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Systematic review of patient-engagement interventions: potentials for enhancing person-centred care for older patients with multi-morbidity

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ABSTRACT

Introduction: Person-centred care based on systematic and comprehensive patient-engagement is gaining momentum across healthcare systems. Providing care that is responsive to the needs, values and priorities of each patient is important for patients, relatives and providers alike, not least for the growing population of older patients living with multi-morbidity and associated complex care trajectories.

Objectives: The aim of this systematic review is to investigate the effects of patient engagement interventions for older patients with multi-morbidity.

Methods: Systematic review. Two reviewers independently screened the international databases Embase and PubMed. Reviewers carried out duplicate and independent data extraction and assessment of study quality. GRADE (Grading of Recommendations Assessment, Development, and Evaluation) was used to assess the quality of the evidence for each study.

Results: We included ten studies with a pooled sample of 7.559 patients from primary care setting and hospitals. The included studies were heterogeneous in terms of characteristics of populations, types of interventions to enhance patient-engagement, outcome measures and length of follow-up. Eight of the ten included studies found significant improvements in health and patient-reported-outcomes such as higher quality adjusted life years, fewer hospital visits and disease specific symptoms. Quality of the included studies was of low to moderate.

Conclusion: This review identifies potential beneficial effects of interventions to enhance patient-engagement in older adults with multi-morbidity. Nevertheless, the limited evidence-base calls for more robust studies into efficient approaches to engaging older adults with multi-morbidity in care trajectories.

ARTICLE SUMMARY

Strengths and limitations of this study

- This systematic review explores the understudied field of interventions to enhance patient-engagement in the growing population of older adults with multimorbidity
- Included studies are not limited to specific health-and patient-reported outcomes in order to capture the broad effectiveness of these interventions
- Meta-analysis was not possible due to heterogeneity in methods and outcomes
- Quality of the included studies was low to moderate overall, hence there is a need for more robust studies using a range of outcomes to identify best practices in patient-engagement in the context of multi-morbidity at old age.

INTRODUCTION

Person-centred care that is responsive towards each patient's needs, values, resources and life situation is a core value in modern healthcare systems. In increasingly complex and prolonged treatment trajectories, engaging older patients in a timely, systematic and holistic manner may improve experiences and outcomes for patients and relatives, and decrease burn-out and enhance meaningfulness among healthcare professionals. Furthermore, it may support adequate use of scarce healthcare resources as treatment plans are tailored to individual needs, potentially improving engagement of more disadvantaged patients and ultimately decreasing social inequality in healthcare utilization.[1, 2]

Identifying the best care trajectory in the light of the uniqueness of each patient's circumstances is particularly important for the growing population of older patients living with multi-morbidity and associated polypharmacy requiring prolonged and complex care trajectories across care settings.[3-5] In the context of population ageing and increased multi-morbidity, more systematically and timely offered conversations with patients related to future scenarios and priorities is crucial. This includes a range of complex decisions on prognosis, treatment options and prioritizing care at the end of life driven by patient perspectives on what is acceptable and meaningful to him/her. Person-centred care requires empowered patients who are met by a responsive and accessible hospital with a culture of engagement, sufficient time, and a skill-set that nurtures daily practices based on unlocking patient perspectives and delivering coherent care to reflect these.[2, 6, 7] While there is overall agreement concerning the importance of person-centred care, there is little scientific evidence documenting significant outcomes of patient engagement regarding patient satisfaction, enhanced shared decision-making, adjustment of treatment plans, or use of resources.[8-12] A recent systematic review[13] aimed at assessing the effect of the interventions for older patients with multi-morbidity aiming to involve them in decision-making in primary care consultations found too limited evidence to interpret with certainty. The systematic review included only randomised-controlled trial's (RCT) in primary health care. To investigate this topic further we included both RCTs and non-randomised studies in primary and secondary health care setting. More focus on patient-engagement tools as interventions to enhance person-centred care in clinical encounters is needed for providing a more substantive evidence base to guide prioritization and implementation into mainstream healthcare delivery.[14] The aim of the systematic review is to investigate the current evidence for effectiveness of patient-engagement tools in enhancing person-centred care for older adults (60+ year) with more than one disease.

METHODS

Literature search and study selection

The review is based on systematic literature searches conducted in December 2019 using the databases PubMed and Embase. Furthermore, reference lists of included articles were assessed to identify additional articles. The complete list of search terms, including MESH terms and free text terms, is presented in Appendix 1.

The software DistillerSR was used to screen and review the studies. Data were independently extracted onto a customised data extraction sheet in DistillerSR by two reviewers, and any discrepancies were resolved by discussion.

The eligibility criteria for study inclusion were as follows:

- Population: Older adults above the age of 60 with more than one disease.
- Intervention: Patient engagement intervention in a hospital and primary care setting.
- Comparison groups: Older patients who received usual care.
- Outcome: Any patient-related outcome e.g. reduced symptoms of disease, reduced duration of disease, reduced costs and reduced hospital stay or rehospitalisation.

We included quantitative observational studies such as prospective and retrospective cohort studies and RCTs. Studies in any geographical area in primary care and hospitals setting were included, and only studies written in English and in one of the Scandinavian languages were included.

Two investigators independently screened the titles, abstracts and full texts for inclusion and exclusion criteria. We excluded commentaries, editorials and studies that did not directly apply a patient-engagement intervention as an exposure. We did not exclude studies based on publication date.

First, the titles of the 603 studies were screened for eligibility. Secondly, duplicates were removed. Third, the abstracts of the studies were screened. Fourth, the full texts of studies initially assessed as relevant for the review were checked against our inclusion or exclusion criteria. Disagreements between the two investigators were resolved by consensus. Figure 1 shows reasons for exclusion for potentially eligible studies.

Data extraction

Two investigators independently extracted information on characteristics of participants, study design, patient engagement intervention and outcomes. Discrepancies in data extraction were resolved by consensus between the two investigators.

Quality assessment

The included studies encompassed a combination of RCT and observational studies. To assess the quality of evidence, we used GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) for all the included studies. GRADE is a transparency framework and is the most widely adopted tool for grading the quality of evidence. The checklist assesses quality of the study across eight domains. The evidence level can be rated down or up depending on missing or existing domains. GRADE certainty ratings have four levels as follows: very low, low, moderate, high. Very low means that the true effect is probably markedly different from the estimated effect. High means that the authors have a lot of confidence that the true effect of is similar to the estimated effect,[15]. To assess the domain risk of bias within GRADE we used two different measures depending on whether the study was randomised or non-randomised. In non-randomised studies we used ROBINS-I to assess risk of bias, which is a tool to understand and appraise strengths and weaknesses in non-randomised studies.[16] In RCTs we used Cochrane Collaboration's tool for assessing risk of bias.[17] Two investigators independently performed a quality assessment of each study. Disagreements were resolved by consensus.

Patient and Public Involvement Statement

Patients were not involved in this systematic review.

RESULTS

Description of included studies

Figure 1 shows the PRISMA diagram in the phases from the 746 studies that were identified to the ten studies that met the inclusion criteria. The main reason for exclusion were due to lack of specific interventions. Table 1 depicts the characteristics of the ten included studies. The included studies were mainly RCT studies.

Table 1: Study characteristics of included studies

Study	Location	Design	Participants	Disease focus	Intervention	Setting	Endpoint
Hochhalter et al., 2010	USA	Randomised Controlled Trial	26 patients in appointment group, 27 in safety group, and 26 in usual group. Mean age 76 in appointment group, 73 in safety group and 73 in usual group.	Multiple chronic illness	Patient engagement, patient group workshop and individual coaching intervention.	Primary care clinics, Scott & White Center for Diagnostic Medicine	PAM-13, Communication with physician's scale, HRQOL-14,
Naik et al. 2019	USA	Randomised Controlled Trial	136 in the intervention group, and 89 in control group. Mean age 61	Uncontrolled diabetes and depression	Proactive population screening and telephone delivery of a collaborative goal-setting intervention	Veterans Affairs Medical Center	Change in depression symptoms using PHQ-9 and HbA1c.
Reed et al., 2018	Australia	Randomised controlled trial	114 in the intervention group, and117 in the control group. Age range: 60+	Multiple chronic conditions	Self-management support program for older with multiple chronic conditions	General practices	Self-rated health
Salisbury et al., 2018	England and Scotland	Cluster-randomised trial	797 patients in the intervention group, and 759 in the usual care group. Mean age 71 in intervention group and 70,7 in the usual care group.	Multimorbidity	Patient-centered strategies for management of multimorbidity, 3D intervention	General practices	Eq-5d-5l

Study	Location	Design	Participants	Disease focus	Intervention	Setting	Endpoint
Shively et al. 2013	USA	Randomised, 2-group, repeated-measures design	43 patients in the Intervention group, and 41 I the group with usually care. Mean age 66,1 years.	Heart failure	Patient activation intervention compared with usual care in patients with Heart failure	Veterans Affairs San Diego Healthcare System	Patient Activation Measure, (PAM), Self-Care of Hearth Failure Index (SCHIF), Medical Outcomes Study (MOS)
Tay et al. 2018	Singapore	Prospective cohort study	170 in the intervention group and 60 in the control group. Mean age in the intervention group is 82 years and 84 years in control group.	Dementia	Person-centered care in Care for Acute Mentally Infirm Elders (CAMIE)	Hospital	Well-being (WB) Ill-being (IB) Pittsburg Agitation Scale (PAS) Modified Barthel Index (MBI) EQ-5D Index Score
Tinsel et al. 2013	Germany	Cluster Randomised Controlled Trial	552 patients in the intervention group, and 568 in the control group. Mean age 63,8 in intervention group and 65 in control group.	Hypertension	Shared decision-making in General practice with patients with uncontrolled hypertension	General practice	SDM-Q-9, systolic blood pressure
Ulin et al. 2016	Sweden	Controlled before-and-after design	125 patients in the intervention group, and 123 in control group. Mean age range: 77-80.	Chronic Heart failure	Gothenburg Person-centered care (gPCC) in patients hospitalized	Department of Medicine at Sahlgrenska University Hospital/Östra in Gothenburg	Number of days from admission to 1. first notice to the municipality 2. second notice to the municipality 3. notice to the municipality that the patient was

Study	Location	Design	Participants	Disease focus	Intervention	Setting	Endpoint
							ready for discharge from hospital.
Wong et al. 2014	Hong Kong	Observational matched cohort study	1.141 in the intervention group and 1.141 in the control group. Mean age 64.	Type 2 diabetes mellitus	Patient Empowerment Program in General Outpatient Clinics (GOPC)	General Outpatient Clinics (GOPC)	HbA1c, Systolic blood pressure (SBP), Diastolic blood pressure (DBP), LDL-cholesterol
Willadsen et al. 2018	Denmark	Randomised Controlled Trial	970 patients in the intervention group and 539 in the group with usual care. Mean age 64,7 in intervention group and 64,5 I usual care group.	Diabetes	Structured personnel care in patients with diabetes	General practice	Self-rated health, diabetes symptoms

This systematic review is based on a pooled sample of 7559 patients, from the ten included studies. The sample sizes ranged widely across studies (mean: 756 patients, median 231/248 patients, range 79-2282). Four studies (40%) were conducted in the Europe, three (30%) in US, and three (30%) elsewhere. The most common study design was RCT (n=7; 70%) followed by Cohort/observational (n=3; 30%). Most studies were conducted in primary care setting (n=6; 60%). A total of four studies (40%) were conducted in general hospitals involving patients from a range of specialties. In the studies, the participants have many different diseases such as diabetes, chronic heart failure, dementia etc. The mean age in the studies was +60 years with a range: 60- 84 years, however, there were two studies that did not indicate the mean age but included an 18+ year population with most 60+ years.

Four studies included a population with two or more chronic diseases. Three studies included people with diabetes and at least one comorbidity. Three studies included people with one main disease and other comorbidities.

The included studies used different patient engagement interventions such as goal setting interventions and disease-specific sessions. Different types of primary outcomes were used in studies such as Patient Activations Measurements (PAM), Self-Rated health (SRH) and EQ-5D.

Quality of included studies

Figure 2 shows the quality assessment for each included study. Three studies were assessed to be of high quality in all domains apart from one, which was judged to be low or moderate. An additional three studies were assessed to be of high quality apart from two domains, which was judged to be low or moderate. The last four studies were only judged to be of high quality in one or none of the five domains.

Risk of bias for RCTs is shown in figure 3. All studies had high risk of bias due to blinding of participants and personnel (performance bias). Furthermore, four studies were rated to high risk of blinding of outcome assessment (detection bias).[18-21]

Figure 4 show risk of bias for non-randomised studies. Two studies were rated to have high risk of bias, and one study was rated moderate risk of bias. One study had high risk of bias due to confounding,[22] and another study had high risk of bias due to deviations from intended intervention.[23] The study rated to moderate risk of bias had moderate risk of bias in five categories.[24] All three studies had unclear risk of bias in more than one category.

In total, the quality of the included studies was of low to moderate and some aspects of quality assessment and risk of bias were unclear across the included studies.

Effect of the interventions

The included studies are using different endpoints to measure the effect of patient engagement interventions. Eight of the included studies found significant effect of interventions.

A RCT by Naik[25] measure the effect of the intervention Healthy Outcomes Through Patient Empowerment (HOPE) which is a six-months goal-setting intervention targeting depression symptoms and diabetes self-care through nine telephone-delivered coaching sessions. The HOPE intervention used an electronic data warehouse to identify specific high-risk population, followed by telephone screening and training of clinicians to deliver a structured telehealth intervention. The endpoints in this study was depression symptoms with The Patient Health Questionnaire (PHQ)-9 and glycaemic control with haemoglobin A1c (HbA1c). They did not find any improvement in six-month follow-up, but found improvement in PHQ-9 after 12-month follow-up; HOPE (Mean [SD] baseline: 15,8 [4,2] to six months: 10,9 [6,1] and 12 months 10,1 [6,5]) compared with Enhanced Usual Care (EUC) (Mean [SD] baseline 16,2 [4,0] to six months 12,4[6,0]) and 12 months 12,6 [6,0]. The PHQ-9 differences between HOPE and EUC were statistically significant at six months (mean diff., 1.74; 95% CI, 0.14-3.33; P = 0.03) and 12 months (mean diff., 2.14; 95% CI, 0.18-4.10; P = 0.03).

The study by Reed[26] examined the effect of the intervention Chronic Disease Self-Management Support (CDSMS) which is a set of tools (Partners in Health scale, Cue and Response interview, Problems and Goals assessment) and a structured process that enable clinicians and patients to collaboratively assess self-management behaviour, identify problems, set goals, and develop individual care plans that address key self-care, medical, psychosocial, and care problems. Participants in each program received three home visits and four follow-up phone calls over a six-month period from a clinician. The population were recruited from five general practices in Adelaide, Australia. The study used self-rated health as endpoint, and they with an intention-to-treat analysis that CDSMS participants were more likely than control participants to report improved self-rated health at six months (R, 2.50; 95% confidence interval, 1.13-5.50; P = 0.02).

A RCT by Shively[19] implemented a six month program developed to enhance self-management in older heart failure patients. The program consisted of individualized goal setting according to baseline activation level. The interventions population was invited to participate through a follow-up visit at the Veterans Affairs San Diego Healthcare system. The study used Patient Activation Measure (PAM), Self-Care of Heart Failure Index (SCHFI), Medical Outcomes Study (MOS), and hospital visits to measure the effect of the intervention. The intervention showed improvement in PAM-score, the intervention group compared with

the usual care group showed a significant increase in PAM-scores from baseline to six months (significant group by time interaction, F = 3.73, P = 0.03) and fewer hospital visits compared with usual group.

A prospective naturalistic cohort study by Tay[22] examined the effect of the intervention Care for Acute Mentally Infirm Elders (CAMIE) which adopt a person-centred care protocol with specialized psychosocial interventions, minimally obtrusive medical care, and physical restraints-free practice targeting patients with dementia. The study population were recruited at a hospital, and all patients received standard treatment. Patients were admitted to the CAMIE unit if they suffered from confusion due to dementia, with/without delirium based on the confusion assessment method criteria, and concomitant acute medical problems. The study used Modified Barthel Index function and Well-being and European Quality of Life (EuroQol) to measure the CAMIE intervention. CAMIE patients showed statistically significant greater gains in Modified Barthel Index function (mean [SD] baseline 47.31 [28.90] to 55.58 [29.37]) and well-Being (mean [SD] baseline 4.94 [3.95] to 8.46 [3.49]), decreased ill-Being and agitation (mean [SD] baseline 3.04 [2.11] to 0.84 [1.26]), and greater improvement in EuroQoL index score (mean [SD] baseline -0.16 [0.43] to 0.15 [0.41]) after adjusting for baseline differences that translated to a quality-adjusted life years gain of 0.045, assuming stability over three months.

A controlled before-and-after design by Ulin et al[24] studied the effect of proactive care-planning based on Gothenburg Person-Centred Care (gPCC). It seeks to identify patient's resources including motivations and goals. This information is used to develop a health plan which includes planned investigations, length of stay in hospital and treatment goals. The health plan is discussed with the patient to reach consensus and the plan is regularly evaluated. The population were recruited from five designated wards at a University Hospital in Sweden. The patients were assessed by a specialised cardiologist before final inclusion, guided by the European Society of Cardiology (ESC) guidelines for diagnosing Congestive Heart Failure (CHF). The study used discharge destination and number of days until the discharge was recorded, to measure the gPCC intervention. They found improved discharge processes (1-5 days for gPCC group vs 1-28 days for control group), and fewer days in hospital (11 days for gPCC group vs 35 days for control group).

A RCT by Willadsen[27] examined the effect of structured personal diabetes care with general practitioners (GPs) that ask GPs and patient to agree on the best possible goal for controlling risk factors. GPs were offered six seminars and were instructed to give advice lifestyle. Patients were invited to attend follow-up examination quarterly and screening for diabetes complications every year. The study used self-rated health and diabetes symptoms to measure the effect of the structured person care intervention. They found that the intervention reduced the diabetes symptoms (OR 0.79; 95% CI: 0.64–0.97), but they didn't find the same after 14 years follow-up.

An observational matched cohort study by Wong[23] implemented a Patient Empowerment Programme (PEP) that aims to provide patient with knowledge and skills about their disease Type 2 Diabetes (T2DM) and to facilitate autonomous self-regulation. The program consisted of generic sessions about self-efficacy enhancement and lifestyle modification as well as disease-specific sessions for a period of up to 12 months. Two non-government organisations (NGO) delivered the intervention, the NGO's invited at general outpatients' clinics or family medicine specialist eligible patients to join the PEP. The study used HbA1c, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), and Low-Density Lipoprotein (LDL-C) to measure the effect of PEP. They found improvement in the clinical outcomes. A significantly greater percentage of patients in the PEP group attained HbA1C ≤7% or LDL-C≤2.6 mmol/L at 12-month follow-up compared with the non-PEP group. PEP group had a mean 0.813 fewer General Outpatient Clinic (GOPC) visits in comparison with the non-PEP group.

A study by Hochhalter[21] measured the effect of Making the Most of Your Healthcare intervention which offered tools and taught skills to (a) prepare for healthcare appointments, (b) communicate effectively and gather information and support during healthcare appointments, and (c) follow through on plans of care. The intervention included a two-hour workshop and two telephone calls individualized to the patient's pre- and post-healthcare appointment needs. The included population were patients in a large Internal Medicine Clinic and had been treated for at least two of seven chronic illnesses. They found a statistically significant improvement in self-efficacy for the intervention group, who received a 2-hour workshop. They used PAM-13 and Health Related Quality of Life (HRQOL)-14 questionnaires as measurement. They found an improvement in Self-Efficacy in the Appointment group (mean [SD] baseline 6,9 [1,9] to 7,4 [1,8]) mean diff. 0,47 95%CI; 0,07-0,87 P = 0,021. They did not find any improvement in health for the control group or safety group.

Whereas the studies described above did show some improvements of patient-engagement interventions in multi-morbid older patients based on a range of outcomes, the following two studies did not find any significant improvements in health outcomes.

A pragmatic cluster-randomised trial by Salisbury[20] examined the effect of the so-called 3D intervention which is based on a patient-centred care model and seeks to improve continuity, coordination, and efficiency of care by replacing disease-focused reviews of each health condition with one 6-monthly comprehensive multidisciplinary review. Each 3D review consists of two appointments with a nurse and a named responsible physician and a records-based medication review by a pharmacist. The population were recruited from three general practices providing National Health Service (NHS) primary medical in England and Scotland. They measured quality of life with a 5Q-5D-5L questionnaire. The intention-to-treat analysis

showed no difference between trial groups (adjusted difference in mean EQ-5D-5L 0.00, 95% CI –0.02 to 0.02; p=0.93). They concluded the intervention did not improve the participant's quality of life.

The study by Tinsel[18] implemented a shared decision-making (SDM) training program that aims to enhance the active role of patients. The program included disease information, physician-patient communication, steps of SDM, motivational interviewing, decision table listing, and role plays simulating consultations. The GP's followed a SDM training programme, and the study population was conducted through GP's in southwest Germany. They used change of patients' perceived participation (SDM-Q-9) and change in systolic blood pressure (BP). According to the mixed model analysis, the average change from T0 was 3.11 points higher in the intervention group than in the control group (97.5% CI [−2.37; 8.61], p = 0.203). The effect was not significant at the (Bonferroni-corrected) 2.5% level. They did not find any statistically significant improvement in systolic BP.

DISCUSSION

Statement of principal findings

This systematic review aimed to provide an overview of the effects of patient engagement interventions for older patients with multi-morbidity. From the 746 studies identified, only ten studies met the inclusion criteria. The included studies were heterogeneous in characteristics of populations, number of participants, types of interventions to enhance patient-engagement, length of follow-up and outcome measures. The majority of studies showed improvements in health and patient-reported outcomes among patients exposed to patient engagement interventions. There was some evidence to indicate that the clinical outcomes (BP, Hba1c, diabetes symptoms and glycaemic outcomes) were improved. Furthermore, some evidence indicates improvements in quality of life (EuroQol, QALY, self-rated health) and fewer health care visits (hospitals, GOPC). However, one study found no significant improvements in quality of life and another study found no significant improvements in BP. As indicated by the limited number of studies and the wide heterogeneity in characteristics of populations, types of interventions to enhance patient-engagement, outcome measures and length of follow-up, there is a need for more substantial studies evaluating patient-engagement tools for both implementation and effect in older patients with multi-morbidity using more longer-term outcomes to capture both patient, provider and system-level effects of patient-engagement. While our review adds to the important field of ensuring that interventions to enhance patient-engagement are developed, implemented and evaluated specifically in the growing

population of older adults living with multi-morbidity, the review supports previous work in finding too fragile evidence for robust conclusions to be made.[8-13]

Strengths

This review has several strengths. This review contributes to providing a more substantive evidence base to guide prioritisation and implementation into mainstream healthcare delivery. Since patient-engagement aims at improving care overall, this review did not restrict itself to studies based on particular health outcomes, and consequently studies into a range of health and patient-reported outcomes were included. Another strength is that the systematic literature search that was undertaken adhering to a pre-specified protocol. To standardise our assessment process, we used DistillerSR to upload the bibliographic reference information. We performed a wide search to allow different study designs to include methodological heterogeneity. However, the majority of the included studies were RCT. Two researchers independently selected studies collected data and rated quality of included studies using GRADE method. Discrepancies were resolved by consensus. We used a transparent framework for developing and presenting summaries of evidence. GRADE is the most widely adopted tool for grading the quality of evidence.

Limitations

Despite of the systematic approach adopted; this review has its limitations. The literature search was completed using two key databases, but additional articles might have been found by searching and including from a broader range of sources. Relevant articles were excluded if they were published in languages other than English, Danish, Swedish, or Norwegian. A minority of the included studies had small participant numbers which might have affected power of the studies. Two studies included less than 100 patients in total. Meta-analysis was not conducted as there was heterogeneity in the outcomes and measurement tools used in the studies. Overall, the quality of the included studies was of low to moderate. Some aspects of quality assessment and risk of bias were unclear across the included studies. This complicates the overall quality assessment. Furthermore, we did not seek clarification with the study authors about whether our assessment of risk of bias in the individual studies was correct.

Implications

This review has highlighted the possible improvements in health and patient-reported outcomes among patients exposed to patient-engagement interventions. However, the evidence base is inconsistente and the quality of the studies is relatively low. Further high quality studies in larger populations over longer time-periods are needed to investigate the long-term effect of patient-engagement interventions.

CONCLUSION

This systematic review found only limited evidence to support the improvements in health and patient-reported outcomes among older multi-morbid patients exposed to patient-engagement interventions. As the quality of the included studies was mostly low, the findings should be interpreted with caution, and there is a need for more robust studies into efficient approaches to engaging older adults with multi-morbidity in care trajectories.

DECLARATION OF CONFLICTING INTERESTS

The authors declare no potential conflicts of interest with respect to the research, authorship and/or publication of this article

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AUTHOR CONTRIBUTIONS

MBS and KA contributed equally to this paper. MK, MBS and KA designed the study. MBS and KA carried out data collection and analysis. All authors contributed to drafting the manuscript. All authors have read and approved the manuscript.

DATA AVAILABILITY STATEMENT

Data from the literature search and selection process are available upon reasonable request to the corresponding author.

FIGURES

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Figure 1: Flowchart

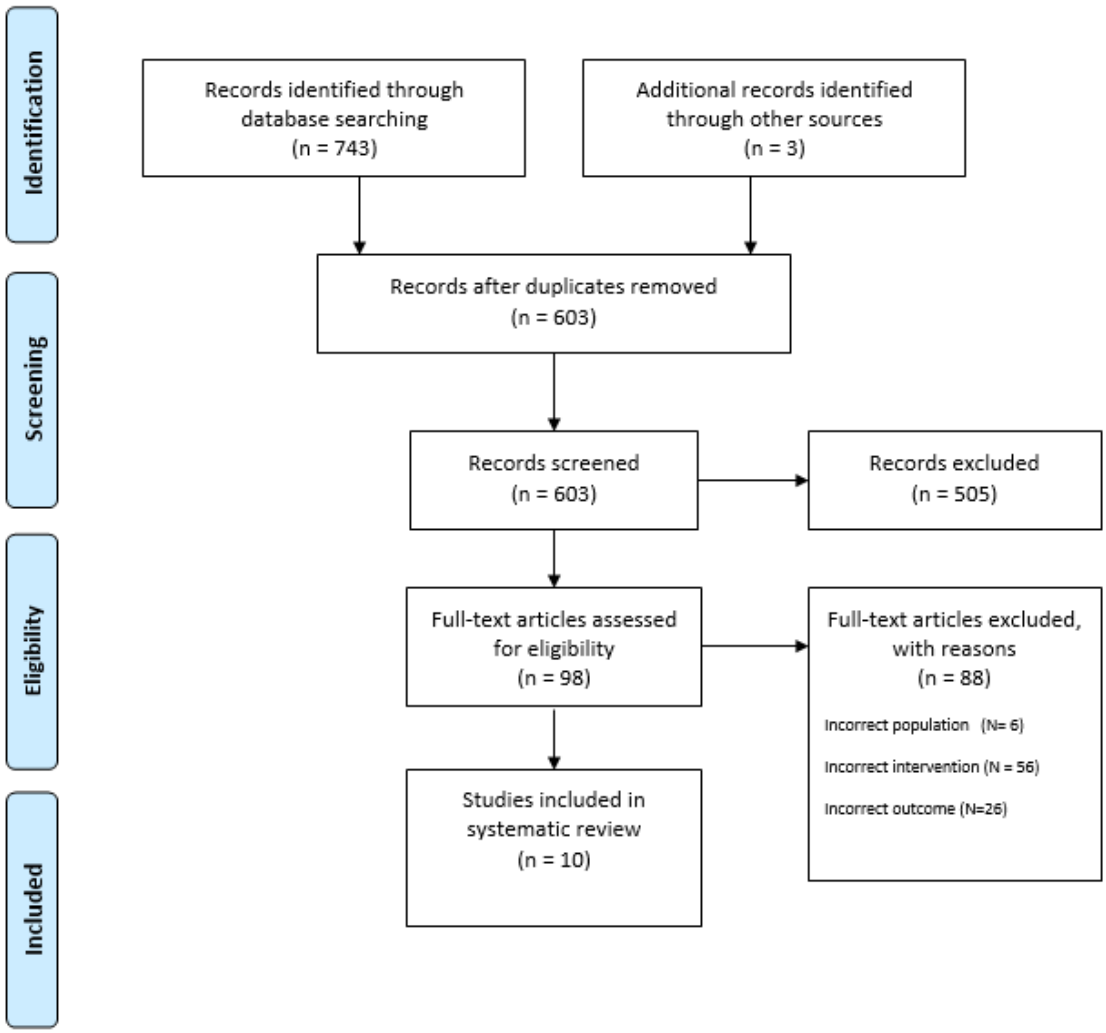


Figure 2: Total GRADE

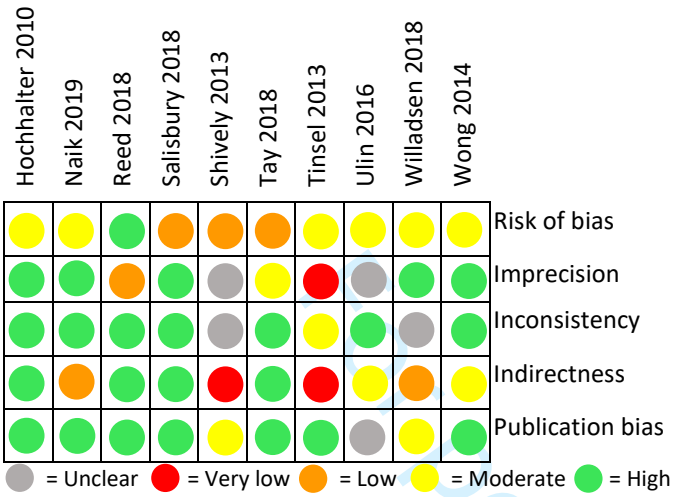


Figure 3: Risk of bias for randomised studies

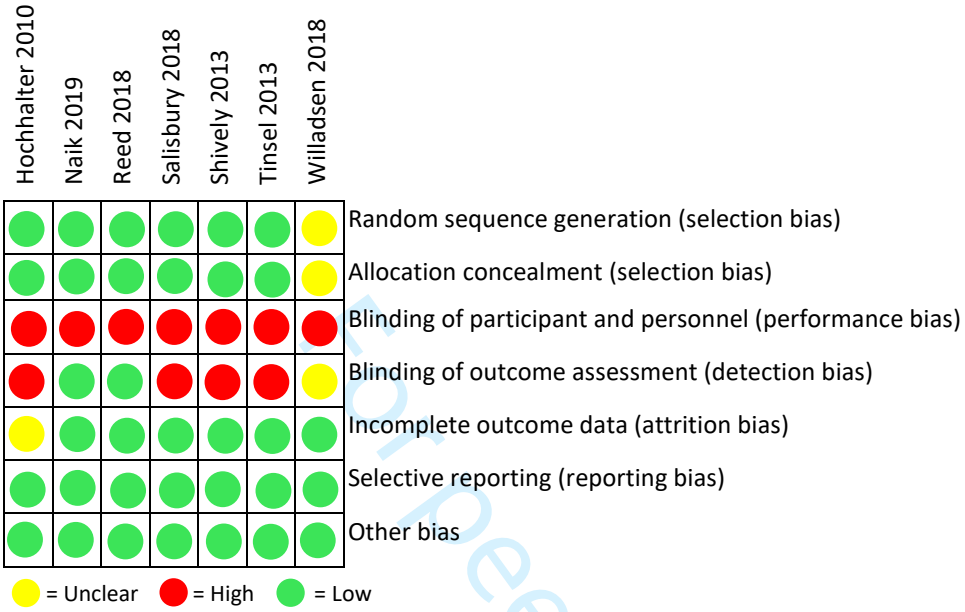
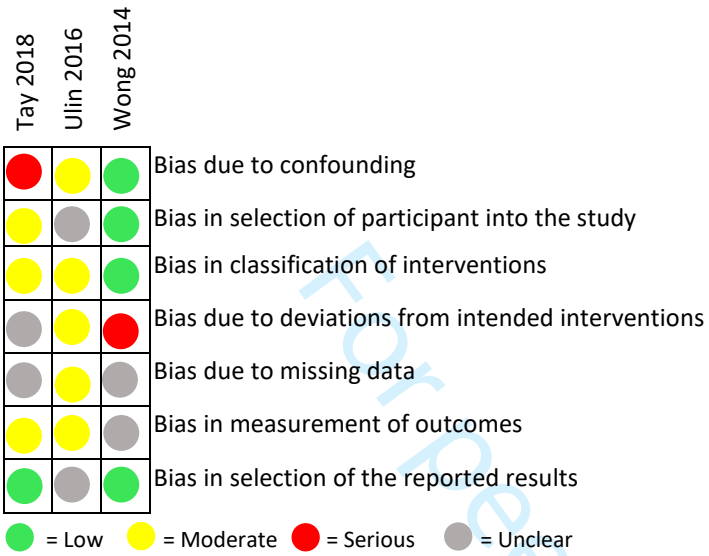


Figure 4: Risk of bias for non-randomised studies



Appendix 1: Keywords

Aspect 1: Patient engagement	**AND**	**Aspect 2:** Multimorbidity	**AND**	**Aspect:** Elderly
Person-centered care		Multimorbidity (MeSH)		Aged (MeSH)
OR		OR		OR
Person centered care		Multi-morbidity		Aged
OR		OR		OR
Patient engagement		Multimorbidity		Elderly
OR		OR		OR
Patient empowerment		Multi-morbidities		Older adult
OR		OR		OR
Patient involvement		Multi morbidities		Older adults
OR		OR		
Patient participation (MeSH)		Comorbidity (MeSH)		
		OR		
		Comorbidity		
		OR		
		Co-morbidity		
		OR		
		Comorbidities		
		OR		
		Co-morbidities		
		OR		
		Multiple chronic conditions (MeSH)		

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6-10
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	6, 10
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6, Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6-10
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	10
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	11-14
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Figure 3 and 4
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	14-15
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	15
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	15-16
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	16

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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Systematic review of patient-engagement interventions: potentials for enhancing person-centred care for older patients with multi-morbidity

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Systematic review of patient-engagement interventions: potentials for enhancing person-centred care for older patients with multi-morbidity

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KEYWORDS: PUBLIC HEALTH, GERIATRIC MEDICINE, QUALITY IN HEALTH CARE

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ABSTRACT

Introduction: Person-centred care based on systematic and comprehensive patient-engagement is gaining momentum across healthcare systems. Providing care that is responsive to the needs, values and priorities of each patient is important for patients, relatives, and providers alike, not least for the growing population of older patients living with multi-morbidity and associated complex care trajectories.

Objectives: The aim of this systematic review is to investigate the effects of patient engagement interventions for older patients with multi-morbidity.

Methods: Systematic review conducted in August 2021. Two reviewers independently screened the international databases Embase and PubMed. Reviewers carried out duplicate and independent data extraction and assessment of study quality. GRADE (Grading of Recommendations Assessment, Development, and Evaluation) was used to assess the quality of the evidence for each study.

Results: We included twelve studies from primary care setting and hospitals. The included studies were heterogeneous in terms of characteristics of populations, types of interventions to enhance patient-engagement, outcome measures and length of follow-up. Nine of the twelve included studies found significant improvements in health and patient-reported-outcomes such as higher quality adjusted life years, fewer hospital visits and disease specific symptoms. Quality of the included studies was of low to moderate.

Conclusion: This review identifies potential beneficial effects of interventions to enhance patient-engagement in older adults with multi-morbidity. Nevertheless, the limited and very diverse evidence-base calls for more robust studies into efficient approaches to engaging older adults with multi-morbidity in care trajectories.

ARTICLE SUMMARY

Strengths and limitations of this study

- This systematic review explores the understudied field of interventions to enhance patient-engagement in the growing population of older adults with multi-morbidity
- Included studies are not limited to specific health-and patient-reported outcomes in order to capture the broad effectiveness of these interventions
- Meta-analysis was not possible due to heterogeneity in methods and outcomes
- Quality of the included studies was low to moderate overall, hence there is a need for more robust studies using a range of outcomes to identify best practices in patient-engagement in the context of multi-morbidity in old age.

INTRODUCTION

Person-centred care is defined as care that is based on elicitation of and responsiveness to the individual patient's needs, values, resources and life situation.[1] In increasingly complex and prolonged treatment trajectories, engaging older patients in a timely, systematic and holistic manner may improve experiences and outcomes for patients and relatives, and enhance meaningfulness among healthcare professionals. Furthermore, it may support adequate use of scarce healthcare resources as treatment plans are tailored to individual needs, potentially improving engagement of more disadvantaged patients and ultimately decreasing social inequality in healthcare utilization.[2, 3]

Identifying the best care trajectory in the light of the uniqueness of each patient's circumstances is particularly important for the growing population of older patients living with multi-morbidity, defined as patients living with two or more co-existing long term conditions,[4] and associated polypharmacy requiring prolonged and complex care trajectories across care settings.[5-7] In the context of population ageing and increased multi-morbidity, more systematically and timely offered conversations with patients related to future scenarios and priorities is crucial. This includes a range of complex decisions on prognosis, treatment options and prioritizing care at the end of life driven by patient perspectives on what is acceptable and meaningful to him/her. Person-centred care requires empowered patients who are met by a responsive and accessible hospital with a culture of engagement, sufficient time, and a skill-set that nurtures daily practices based on unlocking patient perspectives and delivering coherent care to reflect these.[3, 8, 9] While there is overall agreement concerning the importance of person-centred care, there is little scientific evidence documenting significant outcomes of patient engagement regarding patient satisfaction, enhanced shared decision-making, adjustment of treatment plans, or use of resources.[10-14] A recent systematic review[15] aimed at assessing the effect of the interventions for older patients with multi-morbidity aiming to involve them in decision-making in primary care consultations found too limited evidence to interpret with certainty. The systematic review included only randomised-controlled trial's (RCT) in primary health care. To investigate this topic further we included both RCTs and non-randomised studies in primary and secondary health care setting. More focus on patient-engagement tools as interventions to enhance person-centred care in clinical encounters is needed for providing a more substantive evidence base to guide prioritization and implementation into mainstream healthcare delivery.[16] The aim of the systematic review is to investigate the current evidence for effectiveness of patient-engagement tools in enhancing person-centred care for older adults (60+ year) with more than one disease.

METHODS

Literature search and study selection

The review is based on systematic literature searches conducted in August 2021 using the databases PubMed and Embase. Furthermore, reference lists of included articles were assessed to identify additional peer-reviewed articles. The complete list of search terms, including MESH terms and free text terms, is presented in Appendix 1.

The software DistillerSR was used to screen and review the studies. Data were independently extracted onto a customised data extraction sheet in DistillerSR by two reviewers, and any discrepancies were resolved by discussion.

The eligibility criteria for study inclusion were as follows:

- Population: Older adults above the age of 60 living with two or more co-existing diseases.
- Intervention: Patient engagement intervention in health care system settings.
- Comparison groups: Older patients who received usual care.
- Outcome: Any patient-related outcome e.g. reduced symptoms of disease, reduced duration of disease, reduced costs and reduced hospital stay or rehospitalisation.

We included quantitative observational studies such as prospective and retrospective cohort studies and RCTs. Studies in any geographical area in health care systems, thus encompassing both primary and secondary care settings, were included, and only studies written in English and in one of the Scandinavian languages (Danish, Swedish or Norwegian) were included.

Two investigators independently screened the titles, abstracts and full texts for inclusion and exclusion criteria. We excluded commentaries, editorials and studies that did not directly apply a patient-engagement intervention as an exposure. We did not exclude studies based on publication date.

First, the titles of the 805 studies were screened for eligibility. Secondly, duplicates were removed. Third, the abstracts of the studies were screened. Fourth, the full texts of studies initially assessed as relevant for the review were checked against our inclusion or exclusion criteria. Disagreements between the two investigators were resolved by consensus. Figure 1 shows reasons for exclusion for potentially eligible studies.

Data extraction

Two investigators independently extracted information on characteristics of participants, study design, patient engagement intervention and outcomes. Discrepancies in data extraction were resolved by consensus between the two investigators.

Quality assessment

The included studies encompassed a combination of RCT and observational studies. To assess the quality of evidence, we used GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) for all the included studies. GRADE is a transparency framework and is the most widely adopted tool for grading the quality of evidence. The checklist assesses quality of the study across eight domains. The evidence level can be rated down or up depending on missing or existing domains. GRADE certainty ratings have four levels as follows: very low, low, moderate, high. Very low means that the true effect is probably markedly different from the estimated effect. High means that the authors have a lot of confidence that the true effect of is similar to the estimated effect,[17]. To assess the domain risk of bias within GRADE we used two different measures depending on whether the study was randomised or non-randomised. In non-randomised studies we used ROBINS-I to assess risk of bias, which is a tool to understand and appraise strengths and weaknesses in non-randomised studies.[18] In RCTs we used Cochrane Collaboration's tool for assessing risk of bias.[19] Two investigators independently performed a quality assessment of each study. Disagreements were resolved by consensus.

Patient and Public Involvement Statement

Patients were not involved in this systematic review.

RESULTS

Description of included studies

Figure 1 shows the PRISMA diagram in the phases from the 805 studies that were identified to the twelve studies that met the inclusion criteria. The main reason for exclusion were due to lack of specific interventions. Table 1 depicts the characteristics of the twelve included studies. The included studies were mainly RCT studies.

Table 1: Study characteristics of included studies

Study	Location	Design	Participants	Multi-morbidity	Intervention	Setting	Endpoint
Hochhalter et al., 2010	USA	Randomised Controlled Trial	26 patients in appointment group, 27 in safety group, and 26 in usual group. Mean age 76 in appointment group, 73 in safety group and 73 in usual group	At least two of the following chronic illnesses: arthritis, lung disease, heart disease, diabetes, hypertension, depression, or osteoporosis	Patient engagement, patient group workshop and individual coaching intervention	Primary care clinics, Scott & White Center for Diagnostic Medicine	PAM-13, Communication with physician's scale, HRQOL-14
Mateo-Abad et al. 2020	Spain	Quasi-experimental study	101 patients in the intervention group and 99 patients in the usual care group. Mean age 79	A minimum of two chronic diseases, with at least one of them being chronic obstructive pulmonary disease (COPD), diabetes mellitus, or chronic heart failure (CHF)	Care coordination and communication between health providers and patient empowerment and home-based care; all supported by ICT-based platforms	Integrated care organisations	Use of services, clinical variables (such as BMI, blood pressure, heart rate, blood glucose), Geriatric depression scale (GDS), Functional status (Barthel Index)
Naik et al. 2019	USA	Randomised Controlled Trial	136 in the intervention group, and 89 in control group. Mean age 61	Uncontrolled diabetes and depression	Proactive population screening and telephone delivery of a collaborative goal-setting intervention	Veterans Affairs Medical Center	Change in depression symptoms using PHQ-9 and HbA1c
Reed et al., 2018	Australia	Randomised controlled trial	114 in the intervention group, and117 in the control group. Age range: 60+	At least two chronic diseases	Self-management support program for older with multiple chronic conditions	General practices	Self-rated health
Salisbury et al., 2018	England and Scotland	Cluster-randomised trial	797 patients in the intervention group, and 759 in the usual care group. Mean age 71 in intervention group and 70,7 in the usual care group	At least three types of chronic conditions	Patient-centered strategies for management of multi-morbidity, 3D intervention	General practices	Eq-5d-5l
Schwarze et al. 2020	USA	Randomised controlled trial	223 patients in the intervention group, and 223 patients in the usual care group. Mean age 71 in intervention group and 72.6 in usual care group	At least one comorbidity and an oncologic or vascular problem	Question prompt list brochure targeting informational needs of patients considering major surgery	Surgeons' clinics	Number of questions asked by patients and family during the recorded visit, Perceived Efficacy in Patient-Physician Interactions (PEPPI-5), Measure Yourself Concerns and Well-being (MYCaW)

Study	Location	Design	Participants	Multi-morbidity	Intervention	Setting	Endpoint
Shively et al. 2013	USA	Randomised, 2-group, repeated-measures design	43 patients in the Intervention group, and 41 I the group with usually care. Mean age 66,1 years	Heart failure and comorbidities	Patient activation intervention compared with usual care in patients with Heart failure	Veterans Affairs San Diego Healthcare System	Patient Activation Measure, (PAM), Self-Care of Hearth Failure Index (SCHIF), Medical Outcomes Study (MOS)
Tay et al. 2018	Singapore	Prospective cohort study	170 in the intervention group and 60 in the control group. Mean age in the intervention group is 82 years and 84 years in control group	Dementia and comorbidities	Person-centered care in Care for Acute Mentally Infirm Elders (CAMIE)	Hospital	Well-being (WB) Ill-being (IB) Pittsburg Agitation Scale (PAS) Modified Barthel Index (MBI) EQ-5D Index Score
Tinsel et al. 2013	Germany	Cluster Randomised Controlled Trial	552 patients in the intervention group, and 568 in the control group. Mean age 63,8 in intervention group and 65 in control group	Hypertension and at least one relevant comorbid disorder (diabetes mellitus, coronary heart disease, heart attack, stroke, or peripheral arterial occlusive disease)	Shared decision-making in General practice with patients with uncontrolled hypertension	General practice	SDM-Q-9, systolic blood pressure
Ulin et al. 2016	Sweden	Controlled before-and-after design	125 patients in the intervention group, and 123 in control group. Mean age range: 77-80	Chronic heart failure and comorbidities	Gothenburg Person-centered care (gPCC) in patients hospitalized	Department of Medicine at Sahlgrenska University Hospital/Östra in Gothenburg	Number of days from admission to 1. first notice to the municipality 2. second notice to the municipality 3. notice to the municipality that the patient was ready for discharge from hospital
Wong et al. 2014	Hong Kong	Observational matched cohort study	1.141 in the intervention group and 1.141 in the control group. Mean age 64	Type 2 diabetes mellitus and hypertension	Patient Empowerment Program in General Outpatient Clinics (GOPC)	General Outpatient Clinics (GOPC)	HbA1c, Systolic blood pressure (SBP), Diastolic blood pressure (DBP), LDL-cholesterol
Willadsen et al. 2018	Denmark	Randomised Controlled Trial	970 patients in the intervention group and 539 in the group with usual care. Mean age 64,7 in intervention group and 64,5 I usual care group	Diabetes and multi-morbidity	Structured personnel care in patients with diabetes	General practice	Self-rated health, diabetes symptoms

The sample sizes of the twelve included studies ranged widely across studies (mean: 684 patients, range 79-2282). Five studies (42%) were conducted in the Europe, four (33%) in US, and three (25%) elsewhere. The most common study design was RCT (n=8; 67%) followed by Cohort/observational (n=3; 25%) and quasi-experimental design (n=1; 8%). Most studies were conducted in primary care setting (n=7; 58%). A total of five studies (42%) were conducted in general hospitals involving patients from a range of specialties. In the studies, the participants have many different diseases such as diabetes, chronic heart failure, dementia etc. The mean age in the studies was +60 years with a range: 60- 84 years, however, there were two studies that did not indicate the mean age but included an 18+ year population with most 60+ years. A wide range of multi-morbidities is represented in the included studies with some focusing more widely on engagement of patients with multiple coexisting diseases whereas others targeted specific diseases in patients with comorbidities.

The included studies used different patient engagement interventions, such as coaching, health care communication, goal setting interventions, self-management program, 3D intervention, prompt list, and disease-specific sessions. Different types of primary outcomes were used in studies such as Patient Activations Measurements (PAM), Self-Rated health (SRH), hospitalisation, use of health services, change in clinical outcomes (e.g. BMI, blood pressure, blood glucose), Modified Barthel Index (MBI), and quality of life. Disease specific outcomes such as blood pressure, Cholesterol level and blood glucose were used in some of the studies.

Quality of included studies

Figure 2 shows the quality assessment for each included study. Three studies were assessed to be of high quality in all domains apart from one, which was judged to be low or moderate. An additional five studies were assessed to be of high quality apart from two domains, which was judged to be low or moderate. The last four studies were only judged to be of high quality in one or none of the five domains.

Risk of bias for RCTs is shown in figure 3. All studies had high risk of bias due to blinding of participants and personnel (performance bias). Furthermore, four studies were rated to high risk of blinding of outcome assessment (detection bias).[20-23]

Figure 4 show risk of bias for non-randomised studies. Two studies were rated to have high risk of bias, and two studies were rated moderate risk of bias. One study had high risk of bias due to confounding,[24] and another study had high risk of bias due to deviations from intended intervention.[25] One study rated to moderate risk of bias had moderate risk of bias in five categories[26], and the other had moderate risk of bias in two categories [27].All four studies had unclear risk of bias in more than one category.

In total, the quality of the included studies was of low to moderate and some aspects of quality assessment and risk of bias were unclear across the included studies.

Effect of the interventions

The included studies are using different endpoints to measure the effect of patient engagement interventions. Nine of the included studies found significant effect of interventions.

A RCT by Naik[28] measure the effect of the intervention Healthy Outcomes Through Patient Empowerment (HOPE) which is a six-months goal-setting intervention targeting depression symptoms and diabetes self-care through nine telephone-delivered coaching sessions. The HOPE intervention used an electronic data warehouse to identify specific high-risk population, followed by telephone screening and training of clinicians to deliver a structured telehealth intervention. The endpoints in this study was depression symptoms with The Patient Health Questionnaire (PHQ)-9 and glycaemic control with haemoglobin A1c (HbA1c). They did not find any improvement in six-month follow-up, but found improvement in PHQ-9 after 12-month follow-up; HOPE (Mean [SD] baseline: 15,8 [4,2] to six months: 10,9 [6,1] and 12 months 10,1 [6,5]) compared with Enhanced Usual Care (EUC) (Mean [SD] baseline 16,2 [4,0] to six months 12,4[6,0]) and 12 months 12,6 [6,0]. The PHQ-9 differences between HOPE and EUC were statistically significant at six months (mean diff., 1.74; 95% CI, 0.14-3.33; P = 0.03) and 12 months (mean diff., 2.14; 95% CI, 0.18-4.10; P = 0.03).

The study by Reed[29] examined the effect of the intervention Chronic Disease Self-Management Support (CDSMS) which is a set of tools (Partners in Health scale, Cue and Response interview, Problems and Goals assessment) and a structured process that enable clinicians and patients to collaboratively assess self-management behaviour, identify problems, set goals, and develop individual care plans that address key self-care, medical, psychosocial, and care problems. Participants in each program received three home visits and four follow-up phone calls over a six-month period from a clinician. The population were recruited from five general practices in Adelaide, Australia. The study used self-rated health as endpoint, and they with an intention-to-treat analysis that CDSMS participants were more likely than control participants to report improved self-rated health at six months (R, 2.50; 95% confidence interval, 1.13-5.50; P = 0.02).

A RCT by Shively[21] implemented a six month program developed to enhance self-management in older heart failure patients. The program consisted of individualized goal setting according to baseline activation level. The interventions population was invited to participate through a follow-up visit at the Veterans Affairs San Diego Healthcare system. The study used Patient Activation Measure (PAM), Self-Care of Heart

Failure Index (SCHFI), Medical Outcomes Study (MOS), and hospital visits to measure the effect of the intervention. The intervention showed improvement in PAM-score, the intervention group compared with the usual care group showed a significant increase in PAM-scores from baseline to six months (significant group by time interaction, F = 3.73, P = 0.03) and fewer hospital visits compared with usual group.

A prospective naturalistic cohort study by Tay[24] examined the effect of the intervention Care for Acute Mentally Infirm Elders (CAMIE) which adopt a person-centred care protocol with specialized psychosocial interventions, minimally obtrusive medical care, and physical restraints-free practice targeting patients with dementia. The study population were recruited at a hospital, and all patients received standard treatment. Patients were admitted to the CAMIE unit if they suffered from confusion due to dementia, with/without delirium based on the confusion assessment method criteria, and concomitant acute medical problems. The study used Modified Barthel Index function and Well-being and European Quality of Life (EuroQol) to measure the CAMIE intervention. CAMIE patients showed statistically significant greater gains in Modified Barthel Index function (mean [SD] baseline 47.31 [28.90] to 55.58 [29.37]) and well-Being (mean [SD] baseline 4.94 [3.95] to 8.46 [3.49]), decreased ill-Being and agitation (mean [SD] baseline 3.04 [2.11] to 0.84 [1.26]), and greater improvement in EuroQoL index score (mean [SD] baseline -0.16 [0.43] to 0.15 [0.41]) after adjusting for baseline differences that translated to a quality-adjusted life years gain of 0.045, assuming stability over three months.

A controlled before-and-after design by Ulin et al[26] studied the effect of proactive care-planning based on Gothenburg Person-Centred Care (gPCC). It seeks to identify patient's resources including motivations and goals. This information is used to develop a health plan which includes planned investigations, length of stay in hospital and treatment goals. The health plan is discussed with the patient to reach consensus and the plan is regularly evaluated. The population were recruited from five designated wards at a University Hospital in Sweden. The patients were assessed by a specialised cardiologist before final inclusion, guided by the European Society of Cardiology (ESC) guidelines for diagnosing Congestive Heart Failure (CHF). The study used discharge destination and number of days until the discharge was recorded, to measure the gPCC intervention. They found improved discharge processes (1-5 days for gPCC group vs 1-28 days for control group), and fewer days in hospital (11 days for gPCC group vs 35 days for control group).

A RCT by Willadsen[30] examined the effect of structured personal diabetes care with general practitioners (GPs) that ask GPs and patient to agree on the best possible goal for controlling risk factors. GPs were offered six seminars and were instructed to give advice lifestyle. Patients were invited to attend follow-up examination quarterly and screening for diabetes complications every year. The study used self-rated health and diabetes symptoms to measure the effect of the structured person care intervention. They

found that the intervention reduced the diabetes symptoms (OR 0.79; 95% CI: 0.64–0.97), but they didn't find the same after 14 years follow-up.

An observational matched cohort study by Wong[25] implemented a Patient Empowerment Programme (PEP) that aims to provide patient with knowledge and skills about their disease Type 2 Diabetes (T2DM) and to facilitate autonomous self-regulation. The program consisted of generic sessions about self-efficacy enhancement and lifestyle modification as well as disease-specific sessions for a period of up to 12 months. Two non-government organisations (NGO) delivered the intervention, the NGO's invited at general outpatients' clinics or family medicine specialist eligible patients to join the PEP. The study used HbA1c, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), and Low-Density Lipoprotein (LDL-C) to measure the effect of PEP. They found improvement in the clinical outcomes. A significantly greater percentage of patients in the PEP group attained HbA1C ≤7% or LDL-C≤2.6 mmol/L at 12-month follow-up compared with the non-PEP group. PEP group had a mean 0.813 fewer General Outpatient Clinic (GOPC) visits in comparison with the non-PEP group.

A study by Hochhalter[23] measured the effect of Making the Most of Your Healthcare intervention which offered tools and taught skills to (a) prepare for healthcare appointments, (b) communicate effectively and gather information and support during healthcare appointments, and (c) follow through on plans of care. The intervention included a two-hour workshop and two telephone calls individualized to the patient's pre- and post-healthcare appointment needs. The included population were patients in a large Internal Medicine Clinic and had been treated for at least two of seven chronic illnesses. They found a statistically significant improvement in self-efficacy for the intervention group, who received a 2-hour workshop. They used PAM-13 and Health Related Quality of Life (HRQOL)-14 questionnaires as measurement. They found an improvement in Self-Efficacy in the Appointment group (mean [SD] baseline 6,9 [1,9] to 7,4 [1,8]) mean diff. 0,47 95%CI; 0,07-0,87 P = 0,021. They did not find any improvement in health for the control group or safety group.

A quasi-experimental study by Mateo-Abad [27] examined the impact of the CareWell integrated care model on use of health resources and clinical effectiveness. The program is based on coordination between health providers, patient empowerment and home-based care, supported by communication and information technology tools. Relevant differences were observed between the intervention and control group, including reduced numbers of hospitalisations and visits to emergency centres, and clinical outcomes in the intervention group. For instance, when hospitalised their hospital stay was longer for the control group; the mean number of days in the hospital was 13.3 (SD,13.5), whereas the mean stay for the intervention group was 10.4 (SD, 9) days.

Whereas the studies described above did show some improvements of patient-engagement interventions in multi-morbid older patients based on a range of outcomes, the following three studies did not find any significant improvements in health outcomes.

A pragmatic cluster-randomised trial by Salisbury[22] examined the effect of the so-called 3D intervention which is based on a patient-centred care model and seeks to improve continuity, coordination, and efficiency of care by replacing disease-focused reviews of each health condition with one 6-monthly comprehensive multidisciplinary review. Each 3D review consists of two appointments with a nurse and a named responsible physician and a records-based medication review by a pharmacist. The population were recruited from three general practices providing National Health Service (NHS) primary medical in England and Scotland. They measured quality of life with a 5Q-5D-5L questionnaire. The intention-to-treat analysis showed no difference between trial groups (adjusted difference in mean EQ-5D-5L 0.00, 95% CI –0.02 to 0.02; p=0.93). They concluded the intervention did not improve the participant's quality of life.

The study by Tinsel[20] implemented a shared decision-making (SDM) training program that aims to enhance the active role of patients. The program included disease information, physician-patient communication, steps of SDM, motivational interviewing, decision table listing, and role plays simulating consultations. The GP's followed a SDM training programme, and the study population was conducted through GP's in southwest Germany. They used change of patients' perceived participation (SDM-Q-9) and change in systolic blood pressure (BP). According to the mixed model analysis, the average change from T0 was 3.11 points higher in the intervention group than in the control group (97.5% CI [−2.37; 8.61], p = 0.203). The effect was not significant at the (Bonferroni-corrected) 2.5% level. They did not find any statistically significant improvement in systolic BP.

The study by Schwarze et al [31] measured the effect of a question prompt list (QPL) intervention versus usual care among older patients. The QPL intervention target informational needs of patients considering major surgery and include 11 questions that prompt patients and their family members to query their surgeon about treatment options etc. The study population was conducted among surgeons who perform high-risk oncologic or vascular operations on older patients with comorbidities. They measured patient engagement and well-being, including anxiety in patients. For instance, on average, anxiety scores were 1.3 (95% CI, 0.2-2.4) points higher for patients in the QPL intervention group. The authors concluded that these effects were less than the minimally important difference and that the QPL intervention in general did not influence patient engagement and well-being compared with usual care.

DISCUSSION

Statement of principal findings

This systematic review aimed to provide an overview of the effects of patient engagement interventions for older patients with multi-morbidity. From the 805 studies identified, only twelve studies met the inclusion criteria. The included studies were heterogeneous in characteristics of populations, number of participants, types of interventions to enhance patient-engagement, length of follow-up and outcome measures. A range of interventions ranging from prompt list to coaching sessions. This diversity in the evidence base challenges the ability to draw robust conclusion. Overall, the majority of studies showed improvements in health and patient-reported outcomes among patients participating in patient engagement interventions. There was some evidence to indicate that the clinical outcomes (BP, Hba1c, diabetes symptoms and glycaemic outcomes) were improved. Furthermore, some evidence indicates improvements in quality of life (EuroQol, QALY, self-rated health) and fewer health care visits (hospitals, GOPC). However, one study found no significant improvements in quality of life, another study found no significant improvements in patient well-being and anxiety symptoms, and a third study found no significant improvements in BP. As indicated by the limited number of studies and the wide heterogeneity in characteristics of populations, types of interventions to enhance patient-engagement, outcome measures and length of follow-up, there is a need for more substantial studies evaluating patient-engagement tools for both implementation and effect in older patients with multi-morbidity using more longer-term outcomes to capture both patient, provider and system-level effects of patient-engagement. While our review adds to the important field of ensuring that interventions to enhance patient-engagement are developed, implemented and evaluated specifically in the growing population of older adults living with multi-morbidity, the review supports previous work in finding too fragile evidence for robust conclusions to be made.[10-15]

Strengths

This review has several strengths. This review contributes to providing a more substantive evidence base to guide prioritisation and implementation into mainstream healthcare delivery. Since patient-engagement aims at improving care overall, this review did not restrict itself to studies based on particular health outcomes, and consequently studies into a range of health and patient-reported outcomes were included. Another strength is that the systematic literature search that was undertaken adhering to a pre-specified protocol. To standardise our assessment process, we used DistillerSR to upload the bibliographic reference information. We performed a wide search to allow different study designs to include methodological heterogeneity. However, the majority of the included studies were RCT. Two researchers independently selected studies collected data and rated quality of included studies using GRADE method. Discrepancies

were resolved by consensus. We used a transparent framework for developing and presenting summaries of evidence. GRADE is the most widely adopted tool for grading the quality of evidence.

Limitations

Despite of the systematic approach adopted; this review has its limitations. The literature search was completed using two key databases, but additional peer-reviewed articles might have been found by searching and including from a broader range of sources. Relevant articles were excluded if they were published in languages other than English, Danish, Swedish, or Norwegian. Another limitation relates to the differences in transparency as to population characteristics across articles which affected our ability to ascertain types of multi-morbid conditions and the extent of multi-morbidity in the study populations. A minority of the included studies had small participant numbers which might have affected power of the studies. Two studies included less than 100 patients in total. Meta-analysis was not conducted as there was heterogeneity in the outcomes and measurement tools used in the studies. Overall, the quality of the included studies was of low to moderate. Some aspects of quality assessment and risk of bias were unclear across the included studies. This complicates the overall quality assessment. Furthermore, we did not seek clarification with the study authors about whether our assessment of risk of bias in the individual studies was correct.

Implications

This review has highlighted the possible improvements in health and patient-reported outcomes among patients exposed to patient-engagement interventions. However, the evidence base is inconsistent and the quality of the studies is relatively low. Further high quality studies in larger populations over longer time-periods are needed to investigate the long-term effect of patient-engagement interventions.

CONCLUSION

This systematic review found only limited evidence to support the improvements in health and patient-reported outcomes among older multi-morbid patients exposed to patient-engagement interventions. As the quality of the included studies was mostly low, the findings should be interpreted with caution, and there is a need for more robust studies into efficient approaches to engaging older adults with multi-morbidity in care trajectories.

DECLARATION OF CONFLICTING INTERESTS

The authors declare no potential conflicts of interest with respect to the research, authorship and/or publication of this article

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AUTHOR CONTRIBUTIONS

MBS and KA contributed equally to this paper. MK, MBS and KA designed the study. MBS and KA carried out data collection and analysis. All authors contributed to drafting the manuscript. All authors have read and approved the manuscript.

DATA AVAILABILITY STATEMENT

Data from the literature search and selection process are available upon reasonable request to the corresponding author.

FIGURES

Figure 1: Flowchart

Figure 2: Total GRADE

Figure 3: Risk of bias for randomised studies

Figure 4: Risk of bias for non-randomised studies

ETHICS STATEMENT

According to national guidelines, no ethics approval is needed for systematic reviews

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Figure 1: Flowchart

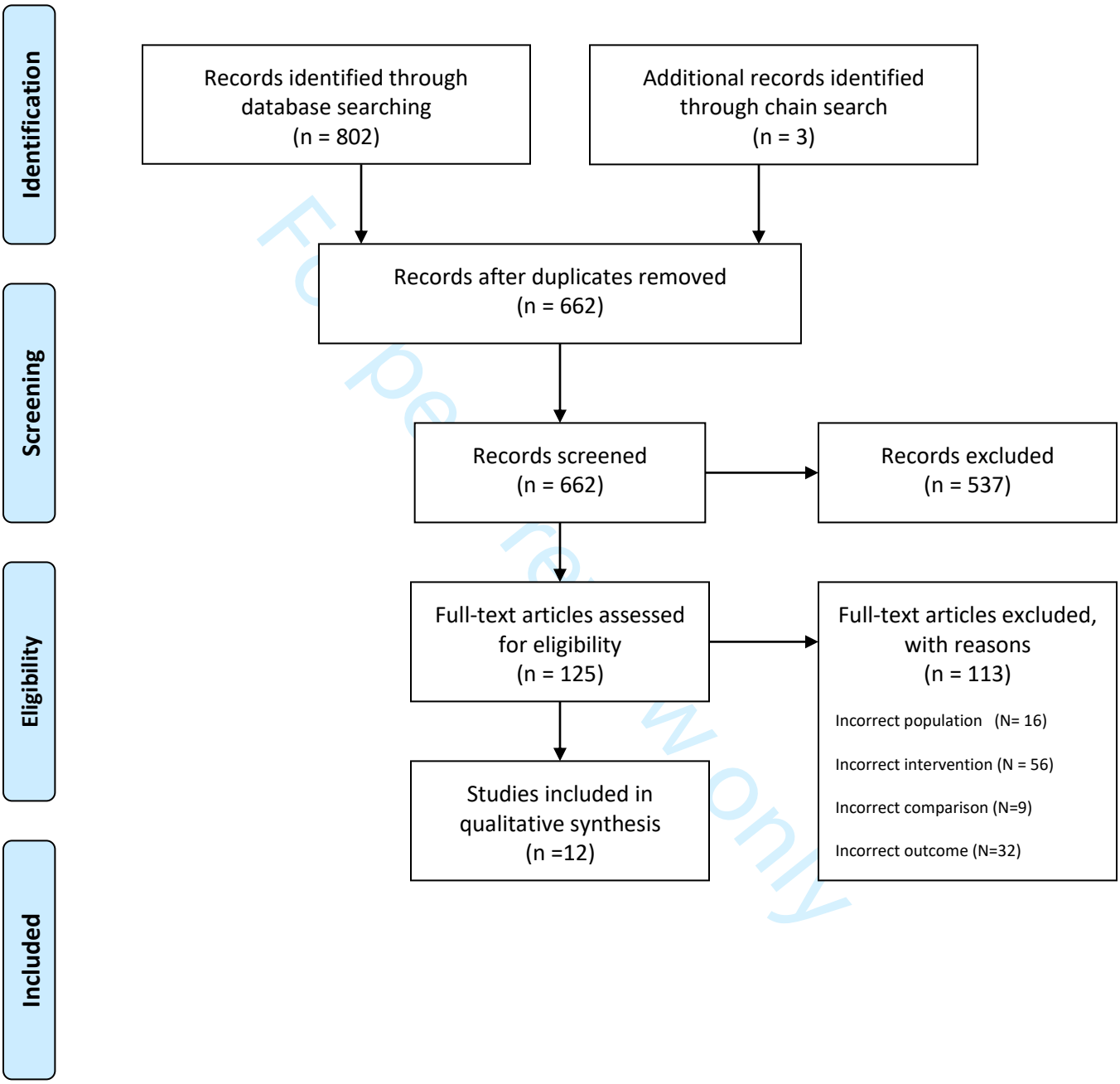


Figure 2: Total GRADE

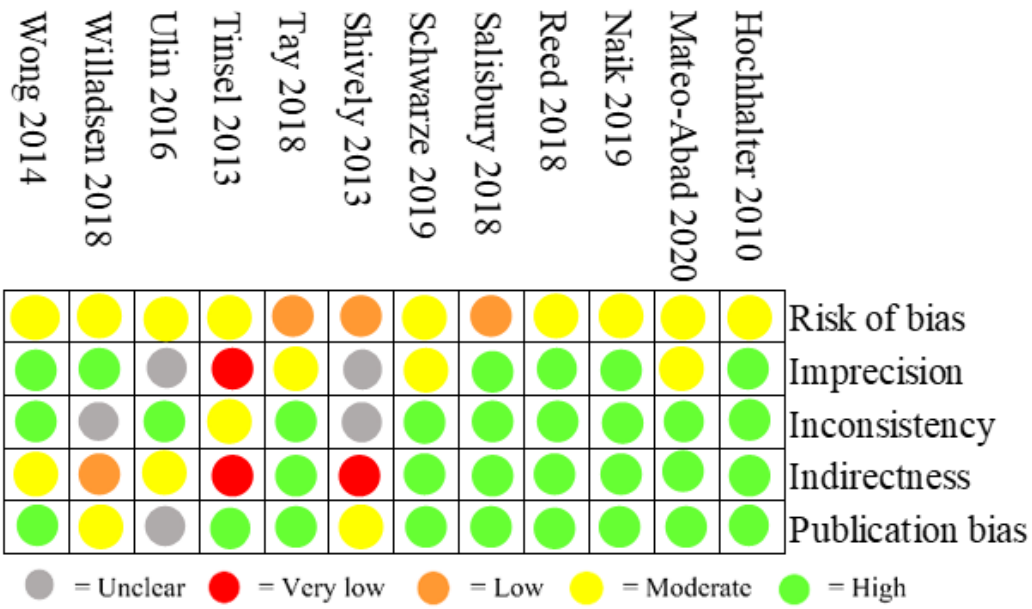


Figure 3: Risk of bias for randomised studies

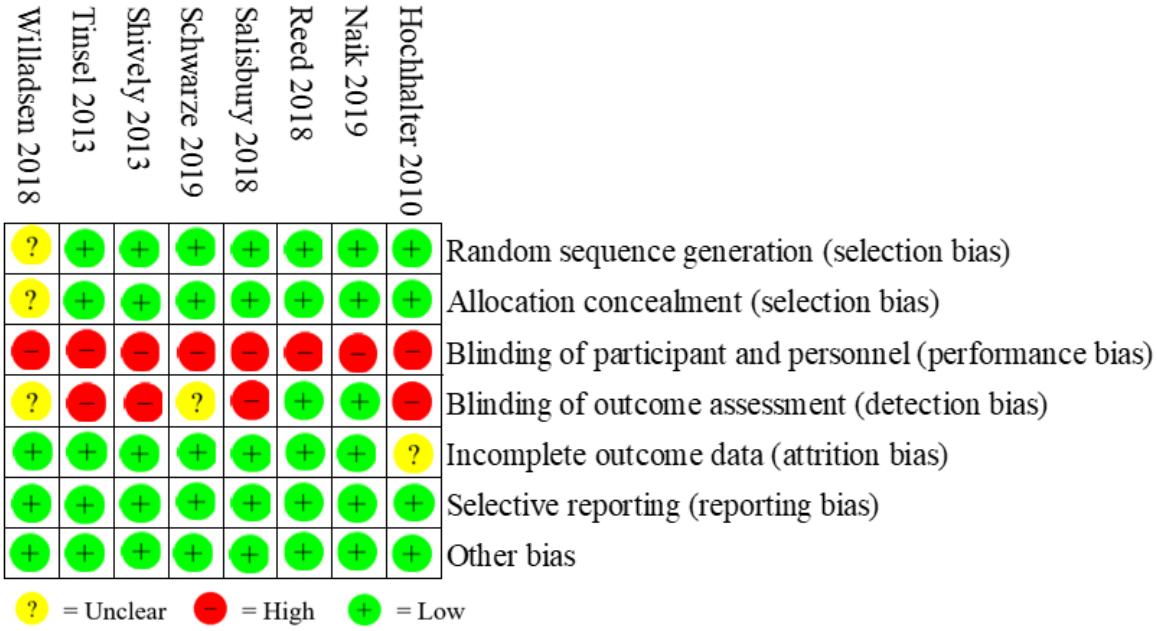
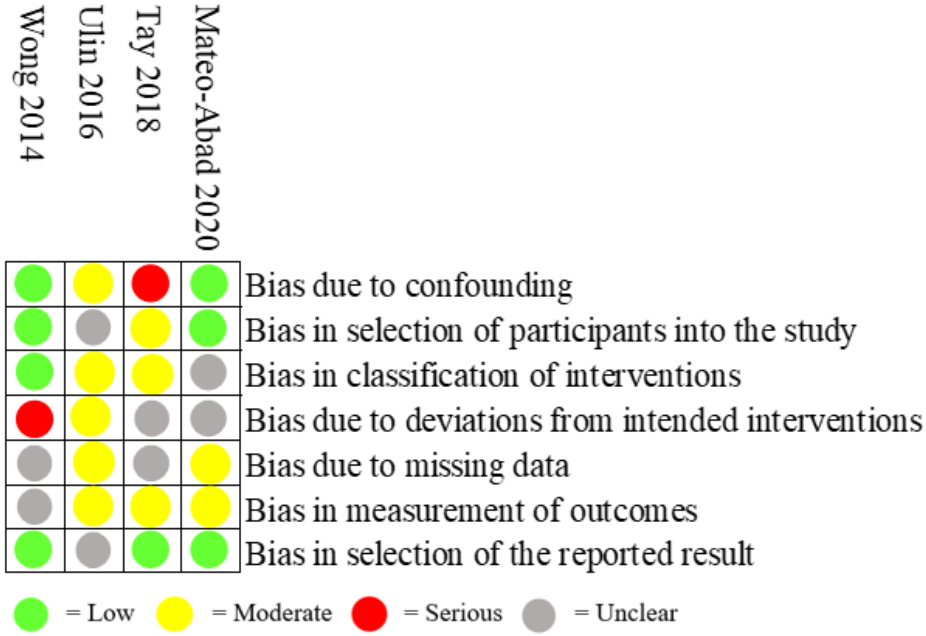


Figure 4: Risk of bias for non-randomised studies



Appendix 1: Keywords and search string

Aspect 1: Patient engagement	**AND**	**Aspect 2:** Multimorbidity	**AND**	**Aspect:** Elderly
Person-centered care		Multimorbidity (MeSH)		Aged (MeSH)
OR		OR		OR
Person centered care		Multi-morbidity		Aged
OR		OR		OR
Patient engagement		Multimorbidity		Elderly
OR		OR		OR
Patient empowerment		Multi-morbidities		Older adult
OR		OR		OR
Patient involvement		Multi morbidities		Older adults
OR		OR		
Patient participation (MeSH)		Comorbidity (MeSH)		
		OR		
		Comorbidity		
		OR		
		Co-morbidity		
		OR		
		Comorbidities		
		OR		
		Co-morbidities		
		OR		
		Multiple chronic conditions (MeSH)		

("person-centered care"[All Fields] OR "person-centered care"[All Fields] OR "patient engagement"[All Fields] OR "patient empowerment"[All Fields] OR "patient involvement"[All Fields] OR "patient participation"[All Fields] OR "patient participation"[MeSH Terms]) AND ("multimorbidity"[MeSH Terms] OR "multi-morbidity"[All Fields] OR "multi-morbidity"[All Fields] OR ("multimorbid"[All Fields] OR "multimorbidities"[All Fields] OR "multimorbidity"[MeSH Terms] OR "multimorbidity"[All Fields]) OR ("multimorbid"[All Fields] OR "multimorbidities"[All Fields] OR "multimorbidity"[MeSH Terms] OR "multimorbidity"[All Fields]) OR "multi-morbidities"[All Fields] OR "multi-morbidities"[All Fields] OR "comorbidity"[MeSH Terms] OR ("comorbid"[All Fields] OR "comorbidity"[MeSH Terms] OR "comorbidity"[All Fields] OR "comorbidities"[All Fields] OR "comorbids"[All Fields]) OR ("comorbidity"[MeSH Terms] OR "comorbidity"[All Fields] OR ("co"[All Fields] AND "morbidity"[All Fields]) OR "co morbidity"[All Fields]) OR "co-morbidities"[All Fields] OR ("comorbid"[All Fields] OR "comorbidity"[MeSH Terms] OR "comorbidity"[All Fields] OR "comorbidities"[All Fields] OR "comorbids"[All Fields]) OR "multiple chronic conditions"[MeSH Terms] OR "multiple chronic diseases"[All Fields]) AND ("aged"[MeSH Terms] OR ("aged"[MeSH Terms] OR "aged"[All Fields]) OR ("aged"[MeSH Terms] OR "aged"[All Fields] OR "elderly"[All Fields] OR "elderlies"[All Fields] OR "elderly s"[All Fields] OR "elderlys"[All Fields]) OR "older adults"[All Fields] OR "older adult"[All Fields])

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Not applicable
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5-9
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5-6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	Not applicable

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	6, 11-12
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	Not applicable
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6, Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6-10
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	9-10
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	10-13
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Not applicable
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Figure 3 and 4
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	Not applicable
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	14-15
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	15
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	15
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	16

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Systematic review of patient-engagement interventions: potentials for enhancing person-centred care for older patients with multi-morbidity

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ABSTRACT

Introduction: Person-centred care based on systematic and comprehensive patient-engagement is gaining momentum across healthcare systems. Providing care that is responsive to the needs, values and priorities of each patient is important for patients, relatives, and providers alike, not least for the growing population of older patients living with multi-morbidity and associated complex care trajectories.

Objectives: The aim of this systematic review is to investigate the effects of patient engagement interventions for older patients with multi-morbidity.

Methods: Systematic review conducted in August 2021. Two reviewers independently screened the international databases Embase and PubMed. Reviewers carried out duplicate and independent data extraction and assessment of study quality. GRADE (Grading of Recommendations Assessment, Development, and Evaluation) was used to assess the quality of the evidence for each study.

Results: We included twelve studies from primary care setting and hospitals. The included studies were heterogeneous in terms of characteristics of populations, types of interventions to enhance patient-engagement, outcome measures and length of follow-up. Nine of the twelve included studies found significant improvements in health and patient-reported-outcomes such as higher quality adjusted life years, fewer hospital visits and disease specific symptoms. Quality of the included studies was of low to moderate.

Conclusion: This review identifies potential beneficial effects of interventions to enhance patient-engagement in older adults with multi-morbidity. Nevertheless, the limited and very diverse evidence-base calls for more robust studies into efficient approaches to engaging older adults with multi-morbidity in care trajectories.

ARTICLE SUMMARY

Strengths and limitations of this study

- This systematic review explores the understudied field of interventions to enhance patient-engagement in the growing population of older adults with multi-morbidity
- Included studies are not limited to specific health-and patient-reported outcomes in order to capture the broad effectiveness of these interventions
- Meta-analysis was not possible due to heterogeneity in methods and outcomes
- Quality of the included studies was low to moderate overall, hence there is a need for more robust studies using a range of outcomes to identify best practices in patient-engagement in the context of multi-morbidity in old age.

INTRODUCTION

Person-centred care is defined as care that is based on elicitation of and responsiveness to the individual patient's needs, values, resources and life situation.[1] In increasingly complex and prolonged treatment trajectories, engaging older patients in a timely, systematic and holistic manner may improve experiences and outcomes for patients and relatives, and enhance meaningfulness among healthcare professionals. Furthermore, it may support adequate use of scarce healthcare resources as treatment plans are tailored to individual needs, potentially improving engagement of more disadvantaged patients and ultimately decreasing social inequality in healthcare utilization.[2, 3]

Identifying the best care trajectory in the light of the uniqueness of each patient's circumstances is particularly important for the growing population of older patients living with multi-morbidity, defined as patients living with two or more co-existing long term conditions,[4] and associated polypharmacy requiring prolonged and complex care trajectories across care settings.[5-7] In the context of population ageing and increased multi-morbidity, more systematically and timely offered conversations with patients related to future scenarios and priorities is crucial. This includes a range of complex decisions on prognosis, treatment options and prioritizing care at the end of life driven by patient perspectives on what is acceptable and meaningful to him/her. Person-centred care requires empowered patients who are met by a responsive and accessible health care system with a culture of engagement, sufficient time, and a skill-set that nurtures daily practices based on unlocking patient perspectives and delivering coherent care to reflect these.[3, 8, 9] While there is overall agreement concerning the importance of person-centred care, there is little scientific evidence documenting significant outcomes of patient engagement regarding patient satisfaction, enhanced shared decision-making, adjustment of treatment plans, or use of resources.[10-14] A recent systematic review[15] aimed at assessing the effect of interventions for older patients with multi-morbidity aiming to involve them in decision-making in primary care consultations found too limited evidence to interpret with certainty. This systematic review included only randomised-controlled trial's (RCT) in primary health care. To investigate this topic further we included both RCTs and non-randomised studies in primary and secondary health care settings. More focus on patient-engagement tools as interventions to enhance person-centred care in clinical encounters is needed to provide a more substantive evidence base to guide prioritization and implementation into mainstream healthcare delivery.[16] The aim of the systematic review is to investigate the current evidence for effectiveness of patient-engagement tools in enhancing person-centred care for older adults (60+ year) with more than one disease.

METHODS

Literature search and study selection

The review is based on systematic literature searches conducted in December 2019 and updated August 2021 using the databases PubMed and Embase. Furthermore, reference lists of included articles were assessed to identify additional peer-reviewed articles. The complete list of search terms, including MESH terms and free text terms, is presented in Appendix 1.

The software DistillerSR was used to screen and review the studies. Data were independently extracted onto a customised data extraction sheet in DistillerSR by two reviewers, and any discrepancies were resolved by discussion.

The eligibility criteria for study inclusion were as follows:

- Population: Older adults above the age of 60 living with two or more co-existing diseases.
- Intervention: Patient engagement intervention in health care system settings.
- Comparison groups: Older patients who received usual care.
- Outcome: Any patient-related outcome e.g. reduced symptoms of disease, reduced duration of disease, reduced costs and reduced hospital stay or rehospitalisation.

We included quantitative observational studies such as prospective and retrospective cohort studies and RCTs. Studies in any geographical area in health care systems, thus encompassing both primary and secondary care settings, were included, and only studies written in English and in one of the Scandinavian languages (Danish, Swedish or Norwegian) were included.

Two investigators independently screened the titles, abstracts and full texts for inclusion and exclusion criteria. We excluded commentaries, editorials and studies that did not directly apply a patient-engagement intervention as an exposure. We did not exclude studies based on publication date.

First, the titles of the 805 studies were screened for eligibility. Secondly, duplicates were removed. Third, the abstracts of the studies were screened. Fourth, the full texts of studies initially assessed as relevant for the review were checked against our inclusion or exclusion criteria. Disagreements between the two investigators were resolved by consensus. Figure 1 shows reasons for exclusion for potentially eligible studies.

Data extraction

Two investigators independently extracted information on characteristics of participants, study design, patient engagement intervention and outcomes. Discrepancies in data extraction were resolved by consensus between the two investigators.

Quality assessment

The included studies encompassed a combination of RCT and observational studies. To assess the quality of evidence, we used GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) for all the included studies. GRADE is a transparency framework and is the most widely adopted tool for grading the quality of evidence. The checklist assesses quality of the study across eight domains. The evidence level can be rated down or up depending on missing or existing domains. GRADE certainty ratings have four levels as follows: very low, low, moderate, high. Very low means that the true effect is probably markedly different from the estimated effect. High means that the authors have a lot of confidence that the true effect of is similar to the estimated effect,[17]. To assess the domain risk of bias within GRADE we used two different measures depending on whether the study was randomised or non-randomised. In non-randomised studies we used ROBINS-I to assess risk of bias, which is a tool to understand and appraise strengths and weaknesses in non-randomised studies.[18] In RCTs we used Cochrane Collaboration's tool for assessing risk of bias.[19] Two investigators independently performed a quality assessment of each study. Disagreements were resolved by consensus.

Patient and Public Involvement Statement

Patients were not involved in this systematic review.

RESULTS

Description of included studies

Figure 1 shows the PRISMA diagram in the phases from the 805 studies that were identified to the twelve studies that met the inclusion criteria. The main reason for exclusion were due to lack of specific interventions. Table 1 depicts the characteristics of the twelve included studies. The included studies were mainly RCT studies.

Table 1: Study characteristics of included studies

Study	Location	Design	Participants	Multi-morbidity	Intervention	Setting	Endpoint
Hochhalter et al., 2010	USA	Randomised Controlled Trial	26 patients in appointment group, 27 in safety group, and 26 in usual group. Mean age 76 in appointment group, 73 in safety group and 73 in usual group	At least two of the following chronic illnesses: arthritis, lung disease, heart disease, diabetes, hypertension, depression, or osteoporosis	Patient engagement, patient group workshop and individual coaching intervention	Primary care clinics, Scott & White Center for Diagnostic Medicine	PAM-13, Communication with physician's scale, HRQOL-14
Mateo-Abad et al. 2020	Spain	Quasi-experimental study	101 patients in the intervention group and 99 patients in the usual care group. Mean age 79	A minimum of two chronic diseases, with at least one of them being chronic obstructive pulmonary disease (COPD), diabetes mellitus, or chronic heart failure (CHF)	Care coordination and communication between health providers and patient empowerment and home-based care; all supported by ICT-based platforms	Integrated care organisations	Use of services, clinical variables (such as BMI, blood pressure, heart rate, blood glucose), Geriatric depression scale (GDS), Functional status (Barthel Index)
Naik et al. 2019	USA	Randomised Controlled Trial	136 in the intervention group, and 89 in control group. Mean age 61	Uncontrolled diabetes and depression	Proactive population screening and telephone delivery of a collaborative goal-setting intervention	Veterans Affairs Medical Center	Change in depression symptoms using PHQ-9 and HbA1c
Reed et al., 2018	Australia	Randomised controlled trial	114 in the intervention group, and117 in the control group. Age range: 60+	At least two chronic diseases	Self-management support program for older with multiple chronic conditions	General practices	Self-rated health
Salisbury et al., 2018	England and Scotland	Cluster-randomised trial	797 patients in the intervention group, and 759 in the usual care group. Mean age 71 in intervention group and 70,7 in the usual care group	At least three types of chronic conditions	Patient-centered strategies for management of multi-morbidity, 3D intervention	General practices	Eq-5d-5l
Schwarze et al. 2020	USA	Randomised controlled trial	223 patients in the intervention group, and 223 patients in the usual care group. Mean age 71 in intervention group and 72.6 in usual care group	At least one comorbidity and an oncologic or vascular problem	Question prompt list brochure targeting informational needs of patients considering major surgery	Surgeons' clinics	Number of questions asked by patients and family during the recorded visit, Perceived Efficacy in Patient-Physician Interactions (PEPPI-5), Measure Yourself Concerns and Well-being (MYCaW)

Study	Location	Design	Participants	Multi-morbidity	Intervention	Setting	Endpoint
Shively et al. 2013	USA	Randomised, 2-group, repeated-measures design	43 patients in the Intervention group, and 41 I the group with usually care. Mean age 66,1 years	Heart failure and comorbidities	Patient activation intervention compared with usual care in patients with Heart failure	Veterans Affairs San Diego Healthcare System	Patient Activation Measure, (PAM), Self-Care of Hearth Failure Index (SCHIF), Medical Outcomes Study (MOS)
Tay et al. 2018	Singapore	Prospective cohort study	170 in the intervention group and 60 in the control group. Mean age in the intervention group is 82 years and 84 years in control group	Dementia and comorbidities	Person-centered care in Care for Acute Mentally Infirm Elders (CAMIE)	Hospital	Well-being (WB) Ill-being (IB) Pittsburg Agitation Scale (PAS) Modified Barthel Index (MBI) EQ-5D Index Score
Tinsel et al. 2013	Germany	Cluster Randomised Controlled Trial	552 patients in the intervention group, and 568 in the control group. Mean age 63,8 in intervention group and 65 in control group	Hypertension and at least one relevant comorbid disorder (diabetes mellitus, coronary heart disease, heart attack, stroke, or peripheral arterial occlusive disease)	Shared decision-making in General practice with patients with uncontrolled hypertension	General practice	SDM-Q-9, systolic blood pressure
Ulin et al. 2016	Sweden	Controlled before-and-after design	125 patients in the intervention group, and 123 in control group. Mean age range: 77-80	Chronic heart failure and comorbidities	Gothenburg Person-centered care (gPCC) in patients hospitalized	Department of Medicine at Sahlgrenska University Hospital/Östra in Gothenburg	Number of days from admission to 1. first notice to the municipality 2. second notice to the municipality 3. notice to the municipality that the patient was ready for discharge from hospital
Wong et al. 2014	Hong Kong	Observational matched cohort study	1.141 in the intervention group and 1.141 in the control group. Mean age 64	Type 2 diabetes mellitus and hypertension	Patient Empowerment Program in General Outpatient Clinics (GOPC)	General Outpatient Clinics (GOPC)	HbA1c, Systolic blood pressure (SBP), Diastolic blood pressure (DBP), LDL-cholesterol
Willadsen et al. 2018	Denmark	Randomised Controlled Trial	970 patients in the intervention group and 539 in the group with usual care. Mean age 64,7 in intervention group and 64,5 I usual care group	Diabetes and multi-morbidity	Structured personnel care in patients with diabetes	General practice	Self-rated health, diabetes symptoms

The sample sizes of the twelve included studies ranged widely across studies (mean: 684 patients, range 79-2282). Five studies (42%) were conducted in the Europe, four (33%) in US, and three (25%) elsewhere. The most common study design was RCT (n=8; 67%) followed by Cohort/observational (n=3; 25%) and quasi-experimental design (n=1; 8%). Most studies were conducted in a primary care setting (n=7; 58%). A total of five studies (42%) were conducted in general hospitals involving patients from a range of specialties. In the studies, the participants have many different diseases such as diabetes, chronic heart failure or dementia. The mean age in the studies was +60 years with a range: 60- 84 years, however, there were two studies that did not indicate the mean age but included an 18+ year population with most 60+ years. A wide range of multi-morbidities is represented in the included studies with some focusing more widely on engagement of patients with multiple coexisting diseases whereas others targeted specific diseases in patients with comorbidities.

The included studies used different patient engagement interventions, such as coaching, health care communication, goal setting interventions, self-management program, 3D intervention, prompt list, and disease-specific sessions. Different types of primary outcomes were used in studies such as Patient Activations Measurements (PAM), Self-Rated health (SRH), hospitalisation, use of health services, change in clinical outcomes (e.g. BMI, blood pressure, blood glucose), Modified Barthel Index (MBI), and quality of life. Disease specific outcomes such as blood pressure, Cholesterol level and blood glucose were used in some of the studies.

Quality of included studies

Figure 2 shows the quality assessment for each included study. Three studies were assessed to be of high quality in all domains apart from one, which was judged to be low or moderate. An additional five studies were assessed to be of high quality apart from two domains, which was judged to be low or moderate. The last four studies were only judged to be of high quality in one or none of the five domains.

Risk of bias for RCTs is shown in figure 3. All studies had high risk of bias due to blinding of participants and personnel (performance bias). Furthermore, four studies were rated to high risk of blinding of outcome assessment (detection bias).[20-23]

Figure 4 show risk of bias for non-randomised studies. Two studies were rated to have high risk of bias, and two studies were rated moderate risk of bias. One study had high risk of bias due to confounding,[24] and another study had high risk of bias due to deviations from intended intervention.[25] One study rated to moderate risk of bias had moderate risk of bias in five categories[26], and the other had moderate risk of bias in two categories [27].All four studies had unclear risk of bias in more than one category.

In total, the quality of the included studies was of low to moderate and some aspects of quality assessment and risk of bias were unclear across the included studies.

Effect of the interventions

The included studies are using different endpoints to measure the effect of patient engagement interventions. Nine of the included studies found significant effect of interventions.

A RCT by Naik[28] measure the effect of the intervention Healthy Outcomes Through Patient Empowerment (HOPE) which is a six-months goal-setting intervention targeting depression symptoms and diabetes self-care through nine telephone-delivered coaching sessions. The HOPE intervention used an electronic data warehouse to identify specific high-risk population, followed by telephone screening and training of clinicians to deliver a structured telehealth intervention. The endpoints in this study was depression symptoms with The Patient Health Questionnaire (PHQ)-9 and glycaemic control with haemoglobin A1c (HbA1c). They did not find any improvement in six-month follow-up, but found improvement in PHQ-9 after 12-month follow-up; HOPE (Mean [SD] baseline: 15,8 [4,2] to six months: 10,9 [6,1] and 12 months 10,1 [6,5]) compared with Enhanced Usual Care (EUC) (Mean [SD] baseline 16,2 [4,0] to six months 12,4[6,0]) and 12 months 12,6 [6,0]. The PHQ-9 differences between HOPE and EUC were statistically significant at six months (mean diff., 1.74; 95% CI, 0.14-3.33; P = 0.03) and 12 months (mean diff., 2.14; 95% CI, 0.18-4.10; P = 0.03).

The study by Reed[29] examined the effect of the intervention Chronic Disease Self-Management Support (CDSMS) which is a set of tools (Partners in Health scale, Cue and Response interview, Problems and Goals assessment) and a structured process that enable clinicians and patients to collaboratively assess self-management behaviour, identify problems, set goals, and develop individual care plans that address key self-care, medical, psychosocial, and care problems. Participants in each program received three home visits and four follow-up phone calls over a six-month period from a clinician. The population were recruited from five general practices in Adelaide, Australia. The study used self-rated health as endpoint, and they with an intention-to-treat analysis that CDSMS participants were more likely than control participants to report improved self-rated health at six months (R, 2.50; 95% confidence interval, 1.13-5.50; P = 0.02).

A RCT by Shively[21] implemented a six month program developed to enhance self-management in older heart failure patients. The program consisted of individualized goal setting according to baseline activation level. The interventions population was invited to participate through a follow-up visit at the Veterans Affairs San Diego Healthcare system. The study used Patient Activation Measure (PAM), Self-Care of Heart

Failure Index (SCHFI), Medical Outcomes Study (MOS), and hospital visits to measure the effect of the intervention. The intervention showed improvement in PAM-score, the intervention group compared with the usual care group showed a significant increase in PAM-scores from baseline to six months (significant group by time interaction, F = 3.73, P = 0.03) and fewer hospital visits compared with usual group.

A prospective naturalistic cohort study by Tay[24] examined the effect of the intervention Care for Acute Mentally Infirm Elders (CAMIE) which adopt a person-centred care protocol with specialized psychosocial interventions, minimally obtrusive medical care, and physical restraints-free practice targeting patients with dementia. The study population were recruited at a hospital, and all patients received standard treatment. Patients were admitted to the CAMIE unit if they suffered from confusion due to dementia, with/without delirium based on the confusion assessment method criteria, and concomitant acute medical problems. The study used Modified Barthel Index function and Well-being and European Quality of Life (EuroQol) to measure the CAMIE intervention. CAMIE patients showed statistically significant greater gains in Modified Barthel Index function (mean [SD] baseline 47.31 [28.90] to 55.58 [29.37]) and well-Being (mean [SD] baseline 4.94 [3.95] to 8.46 [3.49]), decreased ill-Being and agitation (mean [SD] baseline 3.04 [2.11] to 0.84 [1.26]), and greater improvement in EuroQoL index score (mean [SD] baseline -0.16 [0.43] to 0.15 [0.41]) after adjusting for baseline differences that translated to a quality-adjusted life years gain of 0.045, assuming stability over three months.

A controlled before-and-after design by Ulin et al[26] studied the effect of proactive care-planning based on Gothenburg Person-Centred Care (gPCC). It seeks to identify patient's resources including motivations and goals. This information is used to develop a health plan which includes planned investigations, length of stay in hospital and treatment goals. The health plan is discussed with the patient to reach consensus and the plan is regularly evaluated. The population were recruited from five designated wards at a University Hospital in Sweden. The patients were assessed by a specialised cardiologist before final inclusion, guided by the European Society of Cardiology (ESC) guidelines for diagnosing Congestive Heart Failure (CHF). The study used discharge destination and number of days until the discharge was recorded, to measure the gPCC intervention. They found improved discharge processes (1-5 days for gPCC group vs 1-28 days for control group), and fewer days in hospital (11 days for gPCC group vs 35 days for control group).

A RCT by Willadsen[30] examined the effect of structured personal diabetes care with general practitioners (GPs) that ask GPs and patient to agree on the best possible goal for controlling risk factors. GPs were offered six seminars and were instructed to give advice lifestyle. Patients were invited to attend follow-up examination quarterly and screening for diabetes complications every year. The study used self-rated health and diabetes symptoms to measure the effect of the structured person care intervention. They

found that the intervention reduced the diabetes symptoms (OR 0.79; 95% CI: 0.64–0.97), but they didn't find the same after 14 years follow-up.

An observational matched cohort study by Wong[25] implemented a Patient Empowerment Programme (PEP) that aims to provide patient with knowledge and skills about their disease Type 2 Diabetes (T2DM) and to facilitate autonomous self-regulation. The program consisted of generic sessions about self-efficacy enhancement and lifestyle modification as well as disease-specific sessions for a period of up to 12 months. Two non-government organisations (NGO) delivered the intervention, the NGO's invited at general outpatients' clinics or family medicine specialist eligible patients to join the PEP. The study used HbA1c, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), and Low-Density Lipoprotein (LDL-C) to measure the effect of PEP. They found improvement in the clinical outcomes. A significantly greater percentage of patients in the PEP group attained HbA1C ≤7% or LDL-C≤2.6 mmol/L at 12-month follow-up compared with the non-PEP group. PEP group had a mean 0.813 fewer General Outpatient Clinic (GOPC) visits in comparison with the non-PEP group.

A study by Hochhalter[23] measured the effect of Making the Most of Your Healthcare intervention which offered tools and taught skills to (a) prepare for healthcare appointments, (b) communicate effectively and gather information and support during healthcare appointments, and (c) follow through on plans of care. The intervention included a two-hour workshop and two telephone calls individualized to the patient's pre- and post-healthcare appointment needs. The included population were patients in a large Internal Medicine Clinic and had been treated for at least two of seven chronic illnesses. They found a statistically significant improvement in self-efficacy for the intervention group, who received a 2-hour workshop. They used PAM-13 and Health Related Quality of Life (HRQOL)-14 questionnaires as measurement. They found an improvement in Self-Efficacy in the Appointment group (mean [SD] baseline 6,9 [1,9] to 7,4 [1,8]) mean diff. 0,47 95%CI; 0,07-0,87 P = 0,021. They did not find any improvement in health for the control group or safety group.

A quasi-experimental study by Mateo-Abad [27] examined the impact of the CareWell integrated care model on use of health resources and clinical effectiveness. The program is based on coordination between health providers, patient empowerment and home-based care, supported by communication and information technology tools. Relevant differences were observed between the intervention and control group, including reduced numbers of hospitalisations and visits to emergency centres, and clinical outcomes in the intervention group. For instance, when hospitalised their hospital stay was longer for the control group; the mean number of days in the hospital was 13.3 (SD,13.5), whereas the mean stay for the intervention group was 10.4 (SD, 9) days.

Whereas the studies described above did show some improvements of patient-engagement interventions in multi-morbid older patients based on a range of outcomes, the following three studies did not find any significant improvements in health outcomes.

A pragmatic cluster-randomised trial by Salisbury[22] examined the effect of the so-called 3D intervention which is based on a patient-centred care model and seeks to improve continuity, coordination, and efficiency of care by replacing disease-focused reviews of each health condition with one 6-monthly comprehensive multidisciplinary review. Each 3D review consists of two appointments with a nurse and a named responsible physician and a records-based medication review by a pharmacist. The population were recruited from three general practices providing National Health Service (NHS) primary medical in England and Scotland. They measured quality of life with a 5Q-5D-5L questionnaire. The intention-to-treat analysis showed no difference between trial groups (adjusted difference in mean EQ-5D-5L 0.00, 95% CI –0.02 to 0.02; p=0.93). They concluded the intervention did not improve the participant's quality of life.

The study by Tinsel[20] implemented a shared decision-making (SDM) training program that aims to enhance the active role of patients. The program included disease information, physician-patient communication, steps of SDM, motivational interviewing, decision table listing, and role plays simulating consultations. The GP's followed a SDM training programme, and the study population was conducted through GP's in southwest Germany. They used change of patients' perceived participation (SDM-Q-9) and change in systolic blood pressure (BP). According to the mixed model analysis, the average change from T0 was 3.11 points higher in the intervention group than in the control group (97.5% CI [−2.37; 8.61], p = 0.203). The effect was not significant at the (Bonferroni-corrected) 2.5% level. They did not find any statistically significant improvement in systolic BP.

The study by Schwarze et al [31] measured the effect of a question prompt list (QPL) intervention versus usual care among older patients. The QPL intervention target informational needs of patients considering major surgery and include 11 questions that prompt patients and their family members to query their surgeon about treatment options etc. The study population was conducted among surgeons who perform high-risk oncologic or vascular operations on older patients with comorbidities. They measured patient engagement and well-being, including anxiety in patients. For instance, on average, anxiety scores were 1.3 (95% CI, 0.2-2.4) points higher for patients in the QPL intervention group. The authors concluded that these effects were less than the minimally important difference and that the QPL intervention in general did not influence patient engagement and well-being compared with usual care.

DISCUSSION

Statement of principal findings

This systematic review aimed to provide an overview of the effects of patient engagement interventions for older patients with multi-morbidity. From the 805 studies identified, only twelve studies met the inclusion criteria. The included studies were heterogeneous in characteristics of populations, number of participants, types of interventions to enhance patient-engagement, length of follow-up and outcome measures. A range of interventions ranging from prompt list to coaching sessions. This diversity in the evidence base challenges the ability to draw robust conclusions. Overall, the majority of studies showed improvements in health and patient-reported outcomes among patients participating in patient engagement interventions. There was some evidence to indicate that the clinical outcomes (BP, Hba1c, diabetes symptoms and glycaemic outcomes) were improved. Furthermore, some evidence indicates improvements in quality of life (EuroQol, QALY, self-rated health) and fewer health care visits (hospitals, GOPC). However, one study found no significant improvements in quality of life, another study found no significant improvements in patient well-being and anxiety symptoms, and a third study found no significant improvements in BP. As indicated by the limited number of studies and the wide heterogeneity in characteristics of populations, types of interventions to enhance patient-engagement, outcome measures and length of follow-up, there is a need for more substantial studies evaluating patient-engagement tools for both implementation and effect in older patients with multi-morbidity using more longer-term outcomes to capture both patient, provider and system-level effects of patient-engagement. While our review adds to the important field of ensuring that interventions to enhance patient-engagement are developed, implemented and evaluated specifically in the growing population of older adults living with multi-morbidity, the review supports previous work in finding too fragile evidence for robust conclusions to be made.[10-15]

Strengths

This review has several strengths. This review contributes to providing a more substantive evidence base to guide prioritisation and implementation into mainstream healthcare delivery. Since patient-engagement aims at improving care overall, this review did not restrict itself to studies based on particular health outcomes, and consequently studies into a range of health and patient-reported outcomes were included. Another strength is that the systematic literature search that was undertaken adhering to a pre-specified protocol. To standardise our assessment process, we used DistillerSR to upload the bibliographic reference information. We performed a wide search to allow different study designs to include methodological heterogeneity. However, the majority of the included studies were RCT. Two researchers independently selected studies collected data and rated quality of included studies using GRADE method. Discrepancies

were resolved by consensus. We used a transparent framework for developing and presenting summaries of evidence. GRADE is the most widely adopted tool for grading the quality of evidence.

Limitations

Despite of the systematic approach adopted; this review has its limitations. The literature search was completed using two key databases, but additional peer-reviewed articles might have been found by searching and including from a broader range of sources. Relevant articles were excluded if they were published in languages other than English, Danish, Swedish, or Norwegian. Another limitation relates to the differences in transparency as to population characteristics across articles which affected our ability to ascertain types of multi-morbid conditions and the extent of multi-morbidity in the study populations. A minority of the included studies had small participant numbers which might have affected power of the studies. Two studies included less than 100 patients in total. Meta-analysis was not conducted as there was heterogeneity in the outcomes and measurement tools used in the studies. Overall, the quality of the included studies was of low to moderate. Some aspects of quality assessment and risk of bias were unclear across the included studies. This complicates the overall quality assessment. Furthermore, we did not seek clarification with the study authors about whether our assessment of risk of bias in the individual studies was correct.

Implications

This review has highlighted the possible improvements in health and patient-reported outcomes among patients exposed to patient-engagement interventions. However, the evidence base is inconsistent and the quality of the studies is relatively low. Further high quality studies in larger populations over longer time-periods are needed to investigate the long-term effect of patient-engagement interventions.

CONCLUSION

This systematic review found only limited evidence to support the improvements in health and patient-reported outcomes among older multi-morbid patients exposed to patient-engagement interventions. As the quality of the included studies was mostly low, the findings should be interpreted with caution, and there is a need for more robust studies into efficient approaches to engaging older adults with multi-morbidity in care trajectories.

DECLARATION OF CONFLICTING INTERESTS

The authors declare no potential conflicts of interest with respect to the research, authorship and/or publication of this article

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AUTHOR CONTRIBUTIONS

MBS and KA contributed equally to this paper. MK, MBS and KA designed the study. MBS and KA carried out data collection and analysis. All authors contributed to drafting the manuscript. All authors have read and approved the manuscript.

DATA AVAILABILITY STATEMENT

Data from the literature search and selection process are available upon reasonable request to the corresponding author.

FIGURES

Figure 1: Flowchart

Figure 2: Total GRADE

Figure 3: Risk of bias for randomised studies

Figure 4: Risk of bias for non-randomised studies

ETHICS STATEMENT

According to national guidelines, no ethics approval is needed for systematic reviews

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Figure 1: Flowchart

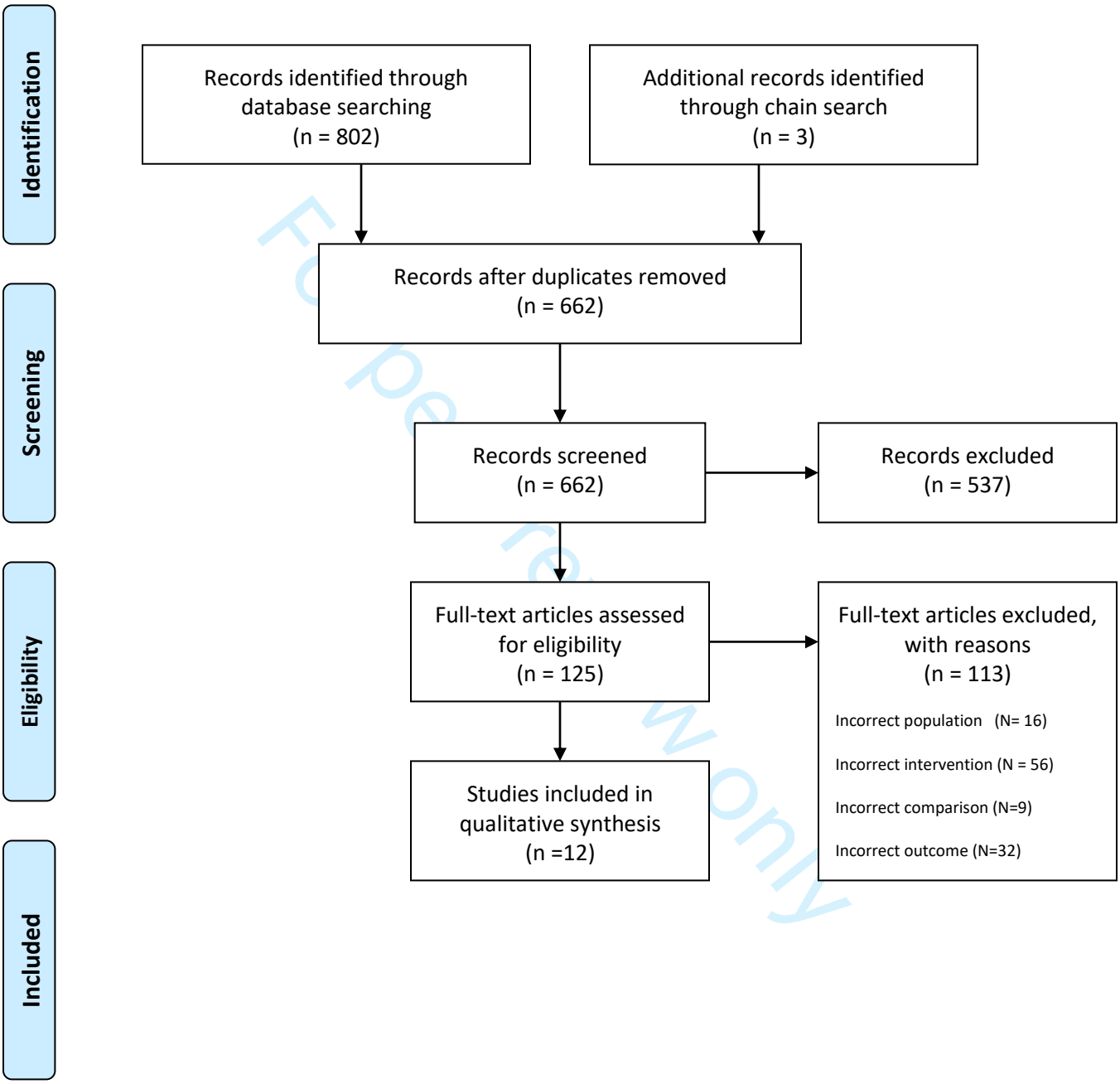


Figure 2: Total GRADE

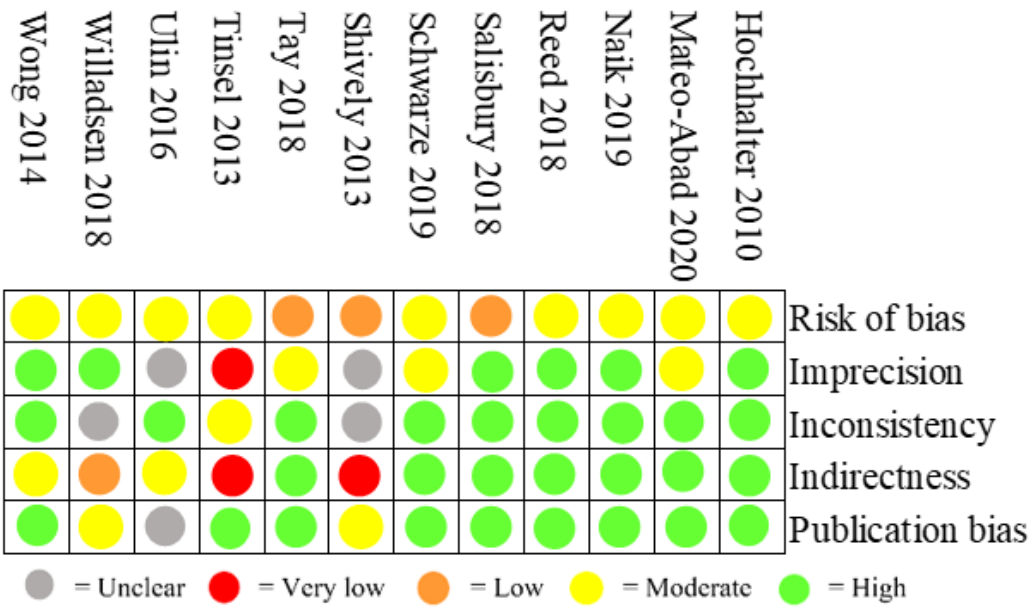


Figure 3: Risk of bias for randomised studies

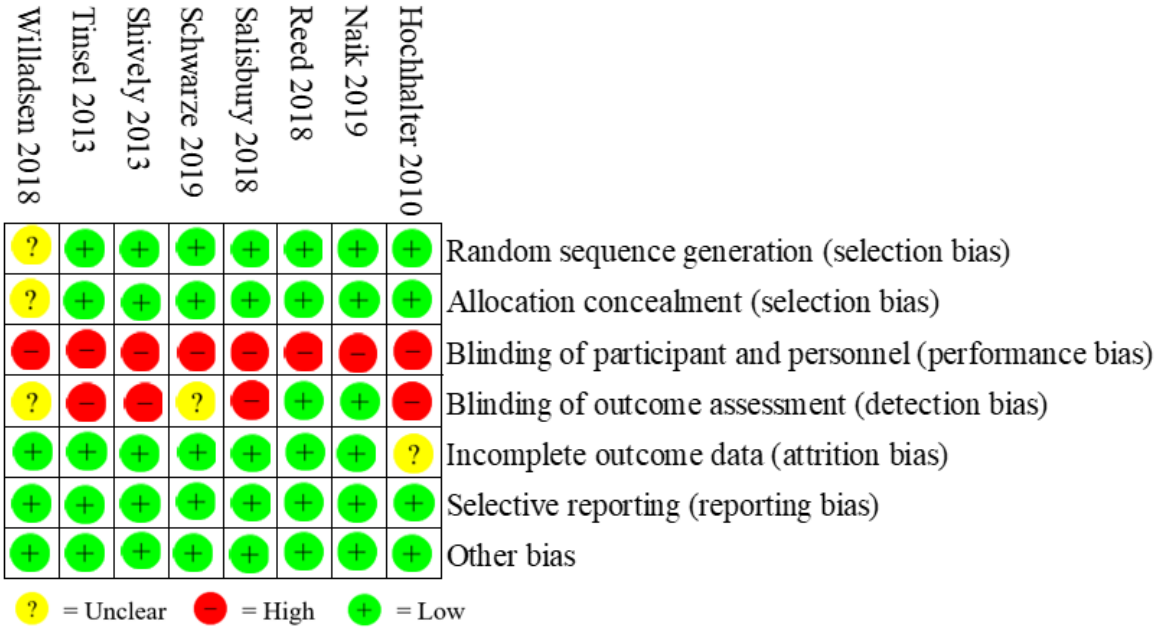
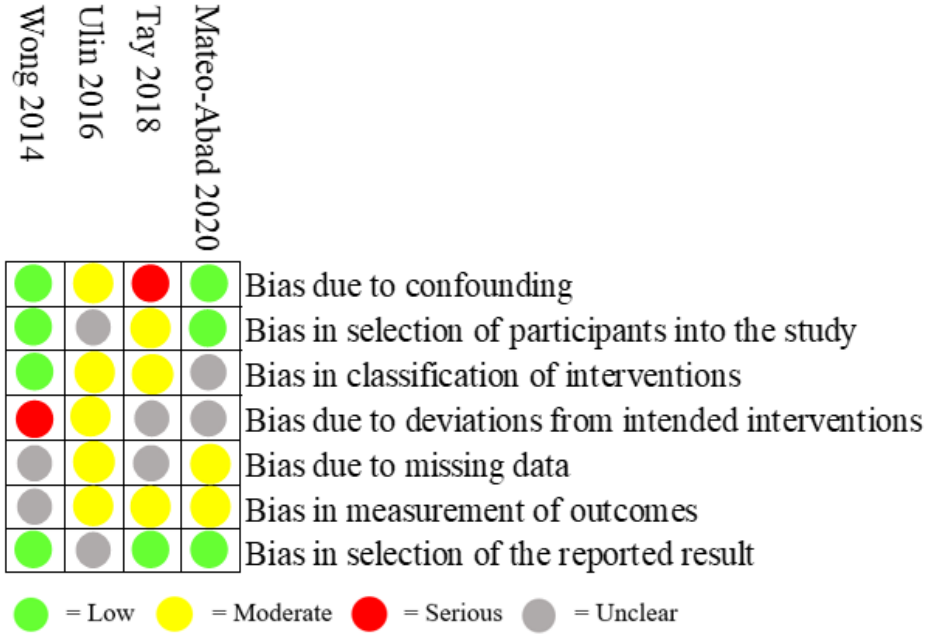


Figure 4: Risk of bias for non-randomised studies



Appendix 1: Keywords and search string

Aspect 1: Patient engagement	**AND**	**Aspect 2:** Multimorbidity	**AND**	**Aspect:** Elderly
Person-centered care		Multimorbidity (MeSH)		Aged (MeSH)
OR		OR		OR
Person centered care		Multi-morbidity		Aged
OR		OR		OR
Patient engagement		Multimorbidity		Elderly
OR		OR		OR
Patient empowerment		Multi-morbidities		Older adult
OR		OR		OR
Patient involvement		Multi morbidities		Older adults
OR		OR		
Patient participation (MeSH)		Comorbidity (MeSH)		
		OR		
		Comorbidity		
		OR		
		Co-morbidity		
		OR		
		Comorbidities		
		OR		
		Co-morbidities		
		OR		
		Multiple chronic conditions (MeSH)		

("person-centered care"[All Fields] OR "person-centered care"[All Fields] OR "patient engagement"[All Fields] OR "patient empowerment"[All Fields] OR "patient involvement"[All Fields] OR "patient participation"[All Fields] OR "patient participation"[MeSH Terms]) AND ("multimorbidity"[MeSH Terms] OR "multi-morbidity"[All Fields] OR "multi-morbidity"[All Fields] OR ("multimorbid"[All Fields] OR "multimorbidities"[All Fields] OR "multimorbidity"[MeSH Terms] OR "multimorbidity"[All Fields]) OR ("multimorbid"[All Fields] OR "multimorbidities"[All Fields] OR "multimorbidity"[MeSH Terms] OR "multimorbidity"[All Fields]) OR "multi-morbidities"[All Fields] OR "multi-morbidities"[All Fields] OR "comorbidity"[MeSH Terms] OR ("comorbid"[All Fields] OR "comorbidity"[MeSH Terms] OR "comorbidity"[All Fields] OR "comorbidities"[All Fields] OR "comorbids"[All Fields]) OR ("comorbidity"[MeSH Terms] OR "comorbidity"[All Fields] OR ("co"[All Fields] AND "morbidity"[All Fields]) OR "co morbidity"[All Fields]) OR "co-morbidities"[All Fields] OR ("comorbid"[All Fields] OR "comorbidity"[MeSH Terms] OR "comorbidity"[All Fields] OR "comorbidities"[All Fields] OR "comorbids"[All Fields]) OR "multiple chronic conditions"[MeSH Terms] OR "multiple chronic diseases"[All Fields]) AND ("aged"[MeSH Terms] OR ("aged"[MeSH Terms] OR "aged"[All Fields]) OR ("aged"[MeSH Terms] OR "aged"[All Fields] OR "elderly"[All Fields] OR "elderlies"[All Fields] OR "elderly s"[All Fields] OR "elderlys"[All Fields]) OR "older adults"[All Fields] OR "older adult"[All Fields])

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Not applicable
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5-9
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5-6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	Not applicable

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	6, 11-12
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	Not applicable
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6, Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6-10
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	9-10
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	10-13
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Not applicable
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Figure 3 and 4
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	Not applicable
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	14-15
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	15
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	15
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	16

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

PRISMA 2009 Checklist