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Blended collaborative care in the secondary prevention of coronary heart disease improves risk factor control: Results of a randomised feasibility study

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Abstract

Background: Risk factor control is essential in limiting the progression of coronary heart disease, but the necessary active patient involvement is often difficult to realise, especially in patients suffering psychosocial risk factors (e.g. distress). Blended collaborative care has been shown as an effective treatment addition, in which a (non-physician) care manager supports patients in implementing and sustaining lifestyle changes, follows-up on patients, and integrates care across providers, targeting both, somatic and psychosocial risk factors.

Aims: The aim of this study was to test the feasibility, acceptance and effect of a six-month blended collaborative care intervention in Germany.

Methods: For our randomised controlled pilot study with a crossover design we recruited coronary heart disease patients with $\geqslant$1 insufficiently controlled cardiac risk factors and randomised them to either immediate blended collaborative care intervention (immediate intervention group, n=20) or waiting control (waiting control group, n=20).

Results: Participation rate in the intervention phase was 67% (n=40), and participants reported high satisfaction (M=1.63, standard deviation=0.69; scale 1 (very high) to 5 (very low)). The number of risk factors decreased significantly from baseline to six months in the immediate intervention group ($t(60)=3.07$, $p=0.003$), but not in the waiting control group $t(60)=-0.29$, $p=0.77$). Similarly, at the end of their intervention following the six-month waiting period, the waiting control group also showed a significant reduction of risk factors ($t(60)=3.88$, $p<0.001$).

Conclusion: This study shows that blended collaborative care can be a feasible, accepted and effective addition to standard medical care in the secondary prevention of coronary heart disease in the German healthcare system.

Keywords

Coronary heart disease, risk factors, behaviour modification, stress, patient-centred care, collaborative care

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Introduction

Coronary heart disease (CHD) continues to be one of the most common causes of mortality, morbidity, and decreased quality of life worldwide.[1–3] Besides somatic factors, psychosocial burden (e.g. distress) contributes to the development and progression of CHD.[4,5] Therefore, European guidelines for the prevention of cardiovascular disease recommend risk factor control as an essential element of CHD treatment.[6] This requires lifestyle changes, which are often not easy to adopt,[7] especially by patients with psychosocial risk factors.[6]

In our pilot study, we deployed the proven effective blended collaborative care (BCC) strategy to enhance CHD care. BCC is an expansion of the collaborative care model (CC), which was first used for patients with depression and showed positive effects on depressive symptoms in multiple studies.[8] However, it did not impact on comorbid somatic conditions (e.g. cardiac morbidity).[9] Therefore, Katon et al. proposed the 'BCC strategy', in which a (non-physician) care manager imparts long-term treatment coordination of both somatic and mental conditions by: contacting patients at regular intervals to monitor the progression of symptoms, promoting guideline-based treatment and supporting adherence and lifestyle changes, all in close collaboration with the patients' treating physician(s) and under supervision of an expert team matched to the patient's somatic and co-morbid mental conditions.[10] In the TEAMcare study, the first BCC study, BCC improved not only mood symptoms, as expected, but also low-density lipoprotein (LDL), cholesterol, blood pressure (BP) and glucose levels (in diabetics), and was also cost-effective.[11,12] The effectiveness of BCC was confirmed in an implementation study, in which patients with depression and co-morbid diabetes mellitus or CHD showed improvements in depressive symptoms and control of BP or blood glucose.[13] Consequently, the most recent update of European prevention guidelines recommends collaborative care strategies as one treatment option to improve psychosocial risk factors in CHD patients.[6] While previous BCC studies addressed diagnosed somatic and co-morbid mental conditions, our study focused on insufficiently controlled cardiac risk factors, both somatic and psychosocial, as a secondary prevention strategy. Furthermore, in contrast to other studies, aiming at improving the cardiovascular profile under supervision of study assistants,[14–16] our BCC intervention includes a close collaboration of the care manager with patient and treating physician(s) under multidisciplinary supervision.

Since BCC has not been tested in the German healthcare system, the present study was designed to primarily test its feasibility and acceptance, and find a signal for its effect in a sample of CHD patients with insufficiently controlled cardiac risk factors to prepare the design of a larger clinical trial.

Methods

Study design and participants

This single-centre, two-arm randomised controlled pilot study with a crossover design was conducted at the University of Göttingen Medical Center in Germany between 2014–2017. The local ethics committee approved the study protocol, which conforms to the principles outlined in the Declaration of Helsinki. All eligible CHD patients signed an informed consent form. We recruited CHD patients from five private practices (four general practitioners, one cardiologist) in the Göttingen area and the cardiology outpatient clinic of the University of Göttingen Medical Center. Study assistants approached patients, assessed their eligibility (Table 1), and, if met, invited them to their in-person baseline assessment. During

Table 1. Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
1. Age 65+.[a]	1. Severe mental disorders or addictions.
2. Documented angiographic (>50% stenosis in a major epicardial coronary vessel) or clinical (confirmed myocardial infarction more than three months ago) evidence of CHD.[a]	2. NYHA class IV for heart failure.
3. At least one of the following insufficiently controlled somatic or psychosocial risk factors:	3. Comorbidities with a life-expectancy <1 year.
• Arterial hypertension (>140/90 mm Hg or >135/85 mm Hg for 24-hour measurements)	4. Competing treatment demands.
• Hyperlipoproteinaemia (LDL>130 mg/dl)	5. Insufficient German language command.
• Diabetes mellitus (HbA1c>7. 5%)	
• Current tobacco use	
• Physical inactivity (<60 min of moderate physical activity per week)	
• High levels of stress (four-item Perceived Stress Scale >5).	

CHD: coronary heart disease; LDL: low density lipoprotein; MI: myocardial infarction; NYHA: New York Heart Association.
[a]Due to slow recruitment, the inclusion criteria were modified after eight months to also include patients with stable CHD but without MI and those younger than 65 years.

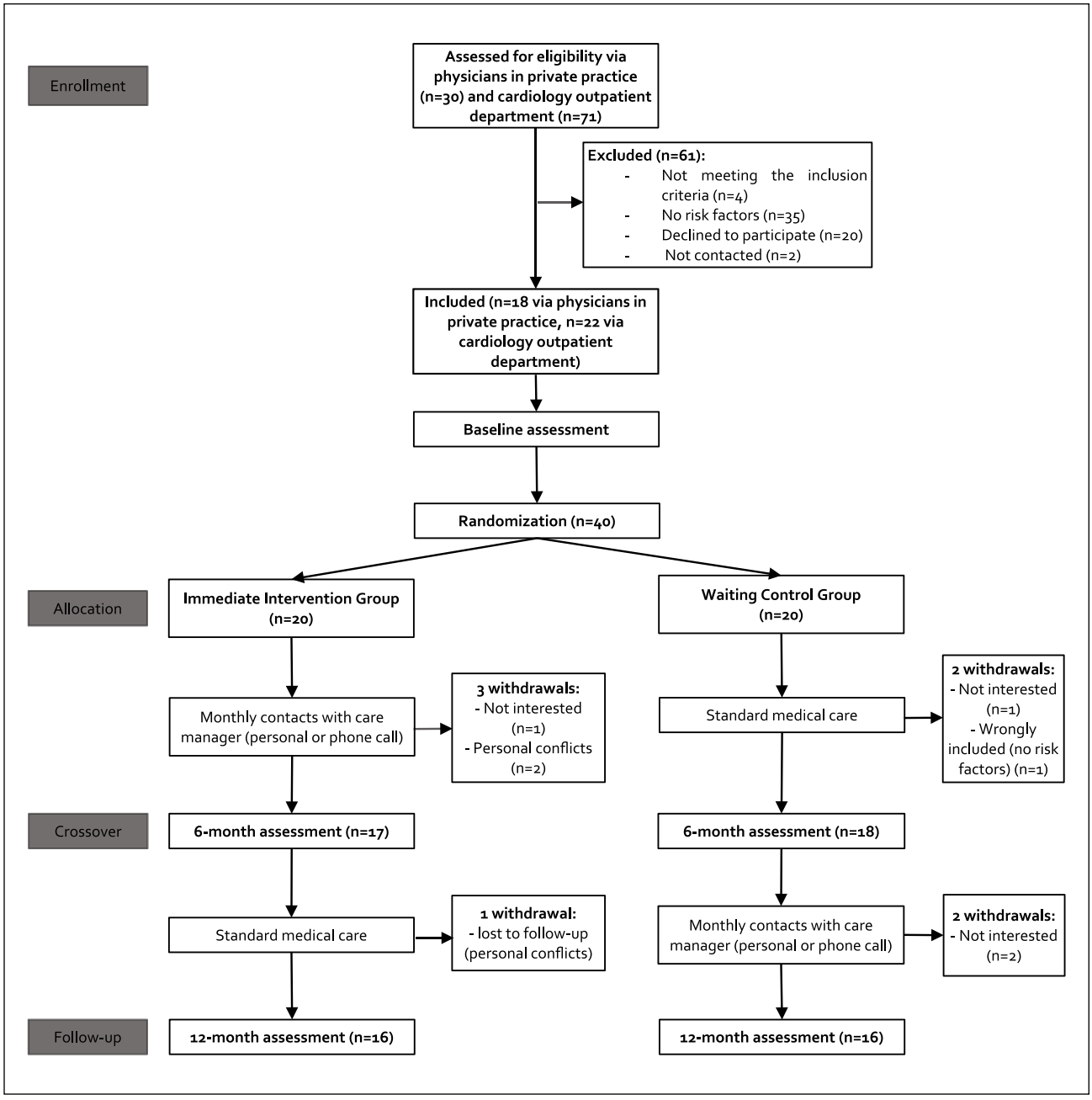

Figure 1. Recruitment flow and intervention schedule.

this meeting, patients were randomly assigned 1:1 by drawing lots to either six months of BCC intervention followed by standard medical care (SMC) for six months (immediate intervention group (IIG)); or six months of SMC alone followed by six months BCC (waiting control group (WCG)) (Figure 1). During the entire study duration (i.e. 12 months for each patient), patients continued to receive SMC by their physicians. The study assistant, who conducted the baseline assessment also served as their care manager for the six-month BCC intervention. Due to the design of our intervention, care managers, patients and their physicians were not blinded to their intervention group.

Assessments

At baseline, study care managers collected sociodemographic characteristics (age, sex, family status, social status and educational level) by patient self-report and administered the assessment battery, which we also administered at six- and 12-months follow-up.

Primary outcomes. To assess the number of risk factors we collected measurements of blood pressure, LDL, hemoglobin A1c (HbA1c) and self-reports of tobacco use and physical activity. LDL and HbA1c were assessed by current

measures obtained from treating physician or if not available, the study team drew blood. We measured participants' subjective experience of stress with the four-item Perceived Stress Scale (PSS-4; range 0-16, relevant cut-off >5).[17,18] At baseline, six- and 12-months, participants rated their satisfaction with their treatment of heart disease and general medical care, and at the end of each intervention phase with our study intervention (scale 1=very good to 5=very poor). Due to a logistical error, the satisfaction questionnaire was only administered to a subsample of 27 participants (12 IIG, 15 WCG).

Secondary outcomes. We measured participants' anxiety and depression with the Hospital Anxiety and Depression Scale (HADS),[19] specific heart-focused anxiety with the Cardiac Anxiety Questionnaire (HAF-17),[20] health-related quality of life (HRQoL) with the Medical Outcomes Short Form Health Survey (SF-12; mental (MCS) and physical components (PCS)),[21] self-efficacy expectation with the General Self-Efficacy Scale (GSE-6),[22] and the participants' subjective perception of social support with the ENRICHD Social Support Instrument (ESSI).[23] All psychometric instruments used in this study have been shown to be reliable and valid, and have been successfully used in cardiac patients.

Intervention

Study care managers (assistant physician, psychologist or study nurse), trained in motivational interviewing[24] and problem solving therapy,[25] delivered our six-month BCC intervention adapted from the TEAMcare study protocol.[10] To ensure uniform intervention delivery, regular supervision meetings took place to ensure the care managers' protocol adherence. Each care manager contacted his/her participants regularly to: (a) review their risk factors and set individual goals for lifestyle changes with each patient using shared-decision making; (b) support them in adhering to treatment plans, which were discussed during the first intervention contact and conformed to national guidelines; (c) monitor progression and coordinate care; and (d) connect them with self-help groups (e.g. for smoking cessation) and other support resources (e.g. psychotherapy). At every contact our care managers administered the Patient Health Questionnaire (PHQ-9) to monitor the level of depressive symptoms (values $\geqslant$10 indicating moderate severity) and possible suicidal ideation.[26] Participants had up to six intervention contacts during the intervention phase, either in person or via telephone (30–60 min each).

Our care managers regularly presented their patients to an expert team consisting of specialists from psychosomatic medicine, cardiology and psychology to discuss insufficiently controlled risk factors and prepare guideline-based treatment recommendations for participants' physicians. They sent at least three written reports per participant to both participants and their treating physicians, providing information about the participant's risk profile, goals and progress. Physicians remained free to decline or modify our suggested recommendations.

During the intervention phase, we also offered participants weekly psychoeducational groups that consisted of 15 90-minute sessions, covering relevant medical background of CHD, somatic and psychosocial risk factors and introducing evidence-based behavioural interventions.

Statistical analysis

We calculated differences between the IIG and WCG with Fisher's exact tests for categorical measures and Wilcoxon rank sum tests for continuous measures across the entire sample randomised at baseline (n=40).

Five participants withdrew during the active intervention (3 IIG, 2 WCG), and three during the SMC phase (1 IIG, 2 WCG). As this pilot trial was merely intended to provide first signals of beneficial effects of our intervention rather than a strict test of its effectiveness, the following analyses of the primary and secondary outcomes are conducted with the 32 participants (80%) who completed both intervention and follow-up assessments (n=16 in each group). This sample size suffices to detect effect sizes of d=0.59 in the group (IIG vs WCG)×time (baseline vs six-months) interaction contrast with α=0.05 and a power of 1-β=0.90, assuming a correlation of r=0.50 between repeated measures (calculated with G*Power Version 3.1.9.2).[27] One of the primary outcomes (number of risk factors) was analysed with multilevel mixed linear models, including group (IIG vs WCG), time (baseline vs six- vs 12-months) and group×time interaction as predictors. Hypotheses were tested using multiple Holm-Bonferroni-corrected t-tests over differences of group means estimated from this model (see Supplemental Material File S1 Tables S2 and S3).

The secondary outcomes were analysed using Wilcoxon signed rank tests comparing pre- and post-intervention assessments aggregated across both groups (i.e. baseline vs six-months in IIG combined with six- vs 12-months in WCG) because of the small number of participants, and because the secondary outcomes should provide only additional indications of the intervention effect.

Results

Baseline characteristics

At baseline, participants in the IIG had a higher education level than those in the WCG, but had otherwise similar sociodemographic characteristics (Table 2). Furthermore, participants in the IIG tended to report higher ratings of cardiac anxiety as measured by HAF-17. Excluding the eight withdrawn participants did not affect the distribution of baseline characteristics between groups as displayed in

Table 2. Comparison of the baseline characteristics of all randomized patients (*n*=40) in the immediate intervention group (IIG) and in the waiting control group (WCG).

Variable	IIG *n*=20	WCG *n*=20	*p*-Value
Demographic variables			
Age in years, mean (*SD*)	65.0 (7.99)	65.7 (8.88)	0.86
Sex, male, *n* (%)	17 (85)	17 (85)	1.00
Family status, *n* (%)			1.00
Alone	4 (20)	4 (20)	
With partner/family	16 (80)	16 (80)	
Social status, *n* (%)			1.00
Retired	12 (60)	13 (65)	
Employed	7 (35)	7 (35)	
Unemployed	1 (5)	0 (0)	
Educational level, *n* (%)			0.003
Lower secondary school	0 (0)	4 (20)	
Vocational training	14 (70)	16 (80)	
University degree	6 (30)	0 (0)	
Risk factors			
SBP, mm Hg mean (*SD*)	138.9 (11.78)	139.8 (21.19)	0.64
DBP, mm Hg mean (*SD*)	81.1 (10.85)	79.1 (11.82)	0.51
LDL, mg/dl mean (*SD*)	103.5 (32.15)	98.47 (30.01)	0.67
HbA1c, % mean (*SD*)	5.71 (0.50)	5.85 (0.84)	0.90
Active smoker, *n* (%)	4 (20)	4 (20)	1.00
Lack of physical exercise, *n* (%)	4 (20)	3 (15)	0.71
PSS-4 sum score, mean (*SD*)	7.0 (2.92)	6.6 (3.05)	0.65
Sum of risk factors, mean (*SD*)	1.65 (0.81)	1.56 (0.88)	0.85
Further medical data			
BMI, kg/m^2 mean (*SD*)	28.0 (3.48)	28.5 (4.28)	0.84
History of heart attack, *n* (%)	15 (75)	15 (75)	1.00
NYHA class, *n* (%)			0.54
I	8 (40)	10 (50)	
II	10 (50)	10 (50)	
III	2 (10)	0 (0)	
β-Blocker medication, *n* (%)	18 (90)	16 (80)	0.66
Statin medication, *n* (%)	18 (90)	19 (95)	1.00
Psychometric variables			
HAF-17, mean (*SD*)	1.46 (0.36)	1.22 (0.52)	0.09
HADS anxiety, mean (*SD*)	7.20 (3.79)	7.25 (2.63)	0.91
HADS depression, mean (*SD*)	5.65 (4.11)	5.65 (4.02)	0.99
SF-12 PCS, mean (*SD*)	43.70 (7.20)	44.68 (8.07)	0.67
SF-12 MCS, mean (*SD*)	46.86 (11.60)	49.29 (11.21)	0.72

BMI: body mass index; DBP: diastolic blood pressure; HbA1c: hemoglobin A1c; HADS: Hospital Anxiety and Depression Scale; HAF-17: Cardiac Anxiety Questionnaire; LDL: low density lipoprotein; NYHA: New York Heart Association; PSS-4: Perceived Stress Scale; SBP: systolic blood pressure; SD: standard deviation; SF-12 MCS: Short Form Health Survey Mental Composite Summary; SF-12 PCS: Short Form Health Survey Physical Composite Summary.

Table 2 (see Supplemental Material File S4 for a comparison of completers vs withdrawals). Adding educational level or HAF-17 sum scores as covariates to the primary analyses did not change the reported pattern of results.

Feasibility and acceptance

During recruitment, 101 patients were assessed for eligibility to participate in our study, 41 (41%) of whom did not meet eligibility criteria or could not be reached. Of the remaining 60 eligible patients 40 (67%) agreed to participate in our trial (Figure 1).

Patient satisfaction was one of the primary outcomes. The 27 participants (67.5%) with post-treatment satisfaction assessments, aggregated across both groups, rated their mean satisfaction with the BCC intervention on a scale from one (very high) to five (very low) as 1.63 (standard deviation (*SD*)=0.69), indicating high to very

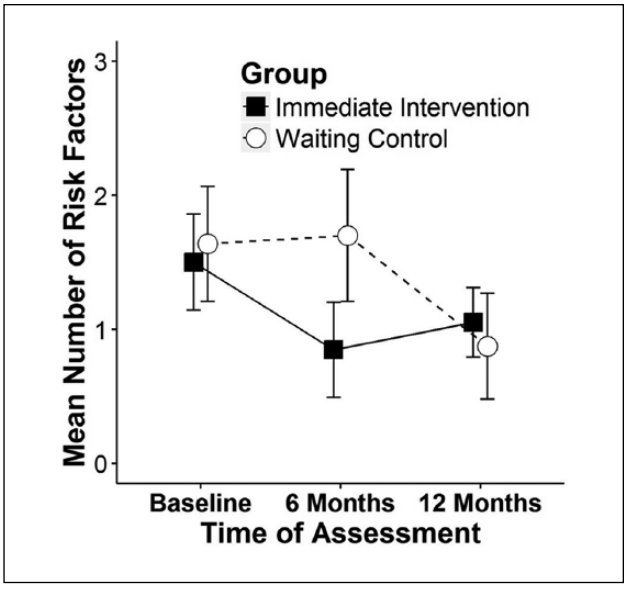

Figure 2. Mean number of risk factors by intervention group and assessment time in the subsample of completers (n=32). Confidence intervals (CIs) indicate 95% CIs.

high satisfaction. None of the participants rated their satisfaction below satisfactory (three on the five-point scale). There were no differences between IIG and WCG in their satisfaction rating (IIG: median (Mdn)=2, WCG: Mdn=1, W=104, p=0.47).

Intervention effect

Primary outcome. The number of RFs decreased from baseline to six months in the IIG group ($M_{baseline}$=1.50, $SD_{baseline}$=0.73, $M_{6\text{-months}}$=0.85, $SD_{6\text{-months}}$=0.72, $t(60)$=3.07, p=0.003, d_{RM}=0.86), while it remained practically unchanged during SMC in the WCG group ($M_{baseline}$=1.64, $SD_{baseline}$=0.88, $M_{6\text{-months}}$=1.70, $SD_{6\text{-months}}$=1.01, $t(60)$=–0.29, p=0.77) (Figure 2). The reduction was significantly larger in the IIG than in the WCG ($t(60)$=2.38, p=0.021, d_{RM}=0.80). Holm-Bonferroni correction did not affect this pattern.

During their intervention phase (at six- to 12-months), the number of RFs also decreased significantly in the WCG ($M_{6\text{-months}}$=1.70, $SD_{6\text{-months}}$=1.01, $M_{12\text{-months}}$=0.86, $SD_{12\text{-months}}$=0.81, $t(60)$=3.88, $p<0.001$, d_{RM}=0.80). Since the number of RFs remained low in the IIG during their SMC phase following intervention ($M_{12\text{-months}}$=1.05, $SD_{12\text{-months}}$=0.53), both groups had similar numbers of RFs at 12-months ($t(60)$=0.64, p=0.53). Comparing pre- and post-intervention assessments of individual RFs aggregated across both groups reveals that stress, the most frequent RF, was on average elevated pre-treatment (Mdn=6.0), but decreased significantly (V=349.5, p=0.016, r=–0.302) and was below the cut-off of 5 points post-treatment (Mdn=4.5). Moreover, none of the five participants who reported low levels of physical activity at baseline remained physically inactive after the intervention. Results were similar for the other RFs across both intervention groups (Supplemental Material Figure S5).

Secondary outcomes. We compared pre- and post-intervention assessments aggregated across both groups (Supplemental Material Table S6). Symptoms of anxiety and cardiac anxiety (HADS-anxiety subscale and HAF-17, respectively) decreased significantly during our intervention (Mdn_{pre}=6.5, Mdn_{post}=5.0, V=279, p=0.009, r=–0.329 and Mdn_{pre}=1.41, Mdn_{post}=1.09, V=401.5, p=0.003, r=–0.375, respectively). HRQoL also improved for the mental component (SF-12 MCS, Mdn_{pre}=52.86, Mdn_{post}=57.54, V=114, p=0.044, r=0.256), but not for the physical component. We did not find any significant changes during intervention for the other secondary outcomes (HADS-depression, GSE and ESSI). Furthermore, no potential harms (such as severe depression, suicidality or critical cardiac symptoms) or other unintended effects occurred.

Discussion

Our pilot study examined the feasibility, acceptance, and effect of a BCC strategy in CHD patients with at least one risk factor in the German healthcare system. The participation rate of 66.7% indicates patients' need to receive additional support. The sub-group of participants (67.5%), who rated their treatment satisfaction, reported high to very high satisfaction with our intervention. Furthermore, our study showed that our six-month intervention had a positive effect on the number of insufficiently controlled risk factors, and that the effect was sustained at the six-month follow-up.

Psychosocial stress is a contributor to increased cardiovascular mortality in patients with stable CHD.[4] In our sample, half of the participants reported increased levels of distress pre-treatment, but had significantly lower levels of perceived stress at the end of our intervention.

Previous studies showed the effectiveness of collaborative care (CC) mainly on symptoms of depression, anxiety and quality of life in various samples of acute and non-acute cardiac patients,[28] but only a few studies were able to show added effects on cardiac risk factors such as BP or blood cholesterol, when only treating depression (e.g. TrueBlue).[29] To our knowledge, since TEAMcare,[10,11] the first BCC study to target both mental and somatic problems, only one implementation study used this strategy,[13] showing improvements in depression and blood glucose or BP in over 3600 patients with depression and diabetes or CHD. As most participants in our study were not depressed at baseline, we did not find any significant decrease in depressive symptoms, but we found significant improvements in mental HRQoL and anxiety symptoms. Our intervention was also successful in reducing distress and increasing patients' physical activity.

Limitations

Due to the nature of a pilot study, our sample size was relatively small. We were able to show a significant overall reduction in the number of risk factors, but the sample was too small to analyse any between-group significance of effects for individual RFs. Moreover, due to a logistical error during reformatting of study questionnaires, only a subset of 27 patients (84%) evaluated their satisfaction with our intervention. Although they reported high satisfaction, this needs to be confirmed in a larger trial. Since only five women participated in the study, the results are not readily generalisable to all CHD patients. Additionally, our sample included only five patients who used tobacco and only one of them quit smoking. To address smoking cessation, more intensive motivational interviewing or other treatment strategies may be needed. Our recruitment was slower than anticipated. Due to the pilot character of our study, we limited the number of cooperating physicians, and were not able to help trouble-shoot with slow recruitment. To improve recruitment, future studies could focus on cardiology outpatient clinics rather than recruit from multiple individual private practices. Additionally, including younger patients (<65 years) would improve recruitment rates. Our withdrawal rate (20%) was higher than we had anticipated. However, this rate is not unusual[30] and did not differ by trial arms. Comparison between withdrawals and completers revealed that participants who withdrew from either group, were significantly more stressed and depressed, and had a lower HRQoL at baseline. Future studies may assess if patients with high baseline psychosocial stressors need more tailored and intensive interventions or an earlier referral to a mental health specialist.

Conclusion

In summary, our study confirmed that the BCC strategy is well-accepted by patients, and feasible in the German healthcare system. It appeared effective in reducing risk factors in CHD patients. Larger multicentre studies are also needed to confirm our results and show the cost-effectiveness of BCC in Germany.

Implications for practice

- Care managers (e.g. study nurses) can effectively motivate and support coronary heart disease (CHD) patients to change and sustain their health behaviour.
- Our blended collaborative care (BCC) intervention can improve the risk profile of CHD patients, especially for behavioural risk factors, such as stress and physical activity.
- BCC is well-accepted by patients.

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Declaration of conflicting interests

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