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Effects of goal-oriented care for adults with multimorbidity: A systematic review and meta-analysis

Angelo Barbato MD[1] | Barbara D'Avanzo PhD[1] | Michela Cinquini BSc[2] | Andrea Veronica Fittipaldo MS[2] | Alessandro Nobili MD[3] | Laura Amato MD[4] | Simona Vecchi MS[4] | Graziano Onder MD[5]

[1]Department of Health Policy, Laboratory for Quality Assessment of Care and Services, Istituto di Ricerche Farmacologiche Mario Negri IRCCS, Milan, Italy

[2]Department of Oncology, Laboratory of Clinical Research Methodology, Istituto di Ricerche Farmacologiche Mario Negri IRCCS, Milan, Italy

[3]Department of Health Policy, Istituto di Ricerche Farmacologiche Mario Negri IRCCS, Milan, Italy

[4]Department of Epidemiology, Lazio Region-ASL Rome1, Rome, Italy

[5]Department of Cardiovascular, Endocrine-Metabolic Diseases and Aging, Istituto Superiore di Sanità, Rome, Italy

Correspondence
Angelo Barbato, MD, Department of Health Policy, Laboratory for Quality Assessment of Care and Services, Istituto di Ricerche Farmacologiche Mario Negri IRCCS, Via Mario Negri 2, Milan 20156, Italy.
Email: angelo.barbato@marionegri.it

Abstract

Objective: To systematically review the evidence from randomized controlled trials comparing the effects of goal-oriented care against standard care for multimorbid adults.

Data Sources/Study Setting: The literature presenting the results of randomized trials assessing the outcomes of goal-oriented care compared with usual care for adults with multimorbidity.

Study Design: Systematic review and meta-analysis.

Data Collection/Extraction Methods: We searched the Cochrane Database of Systematic Reviews (CENTRAL), EMBASE, MEDLINE, CINHAL, trial registries such as ClinicalTrial.gov and World Health Organization International Clinical Trials Registry Platform (ICTRP), and the references of eligible trials and relevant reviews. Goal-oriented care was defined as an approach that engages patients, establishes personal goals, and sets targets for patients and clinicians to plan a course of action and measure outcome. We reviewed 228 trials, and 12 were included. We extracted outcome data on quality of life, hospital admission, patients' satisfaction, patient and caregiver burden. Risk of bias was assessed and certainty of evidence was evaluated using GRADE.

Principal Findings: No study was fully free of bias. No effect was found on quality of life (standardized mean difference [SMD]: 0.05; 95% CI: −0.05 to 0.16) and hospital admission (risk ratio [RR]: 0.87; 95% CI: 0.65 to 1.17). There was a very small effect for patients' satisfaction (SMD: 0.15; 95% CI: 0.00 to 0.29) and caregiver burden (SMD: −0.13; 95% CI: −0.26 to 0.00). Certainty of evidence was low for all outcomes.

Conclusions: No firm conclusions can be reached about the effects of goal-oriented care for multimorbid adults. Future research should overcome the shortcomings of

All authors contributed to the paper on equal basis and all participated in the manuscript revision.

trials assessed in this meta-analysis. Sound application of the indications for research of complex healthcare interventions is warranted.

KEYWORDS
chronic illness, meta-analysis, multimorbidity, primary care, randomized controlled trials

1 | INTRODUCTION

The combination of aging populations and the increasing prevalence of multimorbidity—estimated at around 65% in people over 65 and up to 80% in people over 85[1]—is challenging healthcare systems in high-income countries, irrespective of differences in health policies. As a consequence, the strong need to refocus primary healthcare services became evident more than 20 years ago. The Chronic Care Model first addressed this issue in the framework of evidence-based planned care. It included the use of explicit plans and protocols, reorganization of practice to meet the needs of patients who require more assistance, a broad array of resources, closer follow-up, systematic attention to the information needs and behavioural changes patients have to make, ready access to necessary expertise, and supportive information systems.[2] However, although offering a way forward compared to traditional healthcare delivery, this model still had a disease-centred approach, thus failing to meet the needs of multimorbid patients.[3]

The Patient-Centered Medical Home[4] was a further step in the direction of the transformation of primary care. Its core principles were wide ranging, comprehensive and coordinated care, better accessibility of care, a systems-based approach to quality, and patient-centred orientation of care. Patient-Centered Medical Homes became increasingly widespread in the USA, raising expectations of substantial benefits. However, although some trials showed that this model could improve health outcomes in low-income populations,[5] systematic reviews found broad heterogeneity across programmes, low quality and limited effectiveness.[6]

The English National Institute of Clinical Excellence recommended person-centred care models for multimorbidity aimed at the persons rather than the aspects that sum up the complexity of their health; this included modifications of the relevant factors in the person's environment, in which choices of care closely reflect the individual's preferences and values.[7]

Goal-oriented care was developed as a model considering behaviour led by motivations in line with person's beliefs.[8] Patients must therefore be activated to reach valuable quality-of-life goals, corresponding to what they consider most important. This can be achieved through collaboration among professionals, patients and their interpersonal network.

Quality of care cannot overlap the outcome of any medical condition. Coexisting conditions may even have competing clinical priorities and patients can bring additional perspectives into consideration, making goals, preferences and needs more significant. Collaboration between patients and professionals should help identify the best strategies to reach the goals, in line with the priorities set by the individuals concerned. Outcome is best measured by the extent to which these goals are achieved.[9] Collaborative goal-setting is the core of the model.[10,11]

We searched for systematic reviews assessing the results of goal-oriented care and found a narrative review that looked at the effects on process indicators of goal setting with multimorbid elderly persons.[12] The endpoints were agreement between health professionals and patient, rate of completion of directives established in advance, frequency of goals set out in care plans, perception of care as patient-centred.[13] The results were promising, but outcome indicators were not assessed. No quantitative systematic reviews have been published on this issue.

The lack of quantitative analysis of the evidence led us to plan a systematic review and meta-analysis of controlled trials of goal-oriented care compared with usual care for adults with multimorbidity, considering the effects on outcome indicators. This review was conducted within the framework of the Italian Guideline for management of multimorbidity and polytherapy included in the National Guidelines System (https://snlg.iss.it/wp-content/uploads/2021/10/LG-314-SIGG_multimorbilit%C3%A0-e-polifarmacoterapia_rev3.pdf)

2 | METHODS

This review followed the guidelines for Preferred Reporting Items for Systematic Reviews and Meta-analyses (see Online Appendix A).[14] The protocol is available from the authors.

2.1 | Inclusion criteria

We considered cluster and parallel randomized controlled trials (RCTs) comparing the effects of goal-oriented care against standard care. We defined goal-oriented care as an approach that engages patients, establishes personal goals, and sets targets for patients and clinicians to plan a course of action and measure outcome.[15] This would include the following elements: collaborative identification of goals; valuing and using the individual's resources, skills and interests combined with the medical point of view; full entitlement of the person in the selection of goals.[12] Any model satisfying these criteria was considered for inclusion, even if not labelled as goal-oriented by the authors. Trials were considered eligible if they included adults (≥18 years) with two or more chronic conditions.[7]

2.2 | Outcome measures

Primary outcome was health-related quality of life, defined as the perception of an individual's or group's physical and mental health over time (https://www.cdc.gov/hrqol/index.htm); this included the sense of wellbeing and happiness regardless of illnesses and dysfunctions. Health-related quality of life pertains to physical, mental and social aspects related to symptoms, disabilities and limitations caused by disease.[16]

Secondary outcomes were hospital admission, social functioning, caregiver burden, patient and caregiver satisfaction. Effects on hospital admission were presented as dichotomous data (admission or no admission). Effects on other variables were presented as continuous data, measured with self- or expert-rated scales. In case of multiple follow-ups, we considered data collected at the longest follow-up.

2.3 | Identification of trials

We searched the Cochrane Database of Systematic Reviews (CENTRAL), EMBASE, MEDLINE, CINHAL, trial registries such as ClinicalTrial.gov and World Health Organization International Clinical Trials Registry Platform (ICTRP) using free text and MESH terms, from inception up to January 3, 2022. The reference lists of eligible trials and relevant systematic reviews were hand-searched. The search details are available in the Online Appendix B.

2.4 | Data extraction

Three authors independently screened article titles and abstracts and assessed the full text of potentially relevant trials for final inclusion. Any disagreement was discussed with a third author. Two authors independently extracted data from the articles. The following information was considered: number and characteristics of participants (age, sex, ethnicity, illness contributing to multimorbidity, mental and physical conditions); duration and type of experimental and control intervention; length of follow-up; country and setting of the study.

For dichotomous outcomes, numbers of events and numbers of randomized or analyzed patients were extracted for both arms, while for continuous outcomes posttest mean and its standard deviation was extracted or inversely calculated for both arms.

2.5 | Risk of bias assessment

Two authors independently assessed risk of bias separately for each outcome, following the criteria of the 5.1 version of the Cochrane Handbook,[17] considering the following domains: sequence generation and allocation concealment (selection bias), blinding of participants and providers (performance bias), blinding of outcome assessors (detection bias), incomplete outcome data (attrition bias) and selective outcome reporting (reporting bias). Disagreement was resolved by consensus.

2.6 | Data analysis

We analyzed dichotomous outcomes by calculating the risk ratio (RR) with its 95% confidence interval (CI) to express uncertainty in results. For continuous outcomes, we calculated the mean difference and its 95% CI. When different tools or scales were used to measure an outcome or when an outcome was expressed as either dichotomous or continuous, we pooled the data with the generic inverse of variance methods and expressed results as standardized mean difference (SMD) with its 95% CI.

We interpreted SMD according to Cohen et al.'s criteria,[18] where an effect size of 0.2 implies a small effect, 0.5 a medium effect and 0.8 a large effect. To combine both parallel and cluster RCTs, we followed the 6.1 version of the Cochrane Handbook,[19] calculating the actual sample size for each arm to adjust for clustering.

As we assumed a certain degree of heterogeneity among trials, we pooled data using the random effect model. Statistical heterogeneity was assessed with the Cochrane Q-test, setting a significant threshold of $\alpha = 0.1$, and inconsistency among trials was quantified by the I-squared statistic[19]: an I-squared greater than 50% was judged as substantial heterogeneity and greater than 70% as considerable.

RevMan 5.3[20] was used to depict the results as conventional meta-analysis forest plots.

We visually inspected the funnel plots (plots of the effect estimate from each trial against the sample size or standard error of the effect) to indicate any possible publication bias, if at least ten trials were included in the meta-analysis.

2.7 | Grading the evidence

We assessed the certainty of the evidence for primary and secondary outcomes using five domains (study limitations, consistency of effect, imprecision, indirectness and publication bias), according to the GRADE system.[21] The degree of certainty was classified as high, moderate, low or very low.

The summary of findings provides information about magnitudes of relative and absolute effects of the interventions and certainties of evidence.

3 | RESULTS

3.1 | Trials included

Searching retrieved 1443 records after duplicates had been removed. Following full-text screening, 12 RCTs with 4818 participants[22-33] were included. Since some authors described their trials in more than one paper, whenever it was necessary to comment information presented in articles other than the primary ones, this has been specified, and the relative references have been cited (see the remarks to the studies by Kangovi et al.[34] and Verdoorn et al.[35] in Section 3.3).

The selection of trials through review is presented in Figure 1 and their main characteristics are summarized in Table 1.

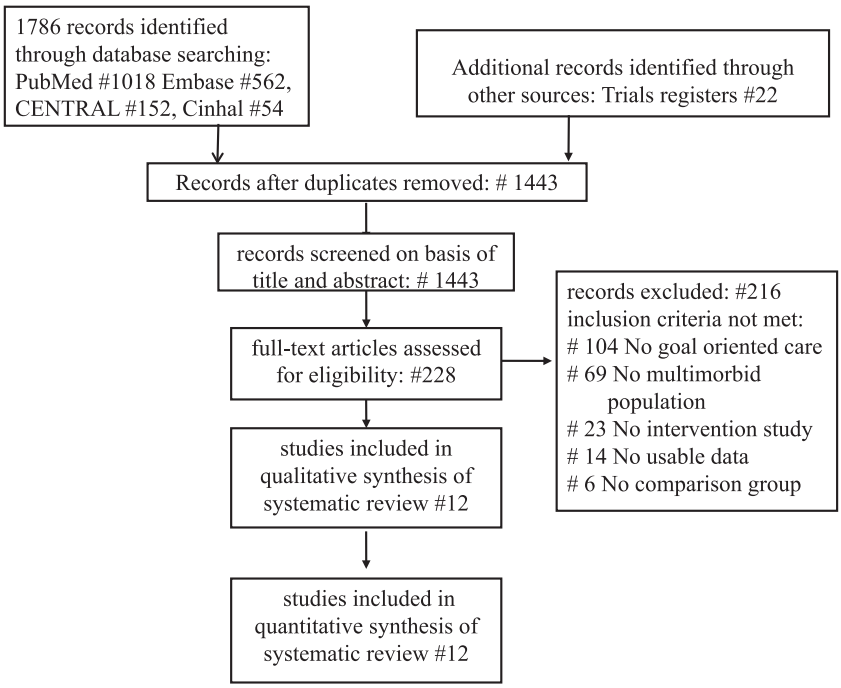

FIGURE 1 Selection of papers through the review process

Four trials were conducted in the USA, two in the UK, two in the Netherlands, one in Ireland, one in Finland, one in Canada and one in South Korea. The studies were conducted between 2009 and 2018. The setting was community care in eleven trials. In one, the intervention started in hospital, and in one, the entire intervention was implemented in a nursing home.[30]

The trial interventions lasted between 2 and 3 weeks[23] and 12 months.[33] In one the duration, although clearly brief, was not specified.[27] In most cases, the duration of the intervention in the control group was not indicated.

Follow-up was at the end of treatment only in five trials.[25,28,30,32,33] In another five, the outcome data were collected at the end of treatment and at follow-up ranging between 1 and 6 months.[22,24,27,30,31] In two trials, data were collected 2 weeks and 1 year after the end of treatment.[23,26] Longer follow-ups after enrolment were at 6 months,[28] 9 months[29] and 12 months.[22,23] In one trial, where the intervention started on hospital admission and continued during aftercare, self-reported data were collected 2 weeks after discharge and data on readmission 1 month later.[27]

3.2 | Study population

In 10 trials, 65% of the subjects (from 52% to 85%) were female.[22,23,25-30,32,33] Only two trials had more than half of male patients.[22,25] Age ranged from working adults in some trials,[24,27,29] to very old persons in others.[23,25,30,31] Ethnicity was mostly African American in three trials,[27-29] white European in five trials,[22,25,31-33] Hispanic in one trial, and Korean in one. Two did not report ethnicity.[23,26]

All trials had multimorbidity as inclusion criterion. The mean number of comorbid conditions ranged from 2.1[24] to 5.[25,26,32] Seven trials did not specify the conditions prevalent among the patients. In the five trials[22,24,28,29,33] reporting the conditions contributing to multimorbidity, the main pathologies were cardiovascular diseases, diabetes, obesity, hyperlipidemia, depression, substance misuse.

3.3 | Interventions

The experimental interventions varied considerably. In Barley et al.'s trial,[22] a case manager conducted a standardized face-to-face biopsychosocial assessment, helping depressed patients identify up to three problems, providing information about resources and using behaviour change techniques to help patients set and achieve goals. The Integrated Systematic Care for Older People (ISCOPE) study[23] used an intervention delivered by trained general practitioners (GPs), consisting of developing a care plan aimed at functional independence, where goals, wishes and expectations of the older person were the starting point. In the Ell et al. trial,[24] the intervention was conducted by trained Spanish-speaking peers providing information and social support, who met patients in six face-to-face visits aiming for engagement, problem formulation, education, action planning and feedback. The intervention followed a problem-solving framework to build skills related to self-management of chronic conditions. In the Ford et al. trial,[25] the goal-setting process was first examined in a qualitative assessment and was subsequently conducted by a trial researcher and a GP in a face-to-face visit, using a goal-setting sheet to be completed by the patient to identify goals and achievement strategies. The GPs then backed patients in achieving the goals and discussed goal attainment after 6 months.

TABLE 1 Characteristics of trials analyzed

Study (year)	Country	Design	Interventions	No. randomized	Female %	Ethnic origin %	Duration of intervention
Barley (2014)	UK	Open-label assessor-blind individual RCT	E, Nurse-led personalized care based on problem identification	E, 41	E, 34	E, 81 White, 5 Asian, 2 Black, 12 other	6 months
			C, Usual GP and nurse care	C, 40	C, 37	C, 85 White, 8 Asian, 5 Asian, 3 other	
Kangovi (2014)	USA	Open-label individual RCT	E, Chronic disease goal-setting supported by community health worker	E, 222	E, 63	E, 93 African American	2 weeks
				C, 224	C, 56		
			C, Routine hospital care and referral to GP			C, 94 African American	
Park (2014)	South Korea	Open-label individual RCT	E, Health coaching self-management	E, 25	E, 86	E and C, 100	8 weeks
			C, Standard nursing home care	C, 25	C, 71[a]	Korean	
Garvey (2015)	Ireland	Open-label individual RCT	E, Occupational therapy-led self-management support	E, 26	E, 65	NR	6 weeks
			C, Usual GP care and wait-list	C, 24	C, 63		
Blom (2016)	Netherlands	Open-label assessor blind cluster RCT	E, Integrated GP- geriatric care plan based on problem identification and goal definition	E, 288	E, 73	NR	2/3 weeks
				C, 1091	C, 72		
			C, Usual care				
Kangovi (2017)	USA	Open-label individual RCT	E, Chronic disease goal-setting supported by community health worker	E, 150	E, 77	E and C, 95 African American	6 months
			C, Chronic disease goal-setting with the primary care provider	C, 152	C, 74		
Ell (2017)	USA	Open-label individual RCT	E, Community based promotor-led psycho-education	E, 178	E, 85	E and C, 99 Hispanic	6 months
			C, County clinic usual care	C, 170	C, 85		
Kangovi (2018)	USA	Open-label individual RCT	E, Chronic disease goal-setting supported by community health worker	E, 304	E, 64	E, 93 African American C, 95 African American	6 months
			C, Chronic disease goal-setting with primary care provider	C, 288	C, 61		
Verdoorn (2019)	Nether-lands	Open-label individual RCT	E, Community medication review focused on personal goals by pharmacists	E, 315	E, 56	E, 97 European	3 months
			C, Usual care and waiting list for community medication review	C, 314	C, 52	C, 98 European	
Ford (2019)	UK	Open-label cluster RCT	E, Goal-setting and goal achievement support by GP	E, 24	E, 54	E and C, 100 White British	6 months
			C, Care planning consultation as usual	C, 28	C, 39		
Fortin (2021)	Canada	Open-label individual RCT with a mixed-methods design	E, Community intervention based on the chronic care model and the patient- centred clinical method, provided by health professionals added to the family medicine group team	E, 144	E, 52	E and C, 100 White	4 months

(Continues)

TABLE 1 (Continued)

Study (year)	Country	Design	Interventions	No. randomized	Female %	Ethnic origin %	Duration of intervention
			C, Usual care provided by family doctors and family medicine group team	C, 140	C, 55	Canadians	
Tusa (2021)	Finland	Open-label individual RCT	E, Community intervention based on participatory patient care planning including goal setting, action planning, documenting, coordinating, supporting and reviewing, provided by trained nurses and GP	E, 304	E, 54	NR	12 months
			C, Usual care provided by GP	C, 301	C, 50		

Abbreviations: C, control; E, experimental; GP, general practitioner; NR, not reported; RCT, randomized controlled trial.
[a]Values are related to analyzed cases.

Group meetings led weekly by occupational therapists for 6 weeks in the Garvey et al. study[26] covered peer support, fatigue management, healthy eating, physical activity and mental health, medication management and effective communication with health professionals. The Kangovi et al. trials[27-29] tested a model (Individualized Management of Patient-Centered Targets, IMPaCT), including organizing a three-stage intervention for low social-economic status patients: goal setting, goal support and connection with primary care by trained community health workers. Before the trial, the authors carried out a qualitative study based on a grounded theory approach to explore patients' goals.[34]

Park et al.[30] implemented an intervention aimed at nursing home residents, the main components being group health education, exercise and individual counselling for goal setting. In the Verdoorn et al. study,[31] a medication review based on personal health goals was done jointly by a pharmacist and a GP. Goal Attainment Scaling was used to prioritize the patient's most important problem.[35] In the Fortin et al. study,[32] pathways started with a contact nurse who made a clinical assessment, elicited patients' goals, and created an individualized care plan. On the basis of this, patients were referred to the professional(s) most appropriate for matching the patient's goals, and a final visit with the contact nurse was scheduled to support and plan sustainability.

The core intervention in the trial by Tusa et al.[33] consisted of participatory patient care, including a patient activation questionnaire and tools for self-monitoring of selected clinical parameters, followed by a goal-setting phase, action planning, documenting, coordinating and reviewing the personalized care plan developed jointly.

Interventions ranged in duration between 2/3 weeks[23,27] and 12 months.[33]

In the control groups, interventions were mainly described as usual care according to the systems of care and settings where the trials were conducted. In two trials by Kangovi et al.,[28,29] the control group received chronic disease management, including goal-setting but without the support of community workers. In the trials by Garvey et al.,[26] Verdoorn et al.,[31] and Fortin et al.,[33] the patients in the control groups received usual care and were placed on a waiting list to receive the experimental treatment following completion of the trial.

3.4 | Risk of bias

Risk of bias assessment is presented in Figure 2. No study was fully free of bias. Six trials[25-27,29,30,33] were judged at low risk of selection bias because both random sequence generation and allocation concealment were appropriate. Two trials were judged at high risk because both random sequence generation and allocation concealment were clearly inadequate.[23,33] The remaining four trials[10,22,24,28] did not provide information about allocation concealment and were judged at unclear risk. All trials were open label and were judged at high risk for performance bias.

Detection bias was assessed according to the outcomes of interest. All outcome indicators except hospital admissions were collected through self-reporting measures and were therefore judged

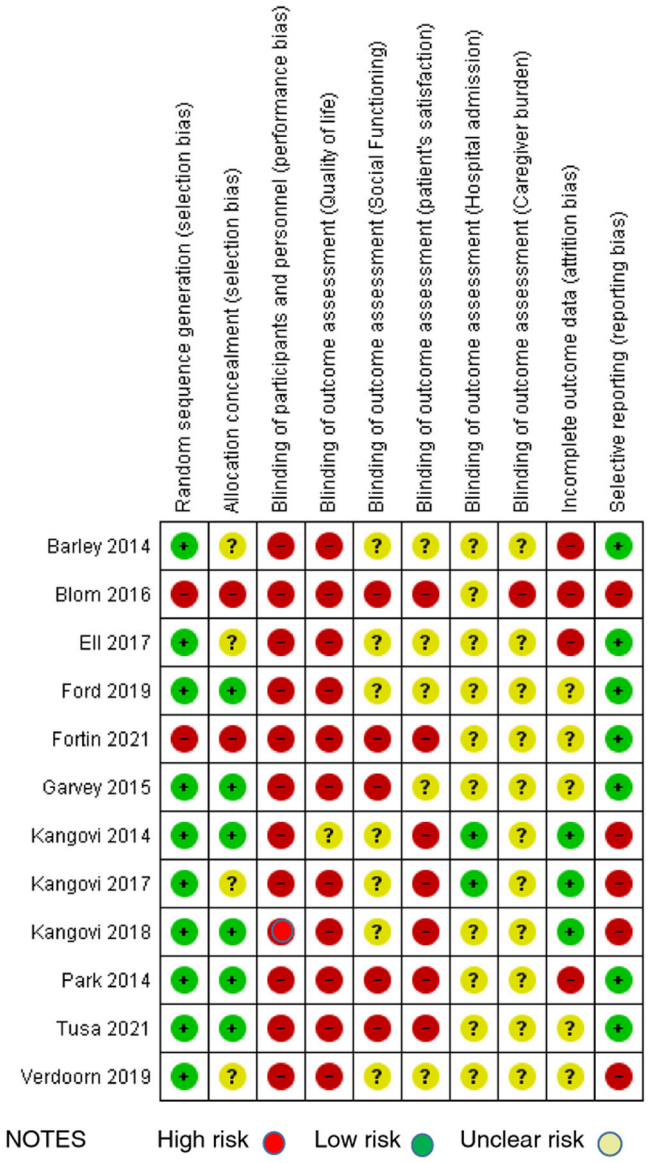

FIGURE 2 Risk of bias assessment

at high risk of bias. Whenever a specific outcome of interest was not assessed, the study was judged at unclear risk. Figure 2 shows the detection bias for each outcome separately.

Only four trials[27-30] were free of attrition bias. The study protocol was available for all trials and the outcomes reported in the final publications coincided with those listed in the protocol. In five trials[23,27-29,31] incomplete outcome data reports prevented their use in the meta-analysis, leading to a judgement of high risk of selective reporting bias.

3.5 | Effects of intervention

Figure 3 compares goal-oriented and standard care. Health-related quality of life, reported by nine trials for 3127 subjects,[22-26,30-33] showed no difference between the experimental and control conditions (SMD: 0.05; 95% CI: −0.05 to 0.16; $I^2 = 33\%$). Risk of hospital admission was reported in three trials for 1340 subjects,[26-28] and no difference was found between the two conditions (RR: 0.87; 95% CI: 0.65 to 1.17; $I^2 = 59\%$).

Caregiver burden was reported in only one study,[22] for 1320 subjects, indicating a difference in favour of goal-oriented care, with a very small effect size (SMD: −0.13; 95% CI: −0.26 to 0.00). An increase in patients' satisfaction, again with a very small effect size (SMD: 0.15; 95% CI: 0.02 to 0.29; $I^2 = 54\%$), favoring goal-oriented care was found in three trials with 2405 subjects.[23,27,29]

No study considered social functioning outcomes. We did not assess publication bias by visual inspection of funnel plots because no outcome data were available from at least 10 trials.

3.6 | Certainty of evidence

The findings related to the GRADE assessment of certainty of evidence are presented in Table 2. Certainty was assessed as very low for hospital admission and quality of life and low for patient satisfaction and caregiver burden. Therefore, little confidence can be laid on all effect estimates.

3.7 | Summary of key findings

Despite the sound rationale and the strong push towards dissemination, the results of this meta-analysis prevent any firm conclusions about goal-oriented care effects. This is due to the low quality of all trials, affecting both their internal and external validity. In any case, no difference was found in primary outcomes compared to standard care. In secondary outcomes too, there was either no difference or very small, negligible differences. No study gave information on harmful effects. Risk of bias was substantial across all domains except the randomization process. It is worth noting that, although goal-setting is a central component of the experimental treatment, only four trials provided information on goal achievement as endpoint.[27-29,31] Moreover, the control interventions as well tended to differ widely and some trials included aspects of goal-setting in the so-called standard care.[25,27,29] There was also considerable heterogeneity among the study populations. Last, the duration of the experimental intervention between 2 weeks and 6 months might have been too short to identify changes in populations with serious long-term illnesses.

4 | DISCUSSION

Before discussing the results of this first quantitative synthesis of research comparing the effects of goal-oriented care with standard care, we have to address its strengths and weaknesses. The strengths are the extensive search of RCTs and the use of the GRADE approach to assess the certainty of evidence. However, some limitations should

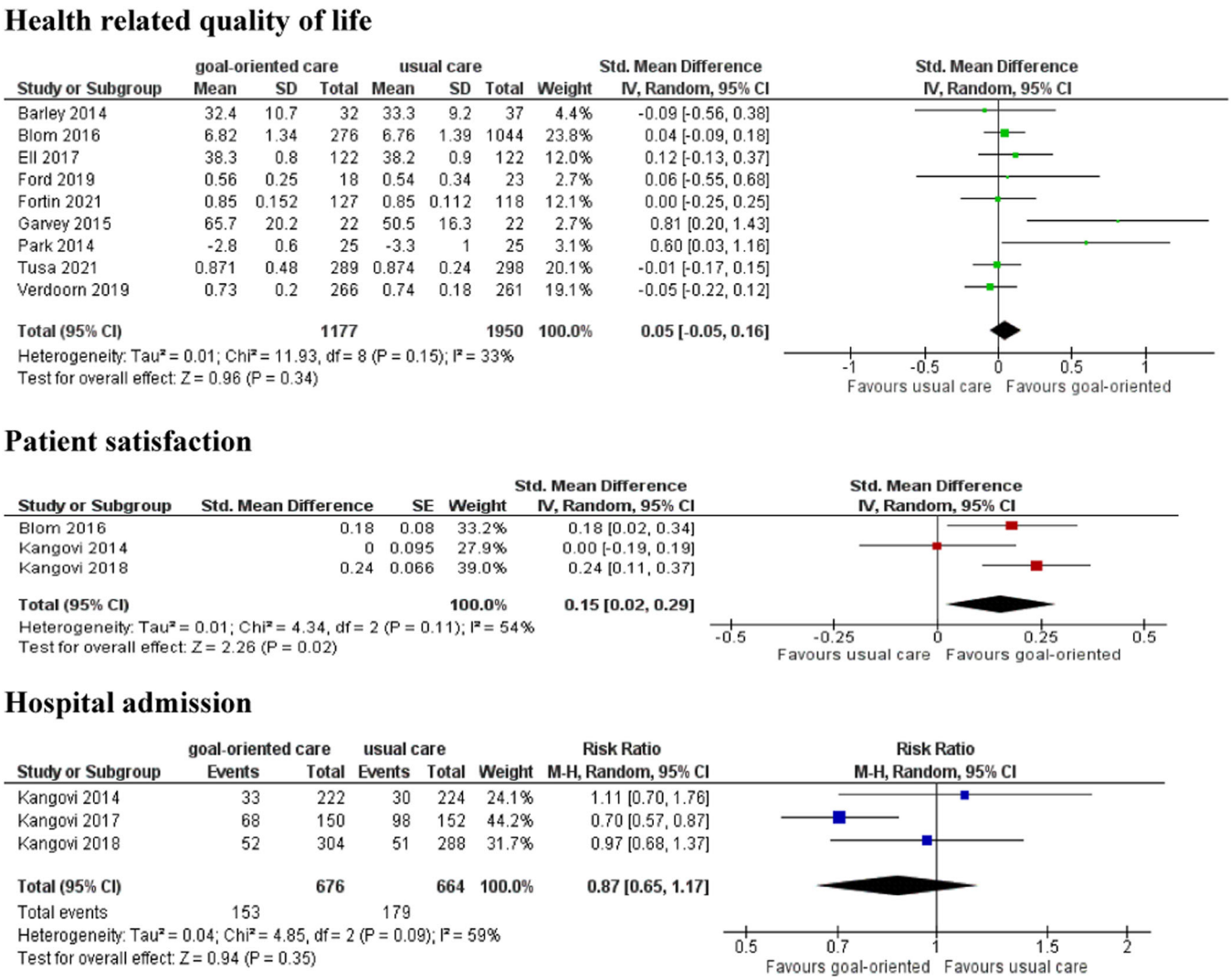

FIGURE 3 Results of the comparisons of goal-oriented care and standard treatment

not be overlooked. First, the restriction to papers in English could have prevented the analysis of suitable trials in other languages. Second, several trials did not label the intervention as goal-oriented care. This is not surprising since it is a complex intervention and may contain more than one component, assembled in different ways and with different emphases. However, we had to rely on a qualitative inspection of the description of the intervention based on the definition of goal-oriented care that we had assumed, and this may have led to some misunderstandings or mistakes.

The risk of bias assessment raised some problems. Performance and detection biases are expected in complex intervention trials assessing patient-reported outcomes such as quality of life and satisfaction. The inherent nature of such pitfalls in trials using self-reported indicators led recently to different, more flexible criteria for assessing performance and detection bias.[36] Although their use has remained limited, partly because of difficulties in the reproducibility of the assessment criteria,[37] the salience of patient-reported outcomes should support the use of more adequate criteria in assessing the quality of trials in meta-analyses, using strategies to reduce the impact of subjective reporting, or at any rate to estimate its effect in observational and experimental studies.[38] Some limits to the external validity of our findings may stem from the assessment of the nature of the interventions, which were defined in different ways across trials and required a qualitative assessment of how closely they corresponded to our definition. This made it difficult to assess treatment fidelity and to some extent jeopardized the comparison of treatments, because of the lack of a common set of suitable endpoints.

The lack of meaningful differences in health-related quality of life between groups may be inherent to the complexity of the construct of this indicator and to the multiple socioeconomic, ecological and psychological determinants that can affect it and the quality of life in general. Goal-oriented care is intended to address the conditions of existence and the preferences of the person, but there is limited the scope for action, however, in tackling more structural and general determinants.

TABLE 2 GRADE evaluation: Summary of findings

Certainty assessment					No. of participants		Effect		
No trials	Risk of bias	Inconsistency	Indirectness	Imprecision	Goal-oriented care	Standard care	Relative (95% CI)	Absolute (95% CI)	Certainty
Hospital admission									
3	Very high[a]	High[b]	Not relevant	Not relevant	153/676 (22.6%)	179/664 (27%)	RR 0.87 (0.65 to 1.17)	35 fewer per 1000 (from 46 more to 94 fewer)	Very low
Health-related quality of life									
9	Very high[c]	High[d]	Not relevant	Not relevant	1177	1950	-	SMD 0.5 SD higher (0.05 lower to 0.16 higher)	Very low
Patient satisfaction									
3	High[e]	High[f]	Not relevant	Not relevant	802	1603	-	SMD 0.15 SD higher (0.2 higher to 0.29 higher)	Low
Caregiver burden									
1	Very high[g]	Not relevant	Not relevant	Not relevant	276	1044	-	SMD 0.13 SD lower (0.26 lower to 0)	Low

[a]Downgraded by two levels because of: (a) high risk of performance bias in all trials due to lack of blindness by participants and personnel delivering the intervention; (b) high or unclear risk due to lack of blindness in assessment of subjective outcomes; (c) all trials at high risk of selective outcome reporting.

[b]I^2 = 59%. Substantial heterogeneity.

[c]Downgraded by two levels because of: (a) unclear risk of selection bias in three trials due to randomization methods; (b) high risk of performance bias in all trials due to lack of blindness by participants and personnel delivering the intervention; (c) high or unclear risk of detection bias due to the lack of blindness in outcome assessment; (d) four trials at high risk of attrition bias due to incomplete outcome data reporting; (e) two trials at high risk of selective outcome reporting.

[d]I^2 = 33%. Moderate heterogeneity.

[e]Downgraded by one level because of: (a) high risk of performance bias in all trials due to lack of blindness by participants and personnel delivering the intervention; (b) high risk due to lack of blindness in assessment of subjective outcomes; (c) high risk of attrition bias due to incomplete outcome data reporting in one study; (d) two trials at high risk of selective outcome reporting.

[f]I^2 = 54%. Substantial heterogeneity.

[g]Downgraded by two levels because of: (a) high risk of selection bias due to randomization method; (b) high risk of performance bias due to lack of blindness by participants and personnel delivering the intervention and of detection bias due to lack of blindness in outcome assessment; (c) high risk of selective outcome reporting.

Abbreviations: CI, confidence interval; RR, risk ratio; SMD, standardized mean difference.

Goal-oriented care must be considered a complex health intervention, including multiple components, causal pathways, feedback loops, synergies, and/or mediators and moderators of effect, requiring multifaceted strategies.[39] The GRADE approach to rating evidence in complex intervention trials is often a challenge, specially if the trialists fail to consider a number of adaptations of the standard trial design and methods.[40] Therefore the quality of trials in systematic reviews is often rated as poor[41] and the case of goal-oriented care confirms this. Some modifications of the trial methodology have been suggested for complex interventions.[42] The use of mixed models has been advocated.[43] However, only three trials in this meta-analysis followed this indication, conducting a qualitative study concurrently with the trial.[24,31,32]

5 | CONCLUSIONS

The importance of evaluating innovative models to face the challenges posed by chronic diseases and multimorbidity calls for close assessment of the introduction in primary care of treatment approaches satisfying the key aspects of goal-oriented care. However, trials in recent years have failed to show to what extent goal-oriented care can improve the outcome of traditional medical care. Therefore, research on this topic remains inconclusive. Future efforts should be directed to overcoming the shortcomings of the trials examined in this meta-analysis. Sound application of the recent indications for research on complex healthcare interventions is warranted.[44] Key features should include the use of mixed models providing qualitative analyses alongside the quantitative evaluations; standardized descriptions of the intervention and comparator; specifications of the hypothetical causal pathways; selection of relevant outcomes on the basis of the causal pathway and assessed by validated instruments; duration of intervention and follow-up consistent with the characteristics and needs of the population receiving the interventions.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data derived from public domain resources. The sources of data are indicated in the article reference list. See references.[22-32]

ORCID

Angelo Barbato http://orcid.org/0000-0001-7142-700X

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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