

Medication Reviews Bridging Healthcare (MedBridge)

Study protocol for a cluster-randomised controlled trial

T.G.H. Kempen^{1,2}, M. Bertilsson³, K.J. Lindner⁴, J. Sulku^{5,6}, E.I. Nielsen⁷, A. Högberg⁶, T. Vikerfors⁸, H. Melhus², U. Gillespie^{1,2}

✉ thomas.kempen@akademiska.se

Background

Mismanaged medication prescribing and use among elderly puts major pressure on current healthcare systems. Performing a medication review, a structured, critical examination of the patient's medications, during hospital stay with active follow-up into primary care could optimise treatment benefit and minimise harm. However, a lack of high quality evidence inhibits widespread implementation. Here we present the rationale, design and preliminary results of a cluster-randomised, crossover trial (the MedBridge study) to fulfil this need for evidence.

Purpose

This study aims to assess the effectiveness of hospital-initiated comprehensive medication reviews, including active follow-up, on elderly patients compared to solely hospital based reviews and usual care.

Methods

Design: Multicentre, three-treatment, cluster-randomised, crossover trial.

Setting: Eight wards with a multidisciplinary team within four hospitals in three Swedish regions.

Participants: Patients aged 65 years or older, admitted to one of the study wards. Exclusion criteria: Palliative stage; residing in other than the three regions; medication review within the last 30 days; one-day admission. See Fig. 1.

Interventions:

1. Comprehensive medication review during hospital stay;
2. Same as 1. with the addition of active follow-up into primary care;
3. Usual care.

Primary outcome measure: Incidence of unplanned hospital visits after 12 months.

Data collection and analyses: Extraction and collection from the counties' medical record systems into a GCP compliant electronic data capture system. Intention-treat-analyses using general estimating equation techniques and frailty models, using SAS or R.

Timeframe: Inclusion: 2017-2018; follow-up: 2018-2019; analyses: 2019-2020.

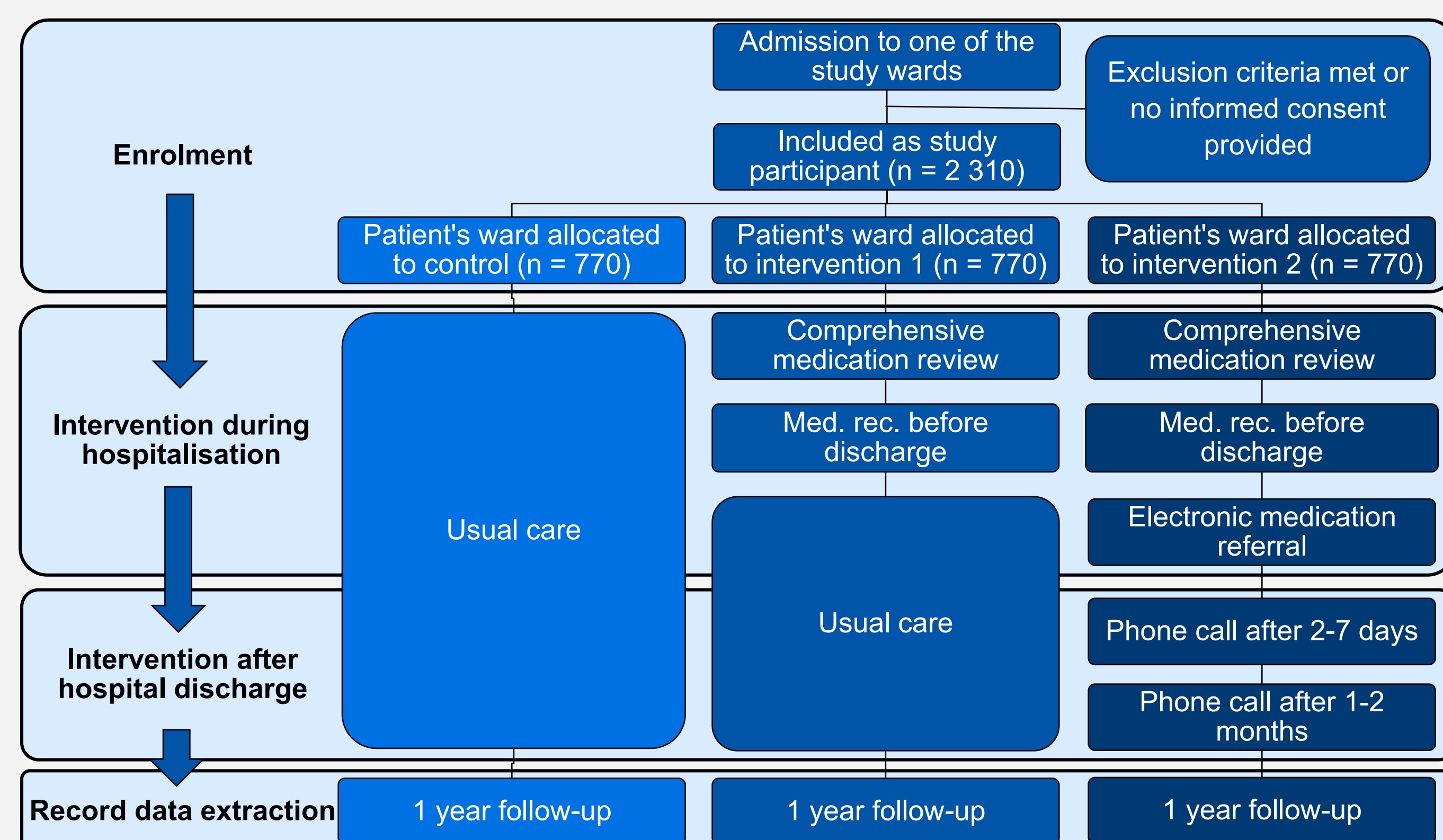


Fig. 1: Participant flow from an individual patient perspective including expected number of included patients. Med. rec. = medication reconciliation

Preliminary results

The intervention and control periods were randomly allocated as shown in Fig. 2. Within the first study period (month number 1 and 2), in total 257 patients met the in- and exclusion criteria, of which 236 (92%) provided informed consent: 126 in Uppsala and 110 in Gävle. All but two patients in the intervention groups (113 out of 115) received a comprehensive medication review during hospital stay.

Hospital	Ward	Month number (timeframe: 2017-2018)															
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Uppsala	ward 1	I2		I1		C		C		I1		I2					
	ward 2	C		I2		I1		I1		I2		C					
Gävle	ward 1	C		I2		I1		I1		I2		C					
	ward 2	I1		C		I2		I2		C		I1					
Enköping	ward 1			I1		I2		C		I1		C		I2			
	ward 2			C		I1		I2		C		I2		I1			
Västerås	ward 1					I2		I1		C		C		I1		I2	
	ward 2					I1		C		I2		I2		C		I1	

C = Control I1 = Intervention 1 I2 = Intervention 2 [] = Block randomisation

Fig. 2: Chart with the result of the block randomisation based on six periods of eight weeks per ward.

Conclusion

The MedBridge study, in which the effectiveness of hospital-initiated comprehensive medication reviews, including active follow-up, on elderly patients will be assessed, is currently progressing according to plan.

In the end, this study has a high potential to show a reduction in elderly patients' healthcare utilisation, contributing to more sustainable healthcare in the long run.

¹Medicines department, Uppsala University Hospital, Uppsala, Sweden

²Department of Medical Sciences, Uppsala University, Uppsala, Sweden

³Uppsala Clinical Research Center, Uppsala University, Uppsala, Sweden

⁴Medicines unit, Region Västmanland, Västerås, Sweden

⁵Centre for Research and Development, Uppsala University / Region Gävleborg, Gävle, Sweden

⁶Department of Development, Region Gävleborg, Gävle, Sweden

⁷Department of Pharmaceutical Biosciences, Uppsala University, Uppsala, Sweden

⁸Department of Infectious Diseases, Västerås Hospital, Västerås, Sweden