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CLINICAL TRIAL

Supporting older people with cognitive impairment during and after hospital stays with intersectoral care management (intersec-CM)—results of a randomised clinical trial

Melanie Boekholt[1], Angela Nikelski[2], Fanny Schumacher-Schoenert[1], Friederike Kracht[1], Horst Christian Vollmar[3], Wolfgang Hoffmann[1,4], Stefan Henner Kreisel[2,‡], Jochen René Thyrian[1,‡]

[1]German Centre for Neurodegenerative Diseases, site Rostock/Greifswald, Ellernholzstraße 1-2, Greifswald 17489, Germany
[2]Department of Psychiatry and Psychotherapy Bethel, Division of Geriatric Psychiatry, Evangelisches Klinikum Bethel gGmbH, Bielefeld, Nordrhein-Westfalen, Germany
[3]Ruhr University Bochum, Bochum, Nordrhein-Westfalen, Germany
[4]Medicine—Department of Epidemiology and Community Health, University Medicine Greifswald Institute of Community, Greifswald, Mecklenburg-Vorpommern, Germany

Address correspondence to: Melanie Boekholt, German Centre for Neurodegenerative Diseases, Ellernholzstraße 1-2, Greifswald 17489, Germany. Email: melanie.boekholt@dzne.de
‡Stefan Henner Kreisel and Jochen René Thyrian shared last authorship.

Abstract

Background: The transition from hospital to primary care is a risk factor for negative health outcomes in people with cognitive impairment.
Objective: To test the effectiveness of intersectoral care management during the transition from hospital to primary care on repeated admission to hospital, functionality and institutionalisation in people with cognitive impairment.
Design: Longitudinal multisite randomised controlled trial with two arms (care as usual and intersectoral care management) and two follow-ups 3 and 12 months after discharge.
Setting: Three hospitals in two different primary care regions in Germany.
Subjects: $n = 401$ people with cognitive impairment: community-dwelling, age 70+. Randomised into control ($n = 192$) or intervention ($n = 209$).
Methods: Primary outcomes for the study after 3 months: admission to hospital, physical and instrumental functionality. Primary outcome after 12 months: institutionalisation, physical and instrumental functionality. Secondary outcomes: health-related quality of life, depressive symptoms, cognitive status and frailty. Statistical analyses include descriptive analyses as well as univariate and multivariate regression models for all outcomes.
Results: There was no statistically significant effect of the intervention on hospital admission and activities of daily living after 3 months, as well as on institutionalisation and activities of daily living after 12 months. There were significantly fewer participants in the intervention group readmitted to the hospital 12 months after discharge. Analyses show a significant effect on health-related quality of life 3 months and 12 months after discharge. Depressive symptoms were significantly less likely in the intervention group 3 months after discharge. No effects on cognition or frailty.
Conclusion: Intersectoral care management supports people with cognitive impairment during discharge and transition. Even though we were not able to show an impact of the intervention on the chosen primary outcomes everyday functionality and

institutionalisation, the effects on health-related quality of life, hospital admission rate and mental health are solid indicators for an improved individual situation.
Trial registration ClinicalTrials.gov, NCT03359408; https://clinicaltrials.gov/ct2/show/NCT03359408

Keywords: cognitive impairment; hospital discharge; dementia care management; randomised controlled trial; Germany; older people

Key Points

- Care management is effective in avoiding admission to hospitals within 12 months.
- People receiving intersectoral care management show higher quality of life 3 and 12 months after discharge.
- No significant differences in physical functionality and institutionalisation between intervention and control groups.

Introduction

Background

People with cognitive impairment represent a high proportion of older people in acute-care hospitals [1–3]. However, the hospital setting portraits a challenge for them, especially when experiencing cognitive impairment or dementia [4]. A recent scoping review indicates significant gaps in hospital care for older people with cognitive impairment [5]. Germany faces a particular challenge at the interface of hospital care and ambulatory care, the discharge [5], since the health care system is strictly sectorised. The hospital discharge procedure needs to be prepared throughout the hospital stay and should include the continuity of care after discharge. In 2017, discharge management was adopted into German Social Law [6], and an expert standard has been defined [7]. However, care gaps remain common, especially in case of the lacking availability of professional contact, leaving informal caregivers or even those impacted to address open care needs [8, 9]. Care gaps increase the risks of early institutionalisation [10], unplanned repeated admission to the hospital [11] and mortality [12].

A current Cochrane review assessing the effectiveness of planned patient discharge from acute-care hospitals has analysed $n = 33$ trials with participants affected by a range of medical conditions [13]. The majority of trials evaluated discharge planning interventions that aimed at facilitating coordination of postdischarge care and improvement of communication between hospitals, primary care and community services. The authors report a small reduction in the primary duration of hospitalisation and a relative reduction in repeated admission to hospitals over an average of a 3-month follow-up. There was little to no difference in participant's health status, functional status and psychological health, assessed by a range of measurement. There was some evidence which would point to increased patient satisfaction. However, studies with interventions going beyond the discharge time threshold were excluded from this review.

In primary care, awareness of specialised care requirements and their associated determinants in the ambulatory setting is advancing [14], and there is ample evidence that dementia care management [15, 16] improves treatment and well-being [17]. Various adaptation and implementation trials are currently conducted [18–21] as the national dementia strategy of Germany aims to make dementia care management available in routine caregiving. However, evidence supporting care management as an adjunctive measure remains limited for the transition between two health care sectors—hospital and primary care—especially in this vulnerable population.

Objective

The objective of this trial is to examine whether an intersectoral collaborative care management programme implemented for people with cognitive impairment and/or dementia during and after a hospital stay (1) reduces readmission to the hospital 3 months after discharge, (2) reduces institutionalisation 1 year after discharge, (3) has a positive effect on everyday functionality after hospital discharge and (4) shows positive effects on cognition, frailty, health-related quality of life and other health indicators.

Methods

Trial design

The intersec-CM trial (Supporting elderly people with cognitive impairment during and after hospital stays with Intersectoral Care Management) was a longitudinal multisite randomised controlled trial with two arms: (1) care as usual (CAU) and (2) CAU + intersectoral care management (ICM). The study protocol and the informed consent forms were approved by the Ethical Committee of the Chamber of Physicians of Mecklenburg—Western Pomerania, Germany (registry number BB 159/17) and the Ethical Committee of the Chamber of Physicians Westphalia-Lippe (Registry number: 2017-688-b-S). The reporting of the study follows the CONSORT statement [22]. The design, eligibility and inclusion criteria, intervention and baseline characteristics of the trial have been described in detail elsewhere [3, 18, 20]. The trial has been registered at ClinicalTrials.gov (NCT03359408).

Participants

A total of $n = 401$ people were enrolled in this study. We conducted a sample size estimation prior to enrolment into the study that yielded $n = 398$ participants to be sufficient to statistically show the hypothesised effect [3]. Participants were recruited in two German regions, in three different hospitals and $n = 6$ types of wards (gastroenterology, geriatrics, internal medicine, nephrology, neurology, trauma surgery). Upon admission to one of the participating hospitals, specially trained study staff identified possible participants for eligibility after scanning their medical records for the following inclusion criteria: age 70+, having lived at home prior to the index admission and living in the catchment area of the hospital. Exclusion criteria were acute stroke as the primary reason for admission as a cooperation requirement of the hospital we recruited in, any terminal disease and nonsufficient command of German language. The list of eligible study participants was briefly discussed with ward care staff who recommended patients based on the following criteria: (1) discharge to home was anticipated, (2) a screening procedure would be not too demanding to the patient and (3) the anticipated stay would be at least 3 days. This approach was chosen based on a pretest and guided by the need to establish a procedure that was not perceived to interfere with routine ward care and decreasing staff motivation. A systematic screening of all patients had been found to be inefficient. The limitations due to this recruitment procedure are discussed in the limitation section. We used a standardised screening instrument, the Mini Mental State Examination (MMSE), to detect possible cognitive impairment, primarily but not exclusively dementia. For this tool, already used in the hospitals we recruited from, we chose a cut-off of $\leq$26 points, as scores of $\geq$27 indicate cognitive health [23]. To ensure the reliability of self-reported data, we excluded patients with severe cognitive impairment (MMSE $<$10). Patients provided written informed consent. When patients were unable to provide written informed consent, their legal representative was asked to sign the consent on their behalf. After written informed consent was obtained, study staff began computer-based data collection at the time of baseline assessment using standardised personal interviews. Collection of baseline data occurred on average 1.9 days after hospital admission (arithmetic mean, SD = 1.31). Participants were enrolled in this study between 1 November 2018 and end of March 2020. The follow-up period ended on 30 April 2021.

Intervention

ICM is an adapted form of Dementia Care Management [15–17], a collaborative model of care. In principle, it consists of (1) a comprehensive, IT-based assessment of medical, nursing and psychosocial needs of the patient while in hospital; (2) the IT-supported, rule-based generation of an individual needs and care plan, which is provided for patient records in hospital, updated and collaboratively finalised after discharge; and (3) support in implementing the plan to address participants' needs, primarily through coordination and consultation.

The focus of the assessments is on medical, nursing and psychosocial needs that will be relevant for treatment and care after discharge. Based on predefined algorithms and expert knowledge, a treatment and care plan is generated and communicated with the hospital staff. A printout of these recommendations is documented in the medical files. As soon as possible after discharge of the patient, the care manager visits the participant at home, re-assesses the needs and updates the treatment and care plan. This updated plan is discussed with the participant and the care manager supports and monitors its implementation for up to 3 months after discharge. This procedure is described in more detail elsewhere [3, 18].

Outcomes and measurements

Outcomes were assessed within a standardised, computer-assisted face-to-face interview at the patients' homes by specifically trained study staff 3 and 12 months after hospital discharge. Predefined primary outcomes were (1) admission to hospital within 3 months after discharge, assessed by direct questioning the participants during the follow-up visits. 12 months after discharge was not predefined but of interest. (2) Physical and instrumental functionality (activities of daily living) 3 and 12 months after hospital discharge, measured using the internationally validated Bayer Activities of Daily Living Scale [24, 25]). This scale provides a score ranging from 1 to 10, with higher scores indicating greater functional deficits. The score reflects the frequency of identified issues in 25 daily activities, each of which the patient is asked to rate its frequency from 1 (never) to 10 (always). (3) Institutionalisation after 12 months, defined as place of residency being a nursing home. Twelve months after discharge was not predefined but of interest. Predefined secondary outcomes include (4) cognitive status, assessed using the MMSE [23], resulting in a scale from 0 to 30, with a higher score indicating better cognitive functioning. The MMSE was used to assess eligibility and document cognitive progression throughout the study, as ongoing documentation is essential when working with individuals with cognitive impairment. (5) Depressive symptoms, screened with the Patient Health Questionnaire (PHQ-2 [26, 27]), assessing two main symptoms of depression loss of interest and depressed mood. In the analysis, this outcome is binary coded as at least one symptom being present or none of the two symptoms being present. (6) Frailty, assessed using the Edmonton Frail Scale [28], including several domains such as health status, functional independence, social support and medication use, resulting in a score from 0 to 17, with a higher score indicating worse everyday functioning and health. (7) Health-related quality of life, assessed using the EQ-5D-5L, a generic measure of health status that can be translated into a single index value ranging from -0.661 to 1, with higher values indicating a better quality of life [29]. Additionally, we assessed the sociodemographic factors age,

Table 1. Baseline values of the whole sample of $N = 401$ and the follow-up samples 3 and 12 months after baseline

Factor/outcome	Baseline $N = 401$		3-Month follow-up $N = 235$		12-Month follow-up $N = 190$	
	Intervention $N = 209$	Control $N = 192$	Intervention $N = 126$	Control $N = 109$	Intervention $N = 110$	Control $N = 80$
Age, mean (SD)	83 (6)	82 (6)	83 (6)	82 (6)	82 (6)	82 (6)
Sex, female, *n* (%)	133 (63.6%)	121 (63.0%)	84 (66.7%)	68 (62.4%)	71 (64.5%)	50 (63.0%)
Living alone, *n* (%)	113 (54.1%)	97 (50.5%)	75 (59.5%)	56 (51.4%)	65 (59.1%)	39 (49.0%)
Recruiting site, *n* (%)						
Hospital 1	38 (18.2%)	24 (12.5%)	24 (19.0%)	12 (11.0%)	24 (21.8%)	10 (13.0%)
Hospital 2	71 (34.0%)	68 (35.4%)	47 (37.3%)	40 (36.7%)	41 (37.3%)	24 (30.0%)
Hospital 3	100 (47.8%)	100 (52.1%)	55 (43.7%)	57 (52.3%)	45 (40.9%)	46 (57.0%)
Cognitive functioning (MMSE score), mean (SD)	22 (4)	22 (4)	23 (3)	22 (4)	23 (3)	23 (3)

sex and living situation (living alone or with others). We did not assess the educational level due to homogeneity of education in this age group in the study region (Germany).

Randomisation and allocation

After baseline assessment, each individual was randomised using computerised permuted blocks and allocated to either ICM or CAU at a ratio of 1:1. Study staff in the hospital recruited patients, while randomisation was conducted at the study centre. Thus, the study staff was blind to the allocation during the initial assessment and was not able to influence the allocation. Complete blinding was not possible because intervention delivery and outcome measurement needed to be performed by the same study nurses.

Statistical analysis

Stata 16.1 was used for the statistical analyses.

Biases

To check possible dropout/attrition bias, we compared participants remaining in the study at the 3-month follow-up with participants who were lost between baseline and the first follow-up, or where no contact was possible regarding age, sex and cognitive status.

To account for possible allocation bias, which might be suspected due to study groups of varying sizes, we fitted a regression model with the study group as dependent variable and age, sex and hospital as independent. As expected due to the computerised randomisation, no effect was found and will therefore not be mentioned further.

Descriptive statistics

Descriptive statistics at each measurement time point are presented in Table 1. Metric variables are presented by means and standard deviations, nominal variables by categories and proportions. For the comparison between intervention and control group, we used Welch's or Satterthwaite's *t*-test, Chi-square test and Fisher's exact test. The statistical significance level was set to $\alpha < 0.05$. Since not all variables could be assessed in all participants, the descriptive statistics provide the respective number of participants.

Outcome analyses

The analyses are conducted for all aforementioned predefined outcomes (primary and secondary), using generalised regression models with a model specification corresponding to the scale level of the outcome variable (i.e. (1) logistic regression models reporting adjusted odds ratios were calculated for the binary outcomes admission to hospital post-discharge, institutionalisation and the presence of depressive symptoms; (2) linear regression models reporting regression coefficients were fitted for all other outcomes). We did not impute for missing values; therefore, depending on the attrition of the respective outcome measure, the models include different numbers of participants. In all multivariable models, the outcome variable at follow-up was the dependent variable; study group was the variable of interest. Where available, the baseline value of the outcome variable was included as a covariate to reduce residual variance and to account for interindividual variance at baseline. As covariates, grand central mean age, sex and living situation (alone vs. not alone) were included. A positive intervention effect was defined as a statistically significant regression coefficient ($\alpha < 0.05$) of the study group variable.

Results

Participants

In total, 401 participants fulfilled all inclusion criteria, provided informed consent and were allocated to intervention ($n = 209$, care as usual and intersectoral care management) and control group ($n = 192$, care as usual), respectively. All participants received the intended treatment. However, the treatment varied in intensity based on individual needs and preferences. A total sample of $n = 235$ could be assessed at 3-month follow-up, $n = 190$ at 12-month follow-up, as illustrated in the CONSORT study flow diagram. An overview of the participant's characteristics at baseline is found in Table 1.

Table 2. Regression analyses for the treatment effect of intersectoral care management[a]

Outcome	Follow-up (months)	*N*	*b*/AOR (95% CI)	*P* value[b]	Effect size[c]
Hospital admission[d]	3	231	1.81 (0.85 to 3.85)	.13	
	12	183	0.45 (0.24 to 0.86)	.02*	0.36
Activities of daily living[d]	3	202	−0.27 (−0.003 to 0.09)	.07	
	12	159	−0.10 (−0.78 to 0.58)	.78	
Institutionalisation[d]	3	364	0.87 (0.34 to 2.19)	.77	
	12	356	0.70 (0.33 to 1.50)	.36	
Cognitive status[e,f]	3	175	−0.25 (−1.17 to 0.67)	.59	
	12	91	−1.24 (−2.65 to 0.17)	.08	
Depressive symptoms[e]	3	219	0.39 (0.20 to 0.77)	.01**	0.36
	12	183	0.66 (0.31 to 1.41)	.28	
Frailty[e]	3	216	0.24 (−0.46 to 0.93)	.50	
	12	153	−0.16 (−1.08 to 0.77)	.74	
Health-related quality of life[d]	3	217	0.14 (0.06 to 0.22)	.001***	−0.47
	12	184	0.14 (0.05 to 0.23)	.003**	−0.43

[a]Mixed-effect regression analyses adjusted for covariates, the study group was the variable of interest; [b]*P* values are given 1 sided, levels of significance are * < .05, ** < .01. *** < .001; [c]Cohen's *d* is the reported effect size for significant coefficients; [d]model adjusted for age, sex, living situation and hospital; [e]model adjusted for age, sex, living situation, hospital and baseline value; [f]the high number of missing values is due to assessment partly happening during COVID-restrictions and being carried out via telephone without the cognitive assessment for which in person contact is necessary.

Dropout bias

There was no statistically significant difference in age and sex. The difference in MMSE score at baseline was statistically significant (22.74 (SD = 3.39) [included in 3-month follow-up] vs. 21.48 (SD = 3.88) [not included]; *P*-value = .0007); however, it was not clinically relevant.

Allocation bias

There is no statistical difference regarding age, sex or MMSE score at baseline in the sample under analysis at 3-month follow-up when comparing intervention and control group.

Outcomes and estimation

Regarding the primary outcomes, there was no statistically significant effect of the intervention on admission to hospital after discharge and activities of daily living after 3 months, and no statistically significant effect on institutionalisation and activities of daily living after 12 months. More details are shown in Table 2.

For the secondary outcomes, analyses indicate that the intervention group demonstrated a significantly enhanced health-related quality of life compared to the control group at both 3 months ($b = 0.14$, 95% confidence interval (CI): (0.06–0.22), $P = .001$, $d = -0.47$) and 12 months ($b = 0.14$, 95% CI: (0.05–0.23), $P = .003$, $d = -0.43$) post–hospital discharge. Furthermore, depressive symptoms were significantly less likely in the intervention group 3 months after discharge (Adjusted Odds Ratio (AOR) = 0.39, 95% CI: (0.20–0.77), $P = .009$, $d = 0.36$). No effects on cognition or frailty were shown.

Table 2 includes all variables of interest for both follow-up time points. While admission to hospital after 12 months was not prespecified as primary outcome, this proportion of participants was significantly less in the intervention group (AOR = 0.45, 95% CI: (0.24–0.86), $P = .02$, $d = 0.36$). All effect sizes for the significant outcomes range from 0.36 to 0.47, indicating small to medium effects that are presumably clinically relevant, particularly at the individual level.

Discussion

The intersec-CM trial adds important, yet inconsistent results to the efficacy of care management on patient outcomes. While providing intersectoral care management as implemented in this study did not have a statistically significant effect on the primarily intended outcomes, it showed statistically significant effects on secondary outcomes. We were not able to show an effect on (1) the rate of readmission to hospital or physical and instrumental functionality after 3 months and (2) the rate of institutionalisation or physical and instrumental functionality after 12 months. The results further strengthen the evidence that care management approaches can be beneficial to patients with cognitive impairment because our analyses show that people receiving intersectoral care management have higher health-related quality of life (at 3 and 12 months postdischarge), show depressive symptoms less frequently (at 3 months) and have lower hospital admission rates (at 12 months)—in comparison to care as usual.

The activities of daily living (ADLs) were chosen as a primary outcome due to their importance in describing the general physical and instrumental functionality in older patients. An acute, at times severe, illness that requires hospitalisation often leads to and is intricately associated with a subsequent decrease in everyday functioning, further to detrimental effects of the hospital stay as such [30]. The trial was designed to support the reversal of this process. However, care management differs from specific physical interventions like occupational or physiotherapy, as it does not directly target daily functioning but addresses resulting support needs. ADLs are commonly used measurements in routine care and serve as good indicators of general health. However, evaluations of complex interventions, such as care

management, may require more targeted outcome measures to clarify the inconsistent results seen in efficacy trials, as noted in a recent systematic review [31].

Contrary to our expectations, the intervention had no effect on the readmission rate to hospital 3 months post-discharge, yet it did at the 12-month follow-up time point. There was no effect on institutionalisation. This might be due to the COVID-19 pandemic during the conduction of the trial, which changed hospital procedures, reduced admission rates in general and prioritised other patient groups or medical treatments. The delayed effect is plausible since the intersectoral care management included encouragement and organisation of medical treatment. This could have led to less need for hospital care in the long run. This would be in line with current research on studies consistently showing positive results of care management on readmission rates [32].

Regarding institutionalisation, there are further explanations possible. The rate of institutionalisation in our study was surprisingly low with only 7.7% of the participants moving into a care facility during the 12 months after discharge. We cannot rule out that our recruitment interfered with this result. Inclusion criterion for the study was that the discharge place was anticipated to be the participants' home. This might have led to systematically excluding patients at risk for institutionalisation, which could explain why this trial was not able to show any effect.

The intervention has the largest effects on health-related quality of life and depression, and thus on patient-reported outcomes. These results are largely consistent with the available evidence, although the complexity of the modes of action is still unclear [32]. Patients are accompanied back to their homes during a critical period following hospitalisation and acute illness. Based on a personal relationship, they experience attention, appreciation, security and professional support. In addition, the intersec-CM intervention aims to ensure support and provision of care tailored to individual needs and specific challenges. Improved mental health in the form of a lower incidence of depressive symptoms after 3 months can be interpreted as a successful transition and coping. The effect flattens out and is no longer detectable after 12 months. This may be due to the temporal and situational context in which care management took place.

Various considerations can be made to explain the persistent positive influence on health-related quality of life. A direct optimisation of the care situation is conceivable. Some specific dimensions of the EQ-5D are specifically addressed by the intervention. For example, mobility may be improved by assistive devices (e.g. walker, wheelchair) without addressing the underlying medical problem. Also conceivable are modes of action via mediating constructs, which include, for example, strengthening self-efficacy, self-management skills and health literacy. These concepts are positively associated with health-related quality of life [33, 34]. Notwithstanding the likely unspecific mechanisms of action, improved health-related quality of life is central for a patients' health, and this finding indicates that participants' daily living situations and well-being have improved in the context of collaborative care management.

Limitations

The generalisability of our results is limited by (1) the inclusion criteria, (2) the sample size under analysis, (3) a possible selection bias, (4) nonblinding of the assessment, (5) the assessment of depression and (6) the COVID-19 pandemic.

(a) Inclusion was based on a screening of cognitive status. We cannot rule out that our sample does include cognitively healthy people because no further information on the cognitive status was available for cross-checking. Thus, the generalisability of the results to cognitively impaired patients may be limited.
(b) The study may have been underpowered due to loss to follow-up, resulting in a smaller analytic sample than anticipated. We expected data from 279 participants, but we have information on 356, with only 190 completing follow-up II.
(c) Our recruiting methods may have led to a selection bias. We relied on hospital staff to pre-select patients. We cannot rule out that patients, who would have fulfilled our eligibility criteria, were not selected for recruitment for other reasons than defined. However, we used this pragmatic approach based on feasibility results in a pre-study.
(d) The intervention and endpoint collection were conducted by the same specially trained study staff, with one to two study nurses at each site. Given this staffing structure, alternative arrangements were not feasible. However, the risk of bias is considered low due to the extensive training provided.
(e) Results regarding depression must be interpreted with caution. Although a valid and sensitive instrument was chosen (PHQ-2) [26], this does not allow a differentiated assessment of depression, and our results should therefore rather be regarded as a positive tendency.
(f) Intervention and follow-up assessments were partially conducted during the COVID-19 pandemic. This had an influence on adherence to protocol, the full implementation and fidelity of the intervention and the utilisation of health care services in general [35–37].

Conclusions

Supporting people with cognitive impairment in hospitals by providing intersectoral collaborative care management during the transition to home has some significant effects on health care of the individual.

The study did not yield the results anticipated and hypothesised. There are several reasons for that, among which are power and sensitivity of outcomes. The intervention was implemented alongside routine care, making

it challenging to identify suitable participants. Complex interventions inherently present difficulties, particularly in selecting appropriate outcomes that accurately reflect participants' situations and development. This complexity contributes to the ambiguity of results.

For clinicians, this study emphasises the importance of early identification of individuals who may benefit from support, particularly in relation to reducing hospital admission rates within 12 months postdischarge. For researchers, the heterogeneity of included participants and disciplines introduces methodological challenges. While more homogeneous studies could yield clearer results, they may not accurately represent real-world scenarios. Future efforts should focus on replicating or optimising these findings, potentially utilising secondary data from hospitals or insurance sources.

The next steps are to examine whether and how efficacy can be changed by targeting more homogenous groups regarding, for example, the diagnoses upon admission and the severity of impairment and medical needs. This might lead to increased effectiveness associated with individual patient variables and/or dose and duration of the intervention.

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