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Intervention fidelity and process outcomes of medication reviews including post-discharge follow-up in older hospitalized patients: Process evaluation of the MedBridge trial

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Abstract

What is known and objective: Drug-related problems (DRPs) are a growing healthcare burden worldwide. In an ongoing cluster-randomized controlled trial in Sweden (MedBridge), comprehensive medication reviews (CMRs) including post-discharge follow-up have been conducted in older hospitalized patients to prevent and solve DRPs. As part of a process evaluation of the MedBridge trial, this study aimed to assess the intervention fidelity and process outcomes of the trial's interventions.

Methods: For intervention delivery, the percentage of patients that received intervention components was calculated per study group. Process outcomes, measured in about one-third of all intervention patients, included the following: the number of identified medication discrepancies, DRPs and recommendations to solve DRPs, correction rate of discrepancies, and implementation rate of recommendations.

Results and discussion: The MedBridge trial included 2637 patients (mean age: 81 years). The percentage of intervention patients (n = 1745) that received the intended intervention components was 94%-98% during admission, and 40%-81% upon and after discharge. The percentage of control patients (n = 892) that received at least one unintended intervention component was 15%. On average, 1.1 discrepancies and 2.0 DRPs were identified in 652 intervention patients. The correction and implementation rates were 79% and 73%, respectively. Stop medication was the most frequently implemented recommendation (n = 293) and 77% of the patients had at least one corrected discrepancy or implemented recommendation.

What is new and conclusion: The intervention fidelity within the MedBridge trial was high for CMRs during hospital stay and lower for intervention components upon and after discharge. The high prevalence of corrected discrepancies and implemented recommendations may explain potential effects of CMRs in the MedBridge trial.

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KEYWORDS

clinical trial, drug therapy, implementation science, pharmaceutical services, quality of health care

1 | WHAT IS KNOWN AND OBJECTIVE

Older patients are at risk of experiencing drug-related problems (DRPs) like adverse drug reactions,[1] particularly at transitions of care.[2,3] DRPs lead to increased morbidity, which poses a growing burden on healthcare resources worldwide.[4,5] One of the proposed activities to prevent and solve DRPs in older patients is the performance of comprehensive medication reviews (CMRs).[3,6] CMR is a structured, critical examination of a patient's medications with the objective of reaching an agreement with the patient about treatment, optimizing the impact of medications and minimizing medication-related harm.[6]

We previously reported the protocol of a pragmatic cluster-randomized controlled trial (cluster-RCT; MedBridge; ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT02999412: NCT02986425) which aimed to study the effects of two interventions compared to usual care (control) on older patients' health outcomes[7]: a CMR by a multiprofessional ward team including a clinical pharmacist during hospital stay (intervention 1); the same as the first intervention, with the addition of a follow-up phone call by the pharmacist 2-7 days and 1-2 months after hospital discharge, and a referral to the patient's general practitioner (GP) if necessary (intervention 2). The primary outcome measure is the incidence of unplanned hospital visits during 12 months. The results are expected in mid-2020. In this trial, the CMR process involves the identification of discrepancies between the patient's medication list and the actual medications taken by the patient and DRPs by a clinical pharmacist. Discrepancies are then corrected, and recommendations to solve DRPs are made and implemented, in collaboration with the ward physician, nurse and patient.

Pragmatic trials, which often include complex interventions such as CMRs, are intended to provide evidence for adoption of interventions into real-world clinical practice.[8] To interpret the results of pragmatic trials, it is important to understand how the interventions were implemented and performed, and which factors may have affected the trial's results.[9,10] Process evaluations to address these questions are therefore recommended.[10]

Two qualitative studies using interviews with patients and carers[11] and healthcare professionals[12] identified multiple factors that may have affected the results of the MedBridge trial. Patients and healthcare professionals generally had positive experiences, valued multiprofessional collaboration, and addressed the need of CMRs and post-discharge follow-up. However, other factors, including pharmacists not being fully integrated in the ward team, difficulties to fit CMRs in existing routines, and patients having problems recalling information, may negatively impact effectiveness of the trial's interventions.[11,12]

Assessing *intervention fidelity*, that is the consistency of the performed interventions with the planned interventions,[10] and intermediate *process outcomes*, like identified discrepancies and DRPs within a CMR,[13] can provide complementary knowledge. This study therefore aimed to assess the *intervention fidelity* and *process outcomes* of CMRs including post-discharge follow-up, as part of a process evaluation of the MedBridge trial.

2 | METHODS

2.1 | Study design

The MedBridge trial process evaluation was based on the UK Medical Research Council framework[10] and included four methods of which two are reported here: *intervention fidelity* assessment and *process outcomes* assessment. Each assessment addressed different research questions (Table 1). Findings from two qualitative studies have been reported elsewhere.[11,12]

2.2 | Setting and exposure

The MedBridge trial was conducted at four hospitals in Sweden: Uppsala University Hospital and the hospitals in Enköping, Gävle and Västerås. The intervention components of the trial were performed at two wards per hospital. The wards differed in terms of medical specialty: geriatric, internal medicine, stroke, neurology and nephrology. The performance of CMRs by pharmacists was an established practice or was implemented at each ward at least six months prior to the start of the trial. Each ward participated in the trial for six consecutive eight-week study periods. During each period, either intervention 1, intervention 2 or usual care (control) was performed at the ward (Figure 1). The sequence of these periods was randomly allocated. All study periods were held between February 2017 and October 2018.

2.3 | Participants

Patients aged 65 years or older and admitted to one of the participating wards were eligible for inclusion in the MedBridge trial. Patients were excluded if they had been subject to a medication review within 30 days prior to admission, resided in another than the hospital's county, were in a palliative stage, and/or admitted for only one day. Medication reconciliation, the process of ensuring an accurate and

TABLE 1 Methods and research questions of the process evaluation reported in this study

Methods	Research questions
Intervention fidelity assessment	• What percentage of patients in each study group received intervention components as defined in the trial protocol? • What were the reasons for protocol deviation?
Process outcomes assessment	• What number and types of discrepancies and DRPs were identified within the CMRs? • What number and types of recommendations were made by the pharmacists to solve DRPs? • What was the correction rate of discrepancies and implementation rate of pharmacist recommendations within the CMRs? • What percentage of patients had at least one corrected discrepancy or implemented recommendation?

Abbreviations: CMRs, comprehensive medication reviews; DRPs, drug-related problems.

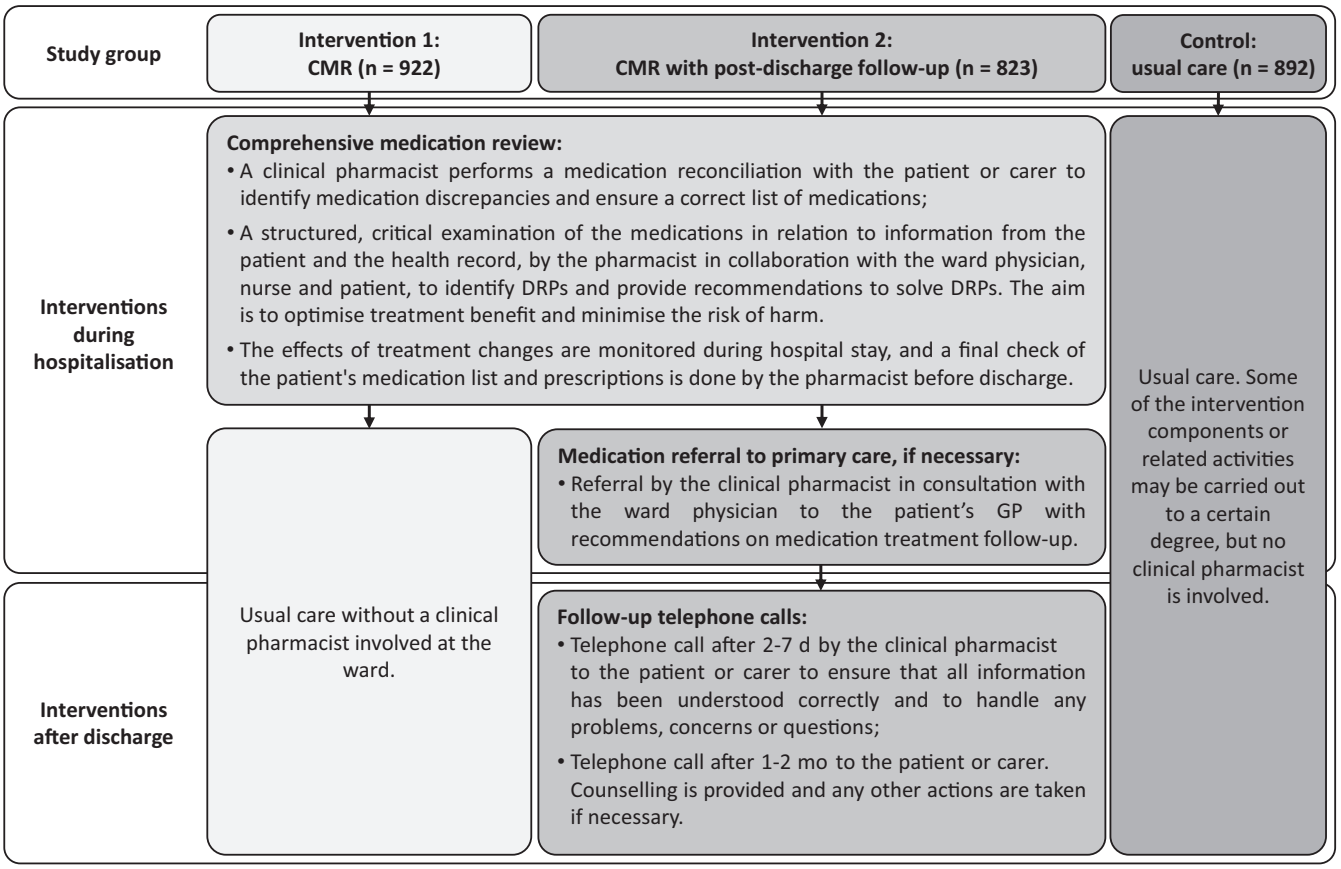

FIGURE 1 Study groups and intervention components within the Medication Reviews Bridging Healthcare (MedBridge) trial.[7] CMR, comprehensive medication review; DRP, drug-related problem; GP, general practitioner

complete medication list, by a pharmacist at the emergency department was not considered an exclusion criterium. All eligible patients were asked for informed consent to participate in the trial and received the intervention components that were allocated to be performed during the ongoing study period (Figure 1). For *intervention fidelity* assessment, all trial participants were included. For *process outcomes* assessment, at least one-third of all participants from each intervention period (either intervention 1 or intervention 2) was randomized to be included using a random sequence generator (RANDOM.ORG, Dublin, Ireland). Patients who had not received a CMR by a pharmacist were excluded from the *process outcomes* assessment.

2.4 | Data collection

2.4.1 | Intervention fidelity assessment

During the trial, pharmacists made notes in the patients' electronic health records (EHRs) as part of their daily clinical routine. Pharmacists were encouraged to record reasons for protocol deviation. The EHRs were retrospectively screened by research assistants to collect data on whether the patients had received intervention components and reasons for protocol deviation. Standardized procedures and training by one researcher (TK)

ensured consistency of data collection across study sites. The intervention components were as follows: medication reconciliation upon admission, CMR during hospital stay, medication reconciliation upon discharge, medication referral sent by the pharmacist to the GP, first and second follow-up phone calls and actions taken by the pharmacist as a result of the phone calls (Figure 1). Data on medication referrals by the ward physician to the GP were also collected to investigate whether CMRs by a pharmacist at the ward would lead to more medication referrals. Any other intervention components performed without pharmacist involvement were considered usual care and therefore not included.

2.4.2 | Process outcomes assessment

Pharmacists' notes in the patients' EHR were assessed to collect data on the number and types of identified medication discrepancies, DRPs and recommendations by the pharmacists. The types of discrepancies were as follows: *commission*, a medication that the patient was not prescribed was listed; *omission*, the patient was prescribed a medication, which was not listed; or *dosage*, the incorrect dose or dosage regimen was listed. The patient's medication list during hospital stay was assessed to categorize each discrepancy as *corrected* or *uncorrected*. DRPs were defined and classified using the definition and system proposed by Strand et al,[1] with minor modifications (Appendix S1). Recommendations to solve DRPs were classified using the system proposed by the French Society of Clinical Pharmacy,[14] with minor adjustments (Appendix S1). Physician's notes and the patient's medication list were then assessed to categorize each recommendation as *implemented* or *not-implemented*. Assessments were performed by final-year pharmacy students and a clinical pharmacist (HC) who were trained and supervised by one researcher (TK). Age, sex and number of prescribed medications upon admission (including *pro re nata* medications) were extracted from the patients' EHR as baseline characteristics. All data were captured in electronic case report forms (eCRFs) with Castor Electronic Data Capture (Ciwit B.V, Amsterdam, the Netherlands).

2.5 | Data analysis

The eCRF data were analysed with R version 3.5.1 (R Foundation for Statistical Computing, Vienna, Austria) using descriptive statistics. Differences between study groups in the percentage of medication referrals by ward physicians were analysed with a Chi-square test ($\alpha = 0.05$). Reasons for protocol deviation were categorized per intervention component. Correction rates of discrepancies and implementation rates of recommendations (ie number of corrected/implemented divided by total number) were calculated.

2.6 | Ethics approval

This study was part of the MedBridge trial which has received ethical approval from the Swedish Central Ethical Review Board (CEPN; registration number: Ö21-2016).

3 | RESULTS

3.1 | Intervention fidelity assessment

Medication reconciliation upon admission and CMR during hospital stay were conducted in 97% (n = 893) and 94% (n = 862) of the intervention 1 patients, respectively, and in 98% (n = 810) and 97% (n = 796; Table 2) of the intervention 2 patients, respectively. Medication reconciliation upon discharge was less often conducted in both intervention 1 (40%, n = 370) and intervention 2 patients (51%, n = 418).

TABLE 2 Frequencies and percentages of performed intervention components per study group in the MedBridge trial (n = 2637)

Intervention components	Intervention 1 (n = 922)	Intervention 2 (n = 823)	Control (n = 892)
Medication reconciliation upon admission, n (%)	893 (97%)	810 (98%)	115 (13%)
CMR during hospital stay, n (%)	862 (94%)	796 (97%)	14 (2%)
Medication reconciliation upon discharge, n (%)	370 (40%)	418 (51%)	29 (3%)
Medication referral by pharmacist to GP, n (%)	9 (1%)	47 (6%)	1 (0%)
First follow-up call, n (%)	1 (0%)	664 (81%)	1 (0%)
On time (within 7 d), n (%)		452 (55%)	
Action in response to the first follow-up call, n (%[a])		389 (59%[a])	
Second follow-up call	1 (0%)	482 (59%)	1 (0%)
On time (within 60 d), n (%)		395 (48%)	
Action in response to the second follow-up call, n (%[a])		269 (56%[a])	

Abbreviations: CMR, comprehensive medication review; GP, general practitioner.

[a]Percentage of the number of phone calls.

TABLE 3 Reported reasons for protocol deviation and unknown reasons (reason not reported) in frequencies and percentages per intervention component

Intervention component	Reason for no intervention (or delayed follow-up call), n (%)
Medication reconciliation upon admission and CMR during hospital stay	Lack of time or missed by pharmacist, 41 (46%) Patient had few or no medications, 7 (8%) Patient palliative or terminally ill, 1 (1%) *Reason not reported, 38 (44%)*
Medication reconciliation upon discharge	Patient moved to a ward without pharmacist, 126 (13%) Patient palliative, terminally ill or deceased, 77 (8%) Lack of time or missed by pharmacist, 48 (5%) Patient had few or no medications, 4 (0%) *Reason not reported, 702 (73%)*
First and second follow-up calls	Difficulties to reach patient or carer by phone, 126 (20%) No need for phone call according to pharmacist, 113 (18%) Patient palliative, terminally ill or deceased, 78 (12%) Patient readmitted to hospital, 47 (7%) No intervention by pharmacist during hospital stay, 30 (5%) Other reasons, 12 (2%) *Reason not reported, 234 (37%)*

Abbreviation: CMR, comprehensive medication review.

Medication referrals to the GP were sent by the pharmacist in 6% (n = 47) of the intervention 2 patients (Table 2). There was no difference in the percentage of patients for which a medication referral was sent by the ward physician to the GP between intervention 1 (42%, n = 390), intervention 2 (44%, n = 359) and the control group (39%, n = 352; P = .22). The first and second follow-up phone calls were performed in 81% (n = 664) and 59% (n = 482) of the intervention 2 patients, respectively. The majority of the first (59%, n = 389) and second follow-up calls (56%, n = 269) led to an action taken by the pharmacist. Most frequent actions were providing information or advice to the patient or carer (n = 566) and contacting another healthcare professional (n = 133), for example consulting the primary care practice nurse on insulin dosages.

Contamination in terms of control patients receiving unintended intervention components by a pharmacist was present (Table 2). The percentage of control patients receiving at least one unintended intervention components was 15% (n = 132).

The most frequent reason for not conducting a medication reconciliation upon admission or a CMR during hospital stay was lack of time or that the patient was missed by the pharmacist (n = 41, Table 3). The most frequently reported reasons for not performing other intervention components were that the patient was moved to a ward without a pharmacist (n = 126) and difficulties to reach the patient or carer by phone (n = 126). The reason was not reported in 58% (977/1684) of the protocol deviations.

TABLE 4 Baseline characteristics of intervention patients (intervention 1 and 2) included in the MedBridge trial (n = 1745) and those included in the *process outcomes* assessment (n = 652)

Baseline characteristic	Intervention 1 and 2 (n = 1745)	*Process outcomes* assessment (n = 652)
Age, mean years ± SD (range)	81 ± 8.1 (65-103)	81 ± 8.2 (65-103)
Female sex, n (%)	909 (52%)	343 (53%)
Medications[a], mean number ± SD (range)	9.3 ± 5.4 (0-30)	9.5 ± 5.6 (0-30)

Abbreviation: SD, standard deviation.

[a]Prescribed medications including *pro re nata* prescriptions.

3.2 | Process outcomes assessment

In total, 1745 intervention patients (intervention 1 and 2) were included in the MedBridge trial, of which 683 (39%) were randomized to be included in the *process outcomes* assessment. Of these patients, 31 had not received a CMR. The 652 patients that were finally included had similar baseline characteristics (on average 81 years old, 9.5 medications in use and 53% female) as the total population (Table 4).

The mean number of identified discrepancies per CMR was 1.1 (range 0-12) and 79% (589/747) of these discrepancies were

TABLE 5 Number and percentage of identified discrepancies, drug-related problems and recommendations, correction rate of discrepancies and implementation rate of recommendations per comprehensive medication review in the *process outcomes* assessment (n = 652)

Discrepancies, mean ± SD (range)	1.1 ± 1.8 (0-12)
Patients with ≥ 1 discrepancy, n (%)	327 (50%)
Correction rate of discrepancies, proportion (%)	589/747 (79%)
DRPs, mean number ± SD (range)	2.0 ± 1.9 (0-14)
Patients with ≥ 1 DRP, n (%)	494 (76%)
Recommendations, mean number ± SD (range)	2.1 ± 2.1 (0-14)
Implementation rate of recommendations, proportion (%)	1006/1380 (73%)
Patients with ≥ 1 discrepancy or DRP, n (%)	555 (85%)
Patients with ≥ 1 corrected discrepancy or implemented recommendation, n (%)	500 (77%)

Abbreviations: DRP, drug-related problem; SD, standard deviation.

corrected in the medication list (Table 5). The mean number of identified DRPs per CMR was 2.0. A mean number of 2.1 recommendations per CMR were made by pharmacists of which 73% (1006/1380) were implemented. The percentage of patients with at least one corrected discrepancy or implemented recommendation was 77% (500/652).

The most frequent discrepancy was *commission* (39%, n = 290). The most frequent DRP was *medication without indication* (18%, n = 233), followed by *improper medication selection* (17%, n = 224, Figure 2). *Stop medication* (21%, n = 293) and *dose adjustment* (20%, n = 274, Figure 3) were the most frequent types of recommendations. The implementation rate for each type of recommendation ranged between 62% and 80%, except for *information to patient* which was implemented in all cases (n = 116).

4 | DISCUSSION

4.1 | Intervention fidelity assessment

The *intervention fidelity* was high for medication reconciliation upon admission and CMR during hospital stay with 94%-98% of the intervention patients receiving these intervention components. In contrast, more than half of these patients did not receive a medication reconciliation by a pharmacist upon discharge. A medication referral was sent by the pharmacist in 6% of the intervention 2 patients. The first and second follow-up calls were performed in 81% and 59% of the patients, respectively. Frequently reported reasons for protocol deviation were a lack of time, patients moving to a ward without a pharmacist, and difficulties to reach the patient or carer by phone.

Healthcare professional interviews identified pharmacists not being integrated in the ward team, the unclear role of the pharmacist, and a lack of time to follow up on treatment changes as important barriers.[12] Patient interviews indicated little patient involvement during hospital stay.[11] Failure to involve patients at discharge and ensure appropriate follow-up on treatment changes may lead to the introduction of new DRPs.[15,16] Pharmacists mentioned not being used to send referrals and preferred to add their recommendations to a referral sent by the ward physician to the GP.[12] Yet, this study found no difference in the prevalence of medication referrals by ward physicians between the intervention and control groups, suggesting limited impact by pharmacists on treatment follow-up by GPs. In interviews, a lack of training for follow-up calls was mentioned and pharmacists questioned the cost-effectiveness of performing these calls to all patients.[11] Nonetheless, more than half of the phone calls (56%-59%) led to an action taken by the pharmacist. Selection of patients at high risk for problems after discharge and tailoring the phone calls to the individual's needs could have increased effectiveness.[17,18] Effective interventions also tend to combine follow-up calls with predischarge support[17] and are in close collaboration with other healthcare professionals.[19] Our findings suggest that we may

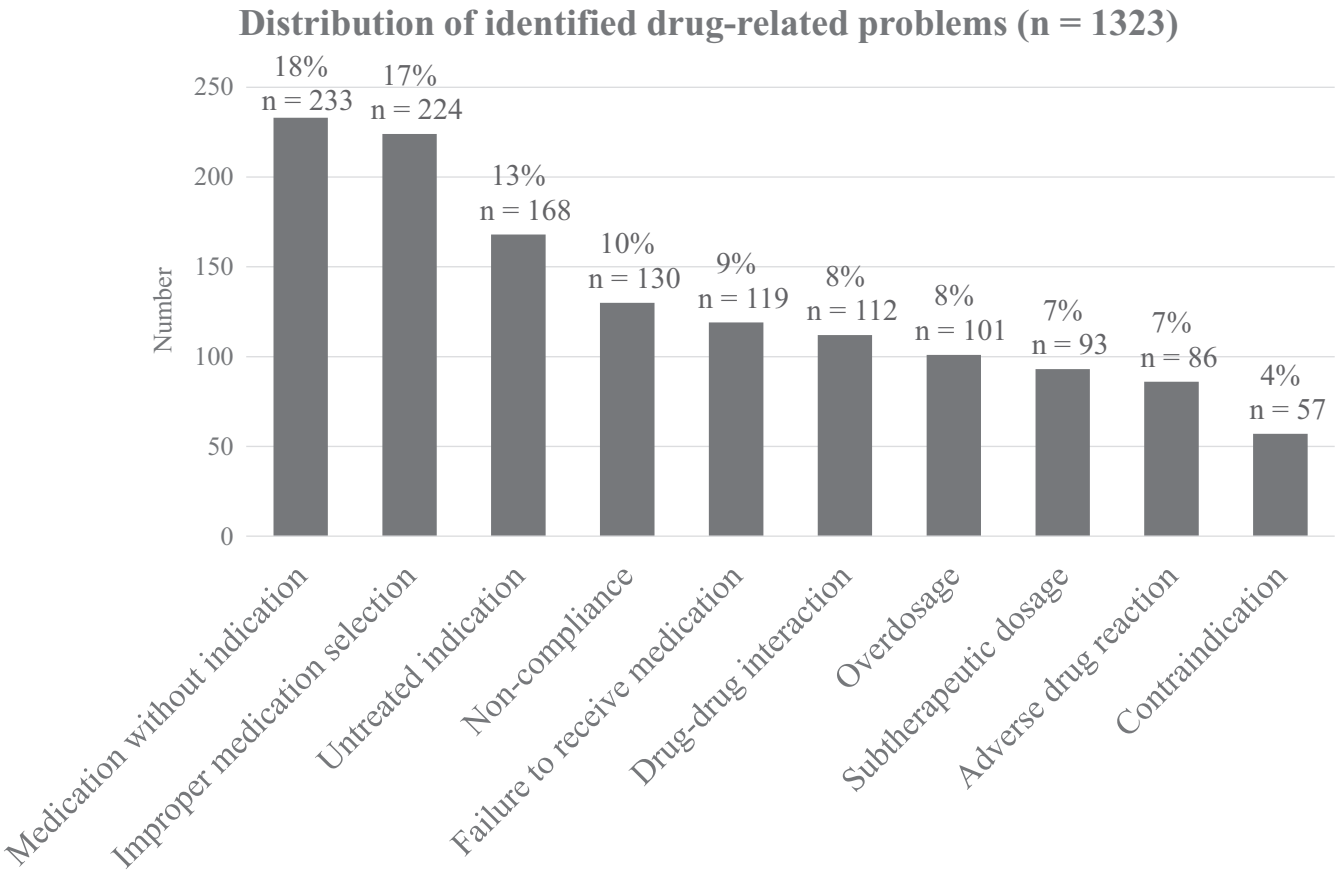

FIGURE 2 Distribution of types of identified drug-related problems (n = 1323) within the comprehensive medication reviews (n = 652)

not have been successful in combining pre- and post-discharge support through multiprofessional collaboration.

Fifteen per cent of the control patients received unintended intervention components by a clinical pharmacist, indicating a risk of contamination bias. Most contamination resulted from pharmacists conducting medication reconciliations at the emergency department at two out of four hospitals. CMRs were conducted in 2% of the control patients, which may have a limited effect on the trial's outcomes.

4.2 | Process outcomes assessment

Process outcomes assessment resulted in on average one discrepancy and two DRPs identified per CMR. The correction rate of discrepancies was 79%, and the recommendation implementation rate was 73%. Most of the patients (77%) had one or more corrected discrepancies or implemented recommendations, and medications were stopped more than twice as often as started. Still, almost a quarter of the patients did not seem to benefit from the CMR in terms of *process outcomes*. Different tools to prioritize patients for clinical pharmacy services in hospitals exist[20] and could have been used to increase effectiveness.

Systematic reviews of trials investigating the effects of medication reviews report a large variation in *process outcomes*, presumably due to differences in population, setting and research method.[21-23] Distinction between discrepancies and DRPs is often not made. However, two to three problems per patient, as in our study, are frequently reported.[21-23] Our results also confirm previous findings that medication reviews generally lead to a net decrease in medication use.[24] The correction and implementation rates in this study seem high in relation to other studies and are consistent with studies where pharmacists and physicians have face-to-face discussions on how to solve identified problems instead of solely written communication.[21,22,25] Face-to-face discussions were held in most CMRs in our trial.[12] The correction and implementation rates may have been lower at wards where physician-pharmacist collaboration was less successful. Other factors present in our study and associated with a higher number of implemented recommendations are patient or carer interviews as part of the medication review process and full accessibility of the patients' EHR.[25,26] Pharmacists generally did not discuss discrepancies and DRPs of little clinical relevance with the ward physician,[12] resulting in lower correction rates.

4.3 | Limitations

This study has some limitations. First, all results of this study are based on the interpretation of healthcare professionals' notes and other information in EHRs. Non-recorded intervention components, overlooked information and misinterpretation of written notes may have affected the quality of our results. We tried to mitigate this issue by encouraging pharmacists to record their findings as part of their daily practice. Those involved in data collection received training by the same researcher to ensure consistency, and established methods were used to classify DRPs and recommendations. Reasons for protocol deviation were highly underreported. The exact numbers per reason are therefore difficult to interpret, but it does provide an indication of the barriers experienced in clinical practice.

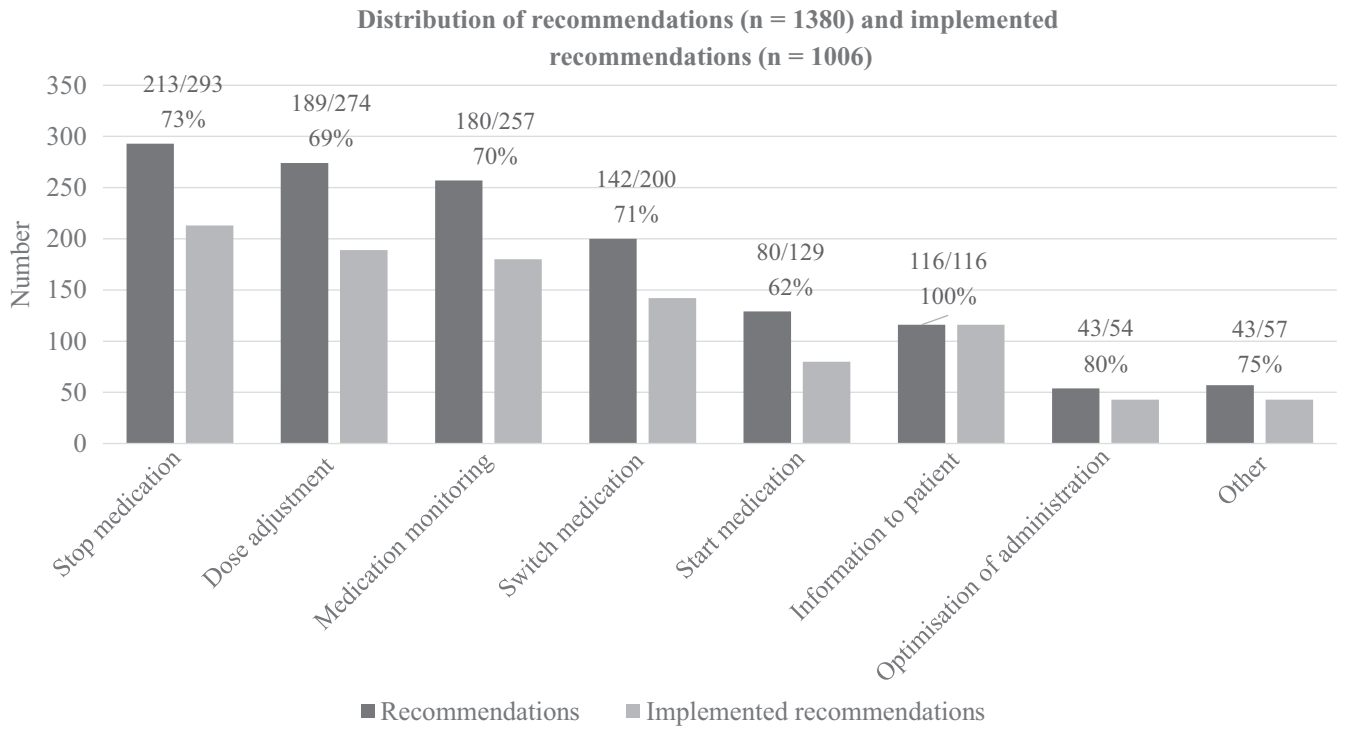

FIGURE 3 Distribution of recommendations by the pharmacists (n = 1380), implemented recommendations (n = 1006) and implementation rate per type of recommendation, within the comprehensive medication reviews (n = 652)

Second, contamination in terms of physicians or nurses performing parts of the interventions in control patients was not measured in this study. Any clinical activities without pharmacist involvement were considered usual care. It is however likely that ward staff providing usual care had previously been influenced by pharmacists during intervention periods or prior to the MedBridge trial, that is putting focus on identifying and solving DRPs in daily practice, which potentially decreases the differences in effects measured within the trial.

Third, we did not investigate the clinical relevance of corrected discrepancies and implemented recommendations. Nor did we investigate the quality of monitoring and follow-up and the extent to which patients or carers understood and agreed with these treatment changes.

4.4 | Implications for research and practice

This study addresses the importance of conducting process evaluations alongside pragmatic trials. Findings from this study and previous qualitative studies suggest that the CMRs were successfully conducted during hospital stay and resulted in medication changes, presumably optimizing patients' medication treatment. Monitoring and follow-up on these CMRs before and after discharge has however been challenging. These findings will support the interpretation of the MedBridge trial's results, which are expected in 2020.

Future initiatives to implement and improve CMRs by ward teams including a pharmacist should focus on integrating the CMR process into existing working routines, involving patients and carers and ensuring appropriate follow-up in primary care. Follow-up phone calls by pharmacists seem feasible, but better patient selection and appropriate training is needed. Furthermore, this study exemplifies that a cluster-RCT design instead of a traditional RCT may not be enough to mitigate the risk of contamination bias. The question arises whether large RCTs of CMRs in multiprofessional teams or other complex interventions are possible to conduct without contamination. It may take several years before such interventions are successfully performed in practice.[27] Throughout this process, any potential control group will subsequently be contaminated.[28]

5 | WHAT IS NEW AND CONCLUSION

The *intervention fidelity* within the MedBridge trial was high for CMRs during hospital stay and lower for intervention components upon and after discharge. The high percentage of patients with changes to their medication may explain potential effects of the CMRs in the MedBridge trial.

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CONFLICTS OF INTEREST

No conflicts of interest have been declared.

AUTHOR CONTRIBUTIONS

Contributions by each author according to the Contributor Roles Taxonomy (CRediT)[29]: Conceptualization and funding acquisition: TK, KJL, HM, EN, JS and UG; Formal analysis, project administration and writing—original draft: TK; Investigation: TK, HC and AK; Methodology: TK, HC, HM, EN and UG; Writing—review and editing: HC, AK, KJL, HM, EN, JS and UG.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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