Aargau

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/07/2027

Individual participant data (IPD) sharing plan
Upon completion of the study, the datasets generated analysed will be made available upon reasonable request from the clinical trial unit KSB (ctu@ksb.ch). Data that will be shared, will need to comply with legal restrictions and be fully anonymized.

IPD sharing plan summary

Available on request