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## A Standardized Heart Team Protocol versus Guideline-based Protocol on Revascularization Decisions Stability in Complex Coronary Artery Disease: Rationale and Design of a Randomized Trial

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4 **Title page**  
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9 **Title:** A Standardized Heart Team Protocol versus Guideline-based Protocol on Revascularization  
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11 Decisions Stability in Complex Coronary Artery Disease: Rationale and Design of a Randomized  
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14 Trial  
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## ABSTRACT

### Introduction

Multidisciplinary heart team approach has been recommended by revascularization guidelines, but how to organize and implement heart team standardly has not been validated. Inter- and intra-team decision instability existed in guideline-based heart team protocol, and our standardized heart team protocol based on a mixed-method study may improve the decision stability. The objective of this study is to evaluate the effect of a standardized heart team protocol versus guideline-based protocol on decision-making stability in complex coronary artery disease (CAD).

### Methods and analysis

Eighty-four eligible interventional cardiologists, cardiac surgeons, or non-interventional cardiologists were enrolled and randomized to a standardized heart team protocol group or a guideline-based protocol group to make revascularization decisions for 480 complex CAD patients. In standardized group, heart team was implemented based on an evidence-based protocol including specialist selection, specialist training, team composition, team training, and standardized meeting process. In guideline-based group, heart team was implemented according to the key principles mentioned in clinical guidelines, including team composition and standardized meeting process. Twelve heart teams were allocated randomly in each of the group. The primary outcome is the overall percent agreement (OPA) in revascularization decisions between heart teams within a group. To demonstrate the clinical implication of decision-making stability, we will further analyze the association between decision stability and 1-year all-cause death, myocardial infarction, stroke, repeated revascularization, and rehospitalization due to ischemic symptom.

## Ethics and dissemination

The study was approved by the Institutional Review Board (IRB) of Fuwai hospital. Results of this trial will be reported to the participating specialists, disseminated through scientific conferences and journals, reported on <https://ClinicalTrials.gov>, and published in full in peer-reviewed journals.

## Trial registrations:

ClinicalTrials.gov, NCT05039567. Registered on 09/08/2021, <https://register.clinicaltrials.gov/>

## Strengths and limitations of this study

1. The standardized heart team protocol was derived from guidelines but more specific than guidelines. Knowledge gained from this trial will facilitate the heart team implementation quality assessment and improvement for complex CAD.
2. Trial procedures are carried out remotely and all heart team meetings are held via video conference using online system, enabling full involvement and eliminating the risk of viral spreading in COVID-19.
3. Up-to-date risk scores were provided for comprehensive assessment in structured information to adjudicate the optimal treatment strategy.
4. Cases were not enrolled prospectively and feasibility of heart team in routine clinical care remains to be known.

## KEYWORDS

Heart team; standardized protocol; decision-making stability

## INTRODUCTION

Heart Team approach has received a Class 1C/1B recommendation in European and American guidelines on myocardial revascularization in patients with complex coronary artery disease (CAD) to optimize the treatment strategies and may lead to better outcomes.<sup>1-5</sup> Clinical guidelines recommend a heart team, consisting of clinical/non-interventional cardiologists, interventional cardiologists and cardiac surgeons, should take sufficient time to assess all available information of complex cases. However, there are relatively limited data on the heart team implementation in detail, such as the ideal composition, meeting frequency, timing of decision making, and outcomes, potentially leading to suboptimal decision-making quality.

Prior efforts have noted insufficient inter-specialist consistency, intra-team reproducibility and inter-team agreement in heart team decision-making. Denvir et al. found poor agreement existed between cardiac clinical specialist ( $\kappa$  0.26)<sup>6</sup>. Several studies reported that on re-discussion of the same patient data 9-12 months later, nearly 20% to 24% decisions differed from the original heart team recommendations.<sup>7,8</sup> In our previous work, the agreement between heart teams for revascularization decision-making was just moderate ( $\kappa$  0.58)<sup>9</sup>.

Clinical guideline and previous practice experience from different centers have summarized several key principles in heart team implementation.<sup>10-12</sup> Clinical guidelines only recommended the composition of heart team and factors for consideration.<sup>1,5</sup> Sanchez et al. summed up the experience of heart team implementation from their single center, including team composition, data collection, and meeting process. The British cardiovascular Society and Society for Cardiothoracic Surgery in Great Britain and Ireland and British Cardiovascular Intervention Society set out the principles for

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4 the functioning of the heart team across United Kingdom, including composition, frequency and the  
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6 type of cases discussed.<sup>12</sup> Although these works provide important experiences for heart team  
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8 implementation, these protocols were not evidence-based and data regarding how these protocols  
9  
10 impact decision-making stability were scarce.<sup>12</sup>  
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14 To determine the potential factors influencing heart team decision-making comprehensively and  
15  
16 explore an evidence-based heart team protocol, we conducted a sequential explanatory mixed method  
17  
18 study and summarized 3 themes (specialist quality, team composition, and meeting process) and 10  
19  
20 subthemes of potential factors. In addition, 9 recommendations of heart team implementation were  
21  
22 derived based on qualitative and quantitative data and a standardized heart team protocol was  
23  
24 developed based on the previous experience, recommendations and guidelines, covering the whole  
25  
26 procedure of heart team implementation.  
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32 However, the practical effect of the standardized protocol versus guideline-based protocol on  
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34 decision-making stability and clinical outcomes remains unknown and randomized trial for  
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36 validation is warranted. Therefore, we designed and conducted the pivotal randomized trial.  
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## 42 **METHODS AND ANALYSIS**

### 43 **Study design overview**

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45  
46 The current study is a randomized, controlled, 2-arm trial involving 84 cardiac specialists in 26  
47  
48 hospitals from China. Eligible specialists were randomized either to standardized implementation  
49  
50 protocol group or guideline-based group and established 12 heart teams in each group to make  
51  
52 revascularization decisions for 480 retrospectively enrolled patients with complex CAD. Decision-  
53  
54 making stability will be evaluated. (**Figure 1**) SPIRIT<sup>13</sup>, CONSORT<sup>14</sup>, and TIDieR<sup>15</sup> checklists are  
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4 in **Supplemental File 1**. All procedures were approved by the Institutional Review Board (IRB) of  
5  
6 Fuwai hospital (2 August 2021). The study start date was 4 January 2022 and the anticipated end  
7  
8 date is 30 November 2022.  
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## 10 11 12 **Objective and hypothesis**

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16 The primary objective of this study was to evaluate the effect of the standardized heart team protocol  
17  
18 versus guideline-based protocol on the stability of decision-making in patients with complex CAD.  
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20 The main study hypothesis is that heart teams organized following the standardized protocol will  
21  
22 result in a better decision-making consistency compared with heart teams based on guideline  
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24 principles. The secondary objectives of this study are to (1) evaluate the association between  
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26 decision-making stability and 1-year composite of death, myocardial infarction (MI), stroke, repeated  
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28 revascularization, and rehospitalization due to ischemic symptoms; (2) assess the appropriateness of  
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30 heart team decision-making.  
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## 36 37 38 **Participants and recruitment**

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41 To have access to enough experienced specialists, we enrolled eligible specialists from hospitals that  
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43 (1) annual volume of percutaneous coronary intervention (PCI)  $\geq 500$ ; (2) annual volume of coronary  
44  
45 artery bypass grafting (CABG)  $\geq 200$ <sup>1</sup>; (3) have at least 2 interventional cardiologists, 2 cardiac  
46  
47 surgeons and 1 non-interventional cardiologists meeting the inclusion criteria and agreeing to  
48  
49 participate in the study. The inclusion criteria for the heart team specialists differs from specialties  
50  
51 and is required for specified operator volumes and experience (**Table 1**). Interventional cardiologist  
52  
53 is required to have annual PCI volume  $\geq 200$ <sup>16</sup>, annual left main (LM)-PCI volume  $\geq 25$ <sup>1</sup>, and is  
54  
55 capable of chronic total occlusion (CTO)-PCI. Cardiac surgeon is required to have total CABG  
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4 volume  $\geq 200^{17}$ , and is proficient in both on-pump and off-pump CABG. We contacted with all the  
5  
6 potential participants via e-mails or telephones to get their information confirmed and obtained their  
7  
8 content during December 1,2021 to January 10, 2022. All participants have provided written  
9  
10 informed consent for enrollment.  
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14 **Table 1. Inclusion criteria for heart team specialists**  
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Disciplines	Inclusion Criteria
Interventional Cardiologist	1) Annual PCI volume $\geq 200^{16}$
	2) Annual LM PCI volume $\geq 25^1$
	3) Capable of CTO PCI
	4) Clinical researcher experience in coronary revascularization
	5) Proficient in clinical guidelines
Cardiac Surgeon	1) CABG total volume $\geq 200^{17}$
	2) Proficient in both on-pump and off-pump CABG
	3) Clinical researcher experience in coronary revascularization
	4) Proficient in clinical guidelines
Non-interventional Cardiologist	1) Proficient in clinical guidelines

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40 CABG indicates coronary artery bypass grafting; CTO, chronic total occlusion; LM, left main; PCI,  
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42 percutaneous coronary intervention.  
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#### 46 **Randomization**

47  
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50 Randomization was stratified by specialties and was conducted by data manager using random  
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52 number generation in SAS. Thirty-six cardiac surgeons and 36 interventional cardiologists were  
53  
54 randomly allocated in a 2:1 ratio to the standardized protocol group (24 surgeons and 24  
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56 interventional cardiologists) or guideline-based group (12 surgeons and 12 interventional  
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4 cardiologists). Twelve non-interventional cardiologists were randomly selected and allocated to  
5  
6 guideline-based group. After the randomization, each group of specialists were randomly assigned to  
7  
8 12 heart teams and will perform heart team meetings according to standardized protocol or guideline-  
9  
10 based protocol. Research staff was informed of the randomization and organized the allocated  
11  
12 specialists to establish heart teams. Participating specialists were unaware of the implementation  
13  
14 conditions. **(Online Figure 1)**

## 20 **Case selection and preparation**

### 23 *Selection of cases to be discussed*

24  
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27 Adult patients with stable CAD according to the National Cardiovascular Data Registry (NCDR)  
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29 CathPCI criteria<sup>18</sup> (stable angina, no or silent myocardial ischemia) and angiographically confirmed  
30  
31 3-vessel disease or left main (3VD/LM) disease were eligible for inclusion in the study. Eligible  
32  
33 cases were randomly selected from a prospective registry of consecutive patients who underwent  
34  
35 coronary angiography between August 2016 and August 2017.<sup>19</sup> Definitions and inclusion/exclusion  
36  
37 criteria of cases can be seen in **Supplemental methods**. All patients have provided written informed  
38  
39 consent for the study **(Online Figure 2)**.

### 46 *Structured patient information*

47  
48  
49 Patient data were presented in a structured information form onto an electronic meeting support  
50  
51 system by a non-clinical coordinator **(Online Table 1)**. The structured information included (a)  
52  
53 demographics; (b) medical histories and clinical risk factors; (c) medical treatment histories and CVD  
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55 symptoms of the index hospitalization; (d) laboratory results; (e) noninvasive testing results (e.g.  
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4 electrocardiogram, echocardiogram, stress testing results); (f) diagnostic angiogram images and  
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6 quantitative flow ratio (QFR)<sup>20</sup>; (g) clinical risk scores (i.e. SYNTAX (Synergy Between  
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8 Percutaneous Coronary Intervention With Taxus and Cardiac Surgery) score<sup>21</sup>, SYNTAX II score<sup>22</sup>,  
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10 SYNTAX II 2020 score<sup>23</sup>, Society of Thoracic Surgeons (STS) score<sup>24 25</sup>, the European System for  
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12 Cardiac Operative Risk Evaluation (EuroSCORE) II<sup>26</sup>, and sinoSCORE II<sup>27</sup>). All the clinical  
13  
14 information were obtained from medical records according to the NCDR CathPCI data definitions<sup>18</sup>.  
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16 All angiogram images were screened and risk scores were evaluated by an independent angiographic  
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18 core laboratory using a computer-based automatic calculator.  
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### 25 ***Case assignment***

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29 Four hundred and eighty cases were randomized into 6 sets of 80 cases each using a stratified  
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31 randomization procedure for discussion to ensure relatively equal heart team exposure to case  
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33 complexity and a similar ratio of actual treatment strategies (CABG, PCI, or medication therapy).  
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### 37 **Intervention**

#### 38 ***Standardized Heart team protocol***

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42 Eligible specialists randomized to this group established 12 heart teams and will conduct heart team  
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44 meetings based on the standardized heart team protocol.<sup>9</sup> **(Figure 2)**  
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50 **i. Specialist selection.** All the cardiac surgeons were required personality test by Ten-Item  
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52 Personality Inventory in China (TIPI-C)<sup>28</sup> and 24 surgeons with moderate scores were randomly  
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54 selected. **(Online Table 2)** Twenty-four interventional cardiologists were randomly selected  
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56 without personality selection.  
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4 **ii. Specialist training.** Unified training is required for all heart team members to achieve consensus  
5  
6 view on the potential factors influencing revascularization decision. The training will be  
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8 conducted and recorded by well-prepared coordinators. Consensus view should include clinical  
9  
10 considerations on the key characteristics (e.g. age, left ventricular ejection fraction (LVEF), and  
11  
12 body mass index (BMI)) and their weightage, interpretation of evidence (e.g. SYNTAX trial,  
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14 Evaluation of XIENCE versus Coronary Artery Bypass Surgery for Effectiveness of Left Main  
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16 Revascularization (EXCEL) trial and the International Study of Comparative Health  
17  
18 Effectiveness with Medical and Invasive Approaches (ISCHEMIA) results). Additionally, the  
19  
20 latest technical advancements in PCI and CABG will be discussed, especially for PCI, to narrow  
21  
22 cognitive gaps among specialists of different expertise. The consensus view document will be  
23  
24 recorded and put onto the electronic meeting support system for specialists' reference at any  
25  
26 time. To maintain the fidelity to the consensus view, each bullet point of the consensus view will  
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28 be presented as a footnote under the corresponding variable.  
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37 **iii. Team composition.** All specialists selected were randomly assigned to 12 heart teams consisting  
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39 of 2 cardiac surgeons and 2 interventional cardiologists in each. Non-interventional cardiologist  
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41 or other disciplinary specialist is not required in the routine heart team unless necessary.  
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43 Moreover, technical level and administration position was balanced in each team.  
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48 **iv. Team training.** Prior to the formal heart team meeting, a pilot discussion (25-50 retrospective  
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50 cases) will be performed following the standard meeting procedure to reinforce the practice of  
51  
52 former consensus view for a more solid team consensus.  
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56 **v. Standardized meeting process.** Heart team meetings will be conducted similarly and standardly  
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58 in both group according to the procedure widely used in previous studies.<sup>10-12</sup> Each heart team  
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4 independently evaluates a set of cases (80 cases) through the heart team assistance system using  
5  
6 structured online case presentations, with the members blinded to the other heart teams and the  
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8 decisions of other heart teams. All specialists are required to make decisions independently  
9  
10 among five treatment categories (PCI, CABG, PCI/CABG equipoise, medical therapy, or further  
11  
12 testing) before (round I) and after (round II) the heart team discussion. The heart team member  
13  
14 only has access to the responses of the other heart team members after all members have  
15  
16 submitted their independent decisions. The final treatment strategy is determined by majority  
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18 decision.<sup>29</sup> (**Online Figure 3**)  
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### 25 ***Guideline-based protocol***

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29 Eligible specialists randomized to this group were randomly assigned to 12 heart teams based on the  
30  
31 basic principles of guidelines (**Figure 2**). Each heart team consists of 1 interventional cardiologist, 1  
32  
33 cardiac surgeon, and 1 non-interventional cardiologist. Pre-meeting training on consensus view and  
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35 pilot discussion is not required in this group. Formal meeting procedures follow the standardized  
36  
37 meeting process as the other group.  
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42 All heart team meetings will be held through video conferencing and a quiet environment will  
43  
44 be required. For each heart team, the frequency of meeting is one or two times per week and lasting  
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46 1.5-2h at a time. Heart teams in each group were divided into six pairs randomly, and each pair of  
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48 heart teams will evaluate the same randomly assigned 80 cases independently to make optimal  
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50 revascularization decisions.  
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### 55 **Outcomes**

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59 The primary outcome is the overall percent agreement, defined as the proportion of patients who  
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4 received coincident decision recommendations from paired heart teams. The secondary outcomes  
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6 include:

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9 (1) 1-year major adverse cardiovascular and cerebrovascular events (MACCEs): a composite of all-  
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11 cause death, MI, stroke, repeated revascularization, and rehospitalization due to ischemic  
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13 symptom;  
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16 (2) Kappa value of heart team decision-making: Fleiss's (more than 2 raters) and Cohen's (2 raters)  
17  
18 kappa coefficients to evaluate inter-team, intra-team, inter-specialist, intra-specialist, and inter-  
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20 round agreement for treatment decisions; At 1 month after the completion of initial discussion, all  
21  
22 assigned cases will be re-presented and re-discussed with the same clinical data but not in the  
23  
24 same order, with the heart team blinded to the outcome of the initial meeting, in order to evaluate  
25  
26 the intra-team stability.  
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29 (3) Inappropriate decision rate: the final heart team recommendations will be adjudicated for  
30  
31 appropriateness using the American College of Cardiology/American Association for Thoracic  
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33 Surgery/American Heart Association 2017 Appropriate Use Criteria for coronary  
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35 revascularization for each case.<sup>30</sup>  
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#### 44 **Data management and monitoring**

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47 Our IRB-approved protocol specifies plans for data entry, coding, security, and storage of data on a  
48  
49 secure server. For retrospective data, all data was double checked or assessed by two independent  
50  
51 coordinators. For prospective data on heart team meetings, the online meeting supporting system  
52  
53 included several mechanisms to protect data integrity and promote data quality (e.g., warning of  
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55 missing values, preventing duplicate team participation), and the data manager will maintain detailed  
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4 data management procedures. Coordinators will report to and discuss with the principal investigator  
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6 about the study progress, including participant recruitment, data collection and analysis, and heart  
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8 team meeting conductions. Any protocol modifications will be discussed with and approved by the  
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10 IRB, and any significant changes in methods will be reported to the project's program officer and  
11  
12 described in an update to the registered protocol on <https://ClinicalTrials.gov>. Data monitoring  
13  
14 committee is not needed in this study, because all the cases discussed were retrospectively selected  
15  
16 and their revascularization strategies would not be influenced by heart team recommendations and  
17  
18 will be no risk for patients. As for participating specialists, heart team discussion will not interfere  
19  
20 their routine clinical work. The Principal Investigator and approved study team members will have  
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22 access to the final trial datasets.  
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### 30 **Statistics**

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34 The pairwise comparison between the heart teams' decisions on each case provides data on the  
35  
36 agreement (**Online Table 3**). The inter-team, intra-team, inter-specialist, intra-specialist, and inter-  
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38 round agreement will be assessed using OPA and Cohen's  $\kappa$  coefficient, whenever applicable. Mean  
39  
40 decision time will be also calculated. Cox proportional hazards models were used to analyze whether  
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42 the patients adhering to heart team was associated with better outcomes when the two corresponding  
43  
44 teams made the same decision. This analysis was used to demonstrate the association between  
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46 decision stability and clinical outcomes. Categorical variables will be expressed as frequency and  
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48 percentage. Continuous variables will be expressed as mean  $\pm$  standard deviation (SD), or median  
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50 and interquartile range. Categorical variables will be analyzed with the likelihood ratio  $\chi^2$  test or  
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52 Fisher exact test if more than 25% of the cells have an expected frequency smaller than 5.  
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4 Continuous variables will be computed with the 2-sample t-test when data follow a normal  
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6 distribution and will be compared with the Wilcoxon rank sum test for a non-normal distribution.  
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9 95% confidence intervals will be computed for all measurements. All the analyses will be performed  
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11 at a significance level of 2-sided 0.05. All tests will be performed using SAS software, version 9.4  
12  
13 (SAS Institute, Cary, NC).  
14  
15

## 16 17 **Sample Size**

### 18 19 20 21 *Number of assessments necessary to evaluate decision-making agreement*

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23 The primary endpoint of this study is to compare the overall percent agreement (OPA) between the  
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25 standardized protocol group and guideline-based group. In previous study, heart teams were  
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27 established and held meetings based on guidelines, and it was estimated that the OPA of the control  
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29 group was 66.3% (unpublished data). We assumed that inter-team agreement is similar to or no better  
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31 than intra-team reproducibility rate, according to relevant literature,<sup>7,8</sup> it is estimated that the OPA of  
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33 the standardized protocol group is 76% (the minimum estimate of previous literature). Under this  
34  
35 circumstance, the standardized protocol group has the smallest effect on improving the decision  
36  
37 consistency rate compared with the guideline-based group. Using a 5% level of 2-side significance  
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39 and a confidence level with 90%, it was estimated that a total number of 454 pairwise comparisons  
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41 for each group would be necessary to meet the study acceptance criterion. Considering the feasibility  
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43 of the study, 480 cases should be reviewed after the sample size was adjusted appropriately.  
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### 50 51 52 *Number of heart teams needed*

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54 Considering the feasibility of implementation and good representation of both samples and heart  
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56 teams, it was decided that 24 heart teams are needed with 12 in each group. Teams in each group will  
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4 be divided into 6 pairs randomly, and each pair of heart teams will evaluate the same randomly  
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6 assigned 80 cases independently to provide inter-team agreement data, generating 480 pairwise  
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8 comparison in each group.  
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### 10 11 ***Number of heart team specialists***

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14 The heart team in standardized group consists of 2 interventional cardiologists and 2 cardiac  
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16 surgeons, and that in guideline based group consists of 1 interventional cardiologist, 1 cardiac  
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18 surgeon, and 1 non-interventional cardiologist. In total, with 12 heart teams in each group, a  
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20 minimum of 36 cardiac surgeons, 36 interventional cardiologists and 12 non-interventional  
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22 cardiologists is needed in the final study.  
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### 28 **Subgroup analysis**

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31 The primary and secondary outcomes will be analyzed in pre-specified subgroups, including  
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33 specialties and professional status. Analysis will also be conducted according to different cases  
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35 stratified by age, left ventricular ejection fraction (LVEF), body mass index (BMI), degree of the  
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37 stenosis, calcified lesion, stenosis severity, tandem and bending/tortuous lesion, LM, SYNTAX  
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39 stratification, SYNTAX II recommendations, and SinoSCORE stratification. The comparisons in  
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41 these analyses are not powered for hypothesis testing and are descriptive in nature.  
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### 48 **Patient and Public Involvement statement**

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51 No patients were actively involved in setting the research question, outcome measures nor involved  
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53 in the design of the study. Patients were not involved in interpretation or write up of the results, nor  
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55 are there plans for the results to be disseminated to the patient community affected by this research.  
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**Current status**

Thirty-six cardiac surgeons, 36 interventional cardiologists and 12 non-interventional cardiologists from 26 eligible hospitals agreed to participate in this study. Four hundred and eighty patients with complex CAD were randomly selected for discussion. Specialist and patient baselines are shown in

**Table 2** and **Table 3**.

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**TABLE 2. Specialist baseline characteristics**

Characteristics	Overall (n=84)	Cardiac Surgeon (n=36)	Interventional Cardiologist (n=36)	Non-interventional Cardiologist (n=12)
Male	71 (84.5)	35 (97.2)	34 (94.4)	2 (16.7)
Status				
Chief specialist	46 (54.8)	21 (58.3)	19 (52.8)	6 (50.0)
Associate specialist	34 (40.5)	15 (41.7)	13 (36.1)	6 (50.0)
Attending specialist	4 (4.8)	0 (0.0)	4 (11.1)	0 (0.0)
Personality (TIPI)*	5.20 (4.80-5.70)	5.20 (4.90-5.50)	5.20 (4.60-5.80)	5.45 (4.80-5.60)
Extraversion	4.50 (4.00-5.00)	4.50 (4.00-5.50)	4.50 (4.00-5.00)	4.50 (4.00-5.00)
Agreeableness	5.50 (4.50-6.00)	5.00 (4.50-5.50)	5.75 (4.50-6.50)	5.75 (5.00-6.00)
Conscientiousness	5.50 (5.00-6.50)	6.00 (5.00-6.50)	5.50 (5.00-6.50)	5.75 (5.00-6.00)
Emotional Stability	5.00 (5.00-6.00)	5.00 (5.00-5.50)	5.00 (4.50-6.00)	6.00 (5.00-6.00)
Openness to Experiences	5.00 (4.50-5.50)	5.00 (4.50-5.50)	5.00 (5.00-5.50)	4.75 (4.50-5.50)

TIPI indicates ten-item personality inventory.<sup>28</sup>Data presented as n (%) and median (interquartile range). \*Personality was evaluated by TIPI scale in Chinese.

TABLE 3. Demographic and clinical characteristics of retrospective patients

Characteristics	Patients for discussion (n=480)	Characteristics	Patients for discussion (n=480)
<b>Demographics</b>		Stable angina	370 (77.1)
Age, y	62.0 (55.0-67.5)	CCS I-II	325 (87.8)
Male (%)	363 (75.6)	CCS III-IV	45 (12.2)
<b>Risk Factors</b>		Number of anti-anginal medications	
Hypertension	334 (69.6)	0	118 (24.6)
Hyperlipidemia	429 (89.4)	1	154 (32.1)
Diabetes	185 (38.5)	2	149 (31.0)
Cerebrovascular disease	102 (21.3)	3	59 (12.3)
COPD	7 (1.5)	Extent of coronary disease	
Chronic renal disease	14 (2.9)	3-vessel disease	451 (94.0)
Smoker	226 (47.1)	Left main disease	129 (26.9)
Body mass index, kg/m <sup>2</sup>	25.6 (23.7-27.5)	<b>Risk Classification</b>	
Ccr <60 mL/min/1.73m <sup>2</sup>	7 (1.5)	SYNTAX score	22.5 (16.5-29.5)
<b>Cardiovascular Characteristics</b>		SYNTAX score tertiles	
Previous MI	49 (10.2)	Low risk (0-22)	237 (49.4)
Previous heart failure	10 (2.1)	Intermediate risk (23-32)	157 (32.7)
Peripheral vascular disease	46 (9.6)	High risk (≥33)	86 (17.9)
Ejection fraction, %	63.0 (59.0-65.0)	SYNTAX score II recommendation	
Ejection fraction ≤40%	23 (4.8)	PCI	11 (2.3)
CAD symptoms		CABG	153 (31.9)
Silent ischemia (after medical therapy)	90 (18.8)	Equipoise	316 (65.8)
Non-ischemia symptom	20 (4.2)	SYNTAX score II 2020 10-year mortality (%)	

Characteristics	Patients for discussion (n=480)	Characteristics	Patients for discussion (n=480)
CABG	14.8 (9.1-24.7)	Prolonged ventilation (%)	3.20 (2.62-3.98)
PCI	19.4 (11.6-32.2)	DSWI (%)	0.10 (0.08-0.14)
Euroscore II mortality (%)	0.80 (0.58-1.06)	Prolonged hospitalization (%)	1.79 (1.33-2.53)
SinoSCORE II mortality (%)	0.82 (0.47-1.18)	<b>Treatment Strategy in Real World</b>	
STS score (incidence of postoperative events)		PCI	287 (59.8)
Mortality (%)	0.49 (0.36-0.70)	CABG	116 (24.2)
Mortality or major complications (%)	5.30 (4.43-6.56)	Medical therapy	77 (16.0)
Reoperation (%)	1.72 (1.46-2.07)		
Renal failure (%)	0.43 (0.32-0.61)		
Stroke (%)	0.96 (0.73-1.36)		

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; Ccr, creatinine clearance rate; CCS, Canadian Cardiovascular Society; COPD, chronic obstructive pulmonary disease; DSWI, deep sternal wound infection; MI, myocardial infarction; PCI, percutaneous coronary intervention; SD, standard deviation; STS, Society of Thoracic Surgeons; and SYNTAX, Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery.

Data presented as median (interquartile range, IQR) and n (%).

## DISCUSSION

The optimization of heart team implementation including team composition, operation, distribution of responsibilities, and other issues still lack of verification by evidence-based trials. The present study is the first trial focusing on the heart team implementation quality assessment and improvement by evaluating the effect of the standardized heart team protocol compared to guideline-based protocol on decision-making stability for complex CAD.

Stability is a potential metric of decision-making quality. As for the expertise of individual specialists is specific to their professional training and experience, cardiologists and surgeons prefer PCI or CABG, respectively.<sup>10</sup> Prior data showed that 18.1% of the overall decision making for stable angina patients was classified as inappropriate, especially among patients undergoing PCI<sup>31</sup>, and heart team recommendations differed from those of the original treating interventional cardiologist in approximately one-third of cases.<sup>32</sup> Therefore, heart team, a medium communication to integrate the input of numerous specialists, can help to minimize fragmented communication between specialists and eliminate specialist-bias in decision-making process. Sanchez et al convened 301 heart team meetings for complex CAD from 2012 to 2015, and reported the concordance of the heart team to appropriate use criteria was up to a 99.3% appropriate primary indication for coronary revascularization.<sup>33</sup> Thus, it is believed that qualified heart teams may perform more evidence-based and neutral in revascularization decision making.

Noteworthy, a dedicated and structured heart team has potential benefit for patient survival. Peyman et al reported patients treated for mitral valve disease based on a dedicated heart team decision have significantly higher survival than a general heart team, which illustrated the

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4 establishment of dedicated heart team consisting of experienced specialists with adequate procedure  
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6 volume benefit patient survival<sup>34</sup>. Thus, we hypothesize that revascularization recommendations of  
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8 dedicated heart teams organized by the standardized heart team protocol might be more consistent  
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10 and more appropriate compared with those of general heart teams based on guideline principles.  
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14 Making heart team approach well-structured and efficient contributes for a better quality of  
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16 cardiovascular care. The current study is essential to answer the following questions: (1) Is it feasible  
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18 to establish and organize heart team meetings with the guidance of the standardized heart team  
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20 protocol in real-world clinical practice. (2) Will the standardized heart team protocol improve the  
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22 decision-making stability in patients with complex CAD compared with the fundamental principles  
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24 of heart team organizing in guidelines. Moreover, it will enhance educational opportunities for all  
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26 team members involved and provide experience on the practice of heart team meeting in prospective  
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28 clinical scenario.  
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34 Several novel design underlies the strength of this study. Firstly, all heart team trainings and  
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36 meetings are held as video conference using an online decision making support system, which make  
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38 it possible to involve specialists from multiple hospitals, reduce the negative implications from a few  
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40 influential individuals on decision-making, and eliminate the risk of viral spreading in COVID-19.<sup>35</sup>  
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42 Secondly, we prepared sufficient cases for discussion based on the premise of sample calculation,  
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44 which provide good representation of the real-world patients and cover as many multiple types of  
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46 complex cases as possible, reducing selection bias from case selection. Thirdly, we provide the most  
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48 up-to-date risk scores (such as SYNTAX II 2020 score<sup>23</sup>, sinoSCORE II<sup>27</sup>) and QFR<sup>20</sup>, a novel  
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50 angiography-derived physiological assessment approach, in structured information for specialist to  
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52 adjudicate the optimal treatment strategy.  
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## SUMMARY

The present randomized trial compares the effect of the standardized heart team protocol versus guideline-based protocol on decision-making stability. Knowledge gained from this trial may further improve heart team implementation quality for complex CAD.

## ETHICS AND DISSEMINATION

### Ethics

The study was reviewed and approved by the Ethics Review Committees of Fuwai hospital (2019-1303) on 2 August 2021; subsequent amendments have been approved. Informed consent was provided by all the participating specialists.

### Safety

All the eligible cases were selected retrospectively and underwent coronary angiography between August 2016 and August 2017. Heart team decisions have no effect on patients' actual treatments. There will be no adverse event or serious adverse event relating to this study.

### Dissemination

Results of this trial will be reported to the participating specialists, disseminated through scientific conferences and journals, reported on <https://ClinicalTrials.gov>, and published in full in the Health Technology Assessment (HTA) Journal series.

## DECLARATIONS

### Consent for publication

1  
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4 Not applicable.  
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## 6 **Availability of data and materials**

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9 Data sharing is not applicable to this article as no datasets were generated or analyzed during the  
10  
11 current study.  
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## 13 **Competing interests**

14  
15  
16 The authors declare that they have no competing interests.  
17

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26  
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## 34 **Contributors**

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37 Study conception: ZZ; Study design: HPM, SL, XL, BX, ZZ; Drafting the manuscript: HPM, SL;  
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39 Statistical consultation: XL, YW; Data collection and interpretation: HPM, SL, BX; Revising the  
40  
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information and assessment of clinical scores.

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27 34. Sardari Nia P, Olsthoorn JR, Heuts S, et al. Effect of a dedicated mitral heart team compared to a  
28  
29 general heart team on survival: a retrospective, comparative, non-randomized interventional cohort  
30  
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33 10.1093/ejcts/ezab065 [published Online First: 2021/03/31]  
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39 2020;41(20):1872-74. doi: 10.1093/eurheartj/ehaa412 [published Online First: 2020/05/12]  
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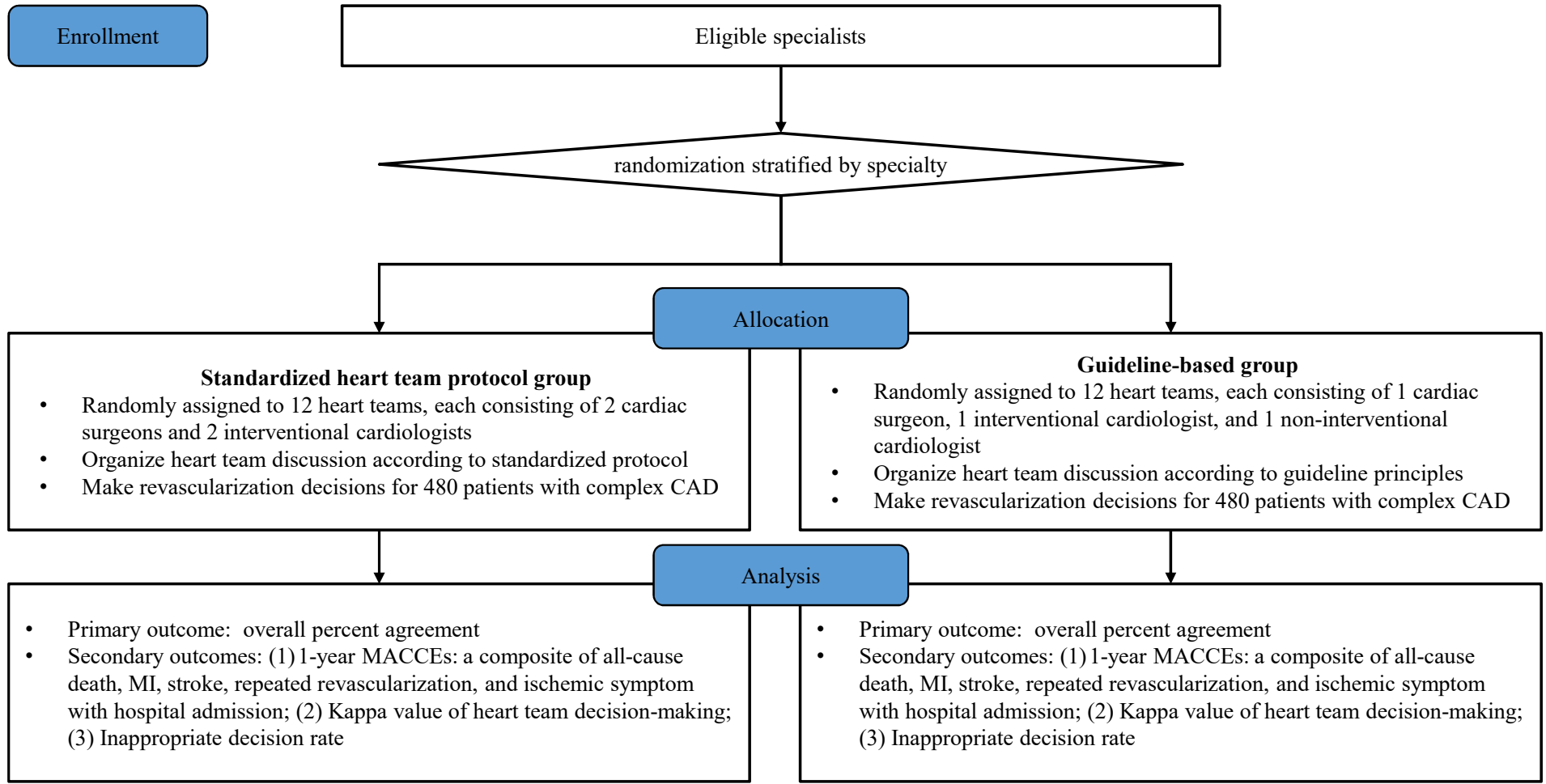
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6 **1 FIGURE LEGENDS**  
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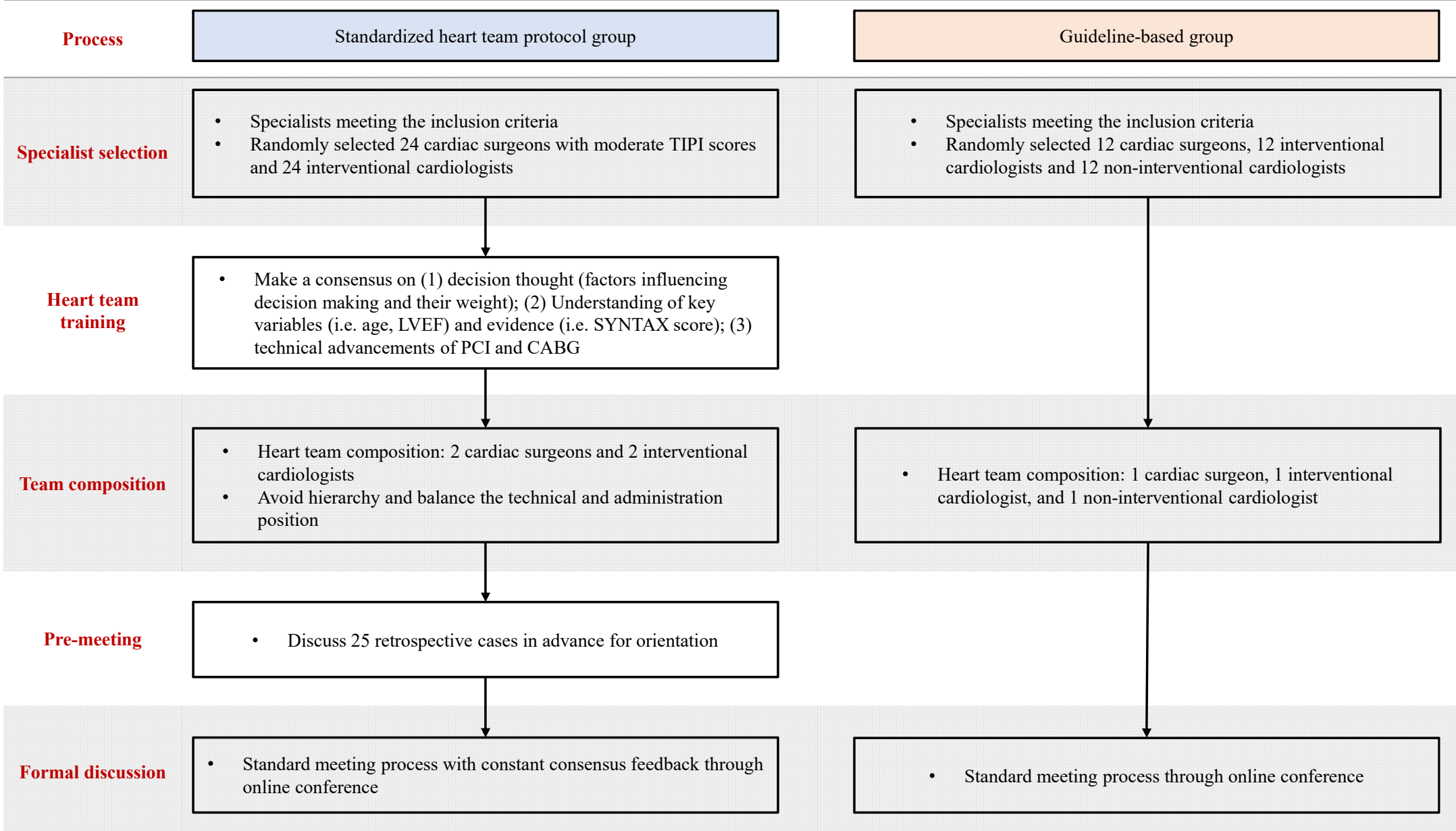
10 **2 Figure 1. Flow chart**

11  
12 Eligible specialists were randomized either to standardized heart team protocol group  
13  
14 or guideline-based group and established 12 heart teams in each group to make  
15  
16 revascularization decisions for 480 retrospectively enrolled patients with complex  
17  
18 CAD. CAD indicates coronary artery disease; MACCE, major adverse cardiovascular  
19  
20 and cerebrovascular event.  
21  
22  
23  
24  
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27

28 **9 Figure 2. Implementation strategies for protocol based group and guideline**  
29  
30 **10 based group**

31  
32  
33 In standardized protocol group, heart team was implemented based on an evidence-  
34  
35 based protocol including specialist selection, specialist training, team composition,  
36  
37 team training, and standardized meeting process. In guideline-based group, heart team  
38  
39 was implemented according to the key principles mentioned in clinical guidelines,  
40  
41 including team composition and standardized meeting process. TIPI indicates ten-item  
42  
43 personality inventory; LVEF, left ventricular ejection fraction; CABG, coronary  
44  
45 artery bypass grafting; PCI, percutaneous coronary intervention; SYNTAX, Synergy  
46  
47 Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery.  
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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	Addressed on page number
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
	2b	All items from the World Health Organization Trial Registration Data Set	see clinicaltrials.gov
Protocol version	3	Date and version identifier	7
Funding	4	Sources and types of financial, material, and other support	24
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1-2, 24
	5b	Name and contact information for the trial sponsor	see clinicaltrials.gov
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	24
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	13-14

1 **Introduction**

2

3 Background and 6a Description of research question and justification for undertaking the trial, including summary of relevant 4-6  
 4 rationale studies (published and unpublished) examining benefits and harms for each intervention  
 5

6 6b Explanation for choice of comparators 4-6  
 7

8 Objectives 7 Specific objectives or hypotheses 7  
 9

10 Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), 6-7  
 11 allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)  
 12  
 13

14 **Methods: Participants, interventions, and outcomes**

15

16 Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will 6-7  
 17 be collected. Reference to where list of study sites can be obtained  
 18

19 Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and 7-8  
 20 individuals who will perform the interventions (eg, surgeons, psychotherapists)  
 21

22 Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be 10-12  
 23 administered  
 24

25 11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose NA  
 26 change in response to harms, participant request, or improving/worsening disease)  
 27

28 11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence 11  
 29 (eg, drug tablet return, laboratory tests)  
 30

31 11d Relevant concomitant care and interventions that are permitted or prohibited during the trial NA  
 32

33 Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood 12-13  
 34 pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg,  
 35 median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen  
 36 efficacy and harm outcomes is strongly recommended  
 37

38 Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for see  
 39 participants. A schematic diagram is highly recommended (see Figure) clinicaltrials.gov  
 40  
 41  
 42

1 Sample size 14 Estimated number of participants needed to achieve study objectives and how it was determined, including 15-16  
 2 clinical and statistical assumptions supporting any sample size calculations

3  
 4 Recruitment 15 Strategies for achieving adequate participant enrolment to reach target sample size 8  
 5

6  
 7 **Methods: Assignment of interventions (for controlled trials)**

8 Allocation:  
 9

10 Sequence 16a Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any 8-9  
 11 generation factors for stratification. To reduce predictability of a random sequence, details of any planned restriction  
 12 (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants  
 13 or assign interventions  
 14  
 15

16 Allocation 16b Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, 8-9  
 17 concealment opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned NA  
 18 mechanism  
 19

20 Implementation 16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to 7-12  
 21 interventions  
 22  
 23

24 Blinding (masking) 17a Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome 9  
 25 assessors, data analysts), and how  
 26

27 17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's 8-9  
 28 allocated intervention during the trial NA  
 29  
 30

31 **Methods: Data collection, management, and analysis**  
 32

33 Data collection 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related 9-10,13-14  
 34 methods processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of  
 35 study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known.  
 36 Reference to where data collection forms can be found, if not in the protocol  
 37

38 18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be 8-9  
 39 collected for participants who discontinue or deviate from intervention protocols NA  
 40  
 41  
 42

1	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13-14
2				
3				
4				
5	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14-15
6				
7				
8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16
9				
10		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	NA
11				
12				
13				
14	<b>Methods: Monitoring</b>			
15				
16	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	13-14
17				
18				
19				
20				
21				
22		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
23				
24				
25	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
26				
27				
28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	13-14
29				
30				
31				
32	<b>Ethics and dissemination</b>			
33				
34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	21
35				
36				
37	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	21
38				
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1	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8, 24
2				
3				
4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
5				
6				
7	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13-14
8				
9				
10	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	24
11				
12				
13	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	24
14				
15				
16				
17	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
18				
19				
20	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	21
21				
22				
23				
24		31b	Authorship eligibility guidelines and any intended use of professional writers	21
25				
26		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	24
27				
28				
29	<b>Appendices</b>			
30				
31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	available from authors
32				
33				
34	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA
35				
36				

37 \*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.  
 38 Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons  
 39 "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.  
 40  
 41  
 42



## CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3-4
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	4-6
	2b	Specific objectives or hypotheses	7
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6-7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	7-8
	4b	Settings and locations where the data were collected	7-8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	10-12
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	12-13
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	15-16
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
<b>Randomisation:</b>			
Sequence generation	8a	Method used to generate the random allocation sequence	8-9
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	9-10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7-12
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	9

1		assessing outcomes) and how	
2	11b	If relevant, description of the similarity of interventions	13-14
3	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
4		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses
5			16
6	<b>Results</b>		
7	Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and
8	diagram is strongly		were analysed for the primary outcome
9	recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons
10			NA
11	Recruitment	14a	Dates defining the periods of recruitment and follow-up
12		14b	Why the trial ended or was stopped
13			NA
14	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
15	Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was
16			by original assigned groups
17			NA
18	Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its
19	estimation		precision (such as 95% confidence interval)
20		17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
21	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing
22			pre-specified from exploratory
23			NA
24	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
25			NA
26	<b>Discussion</b>		
27	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
28	Generalisability	21	Generalisability (external validity, applicability) of the trial findings
29	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
30			NA
31	<b>Other information</b>		
32	Registration	23	Registration number and name of trial registry
33	Protocol	24	Where the full trial protocol can be accessed, if available
34			See
35			ClinicalTrial.gov
36	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders
37			24

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).

**The TIDieR (Template for Intervention Description and Replication) Checklist\*:**  
 Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
1.	<b>BRIEF NAME</b> Provide the name or a phrase that describes the intervention.	10-12	
2.	<b>WHY</b> Describe any rationale, theory, or goal of the elements essential to the intervention.	10	Ma H, Lin S, Li X, et al. Exploring optimal heart team protocol to improve decision-making stability for complex coronary artery disease: a sequential explanatory mixed method study. Eur Heart J Qual Care Clin Outcomes 2021 doi: 10.1093/ehjqcco/qcab074 [published Online First: 2021/10/12]
3.	<b>WHAT</b> Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	10-12	Online table 1
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	9-12	

1	<b>WHO PROVIDED</b>	
2	5. For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise,	9-12
3	background and any specific training given.	
4		
5	<b>HOW</b>	
6		
7	6. Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of	11
8	the intervention and whether it was provided individually or in a group.	
9		
10	<b>WHERE</b>	
11		
12	7. Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or	11
13	relevant features.	
14		
15		
16	<b>WHEN and HOW MUCH</b>	
17		
18	8. Describe the number of times the intervention was delivered and over what period of time including the	12
19	number of sessions, their schedule, and their duration, intensity or dose.	
20		
21	<b>TAILORING</b>	
22		
23	9. If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	N/A
24		
25	<b>MODIFICATIONS</b>	
26		
27	10.† If the intervention was modified during the course of the study, describe the changes (what, why, when, and	N/A
28	how).	
29		
30	<b>HOW WELL</b>	
31		
32	11. Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies	11
33	were used to maintain or improve fidelity, describe them.	
34		
35	12.† Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was	N/A
36	delivered as planned.	
37		
38		

\*\* **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported.

1 † If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other  
2 published papers (provide citation details) or a website (provide the URL).

3 ‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

4  
5 \* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

6 \* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of  
7 studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the  
8 TIDieR checklist should be used in conjunction with the CONSORT statement (see [www.consort-statement.org](http://www.consort-statement.org)) as an extension of **Item 5 of the CONSORT 2010 Statement**.  
9 When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013**  
10 **Statement** (see [www.spirit-statement.org](http://www.spirit-statement.org)). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see [www.equator-](http://www.equator-network.org)  
11 [network.org](http://www.equator-network.org)).

## SUPPLEMENTAL MATERIALS

### A Standardized Heart Team Protocol versus Guideline-based Protocol on

### Revascularization Decisions Stability in Complex Coronary Artery Disease: Rationale and

### Design of a Randomized Trial

#### Contents

#### Supplemental method

Full Definitions of key variables

Inclusion and exclusion criteria of cases to be discussed

#### Supplementary Figures

Online Figure 1. Specialist Enrollment Flowchart

Online Figure 2. Patient Enrollment Flowchart

Online Figure 3. Standard heart team meeting flow

#### Supplementary Tables

Online Table 1. Structured patient information

Online Table 2. Ten-Item Personality Inventory in China (TIPI-C)

Online Table 3. Tabular analysis of inter-team agreement

## 17 Supplemental Methods

### 18 *Full Definitions of key variables and clinical endpoints*

- 19 **1. Three-vessel disease:** three lesions with a percent diameter stenosis (DS%) between 50%-  
20 99% or total occlusion in a coronary artery with a  $\geq 2.5$  mm reference vessel diameter by  
21 visual assessment.
- 22 **2. Left main disease:** left main coronary artery is visually assessed DS%  $\geq 50\%$ .
- 23 **3. Major adverse cardiovascular and cerebrovascular events (MACCEs):** a composite of  
24 death, myocardial infarction, stroke, repeated revascularization, and rehospitalization due to  
25 ischemic symptoms.
- 26 **4. Death:** death from any cause. The cause of death will be adjudicated as being due to cardiac  
27 death or non-cardiac death.
- 28 **5. Myocardial infarction (MI)**
  - 29 **(1) In-hospital MI:** Defined as the occurrence during hospitalization after PCI, CABG or  
30 coronary angiography meeting at least 1 of the following criteria:
    - 31 1) The rise in cardiac troponin I (cTnI) is  $\geq 70$  times the 99th percentile URL (where  
32 the baseline is lower than the URL, elevated and stable, or falling).
    - 33 2) If cTnI was not available, MI was defined with at least one of the following:
      - 34 i. New ischaemic ECG changes;
      - 35 ii. Development of new pathological Q waves;
      - 36 iii. Imaging evidence of loss of viable myocardium that is presumed to be new and  
37 in a pattern consistent with an ischaemic etiology;



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3  
4 38 iv. Angiographic findings consistent with a procedural flow-limiting complication  
5  
6 39 such as coronary dissection, occlusion of a major epicardial artery or graft,  
7  
8  
9 40 side-branch occlusion-thrombus, disruption of collateral flow or distal  
10  
11  
12 41 embolization.

13  
14 42 **(2) Spontaneous MI:** Defined as detection of a rise and/or fall of cTn values with at least  
15  
16  
17 43 one value above the 99th percentile URL after discharge and with at least one of the  
18  
19  
20 44 following:

- 21  
22 45 1) Symptoms of acute myocardial ischemia;  
23  
24  
25 46 2) New ischaemic ECG changes;  
26  
27  
28 47 3) Development of pathological Q waves;  
29  
30 48 4) Imaging evidence of new loss of viable myocardium or new regional wall motion  
31  
32  
33 49 abnormality in a pattern consistent with an ischaemic etiology;  
34  
35 50 5) Identification of a coronary thrombus by angiography including intracoronary  
36  
37  
38 51 imaging or by autopsy.

39  
40 52 **6. Stroke** was confirmed by a neurologist on the basis of imaging studies and was defined as  
41  
42  
43 53 follows:

- 44  
45 54 1) A focal neurologic deficit of central origin lasting >72 hours, or  
46  
47  
48 55 2) A focal neurologic deficit of central origin lasting >24 hours, with imaging evidence of  
49  
50  
51 56 cerebral infarction or intracerebral hemorrhage, or  
52  
53  
54 57 3) A non-focal encephalopathy lasting >24 hours with imaging evidence of cerebral  
55  
56 58 infarction or hemorrhage adequate to account for the clinical state.  
57  
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1  
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4 59 **7. Repeat revascularization** was defined as any repeat coronary artery bypass graft (CABG)

5  
6  
7 60 or PCI.

8  
9 61 1) Target Lesion: Lesions were revascularized in the index procedure (or during a planned  
10  
11 or provisional staged procedure).  
12 62

13  
14 63 2) Non-Target Vessel: Lesions were not treated by either PCI or CABG at the index  
15  
16 procedure.  
17 64

18  
19 65 **8. Rehospitalization due to ischemic symptoms:** rehospitalization because of ischemic  
20  
21 discomfort (angina or symptoms thought to be equivalent).  
22 66  
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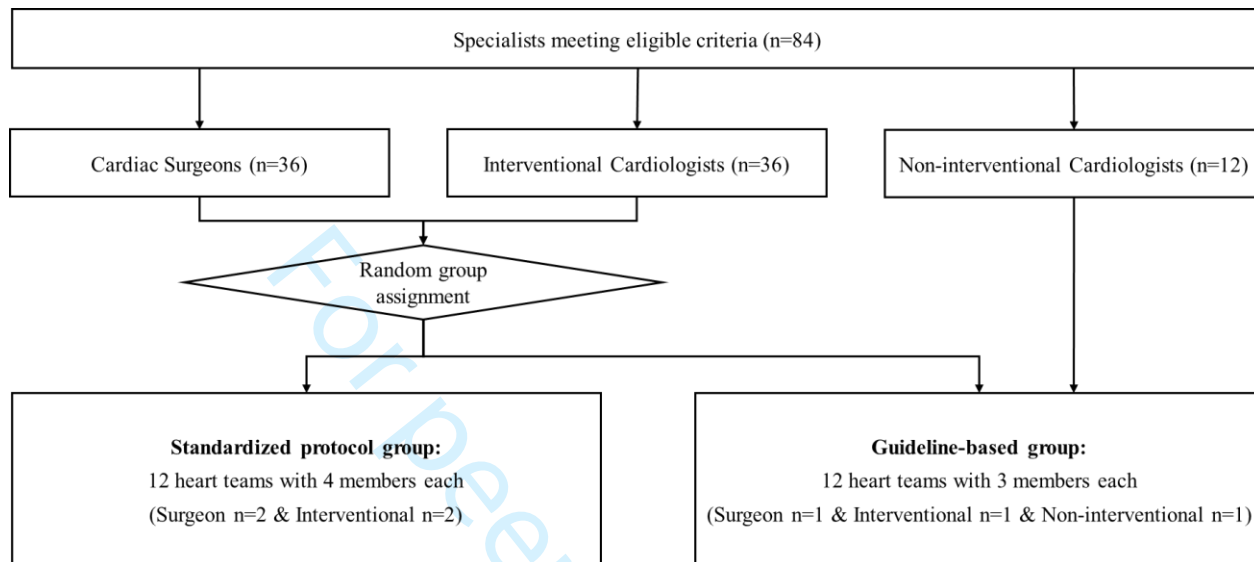
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4 68 ***Inclusion and exclusion criteria of cases to be discussed***  
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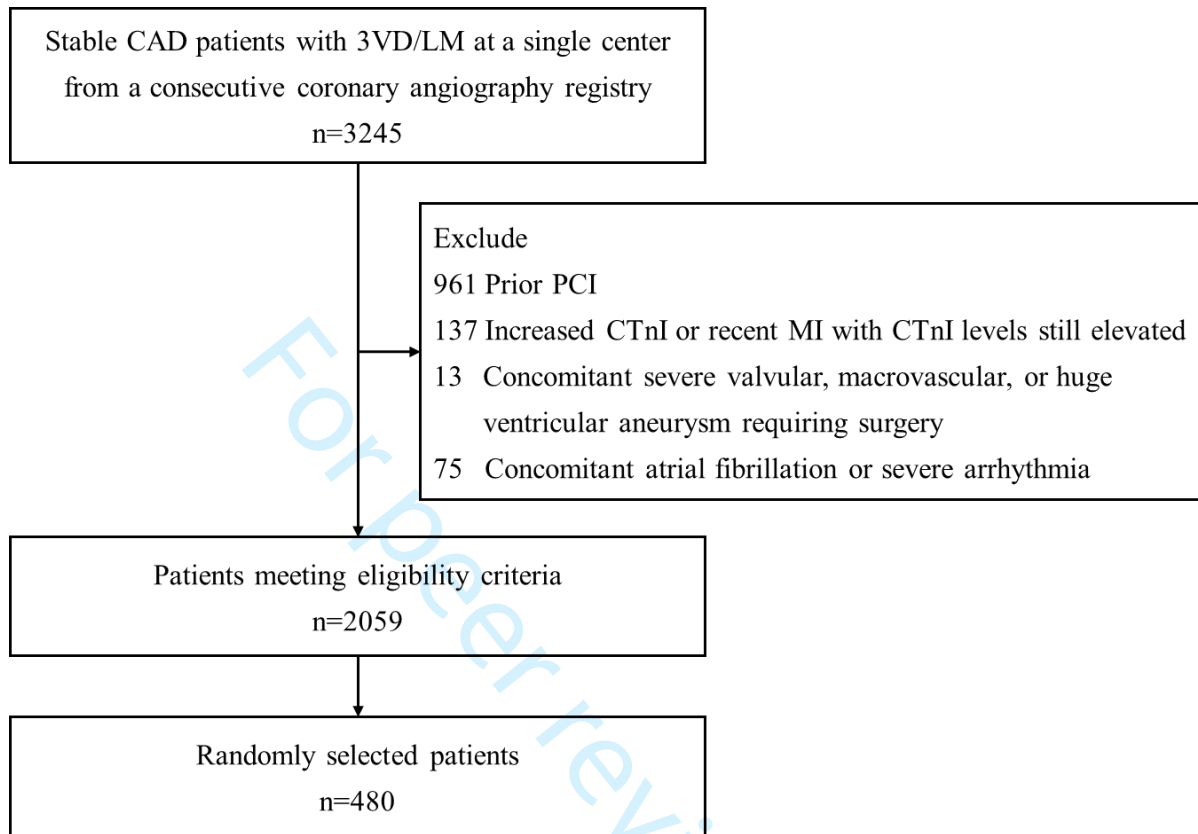
6  
7 69 Adult patients with stable CAD according to the National Cardiovascular Data Registry (NCDR)  
8  
9 70 CathPCI criteria (stable angina, no or silent myocardial ischemia) and angiographically  
10  
11 71 confirmed 3-vessel disease or left main (3VD/LM) disease will be eligible for inclusion in the  
12  
13 72 study. The exclusion criteria included: (1) prior coronary artery bypass grafting (CABG); (2)  
14  
15 73 cardiac troponin I (CTnI) greater than the local laboratory upper limit of normal or recent  
16  
17 74 myocardial infarction with CTnI levels still elevated; (3) concomitant severe valvular disease,  
18  
19 75 macrovascular disease, or huge ventricular aneurysm requiring surgery; (4) concomitant atrial  
20  
21 76 fibrillation or severe arrhythmia; or (5) unavailable de novo angiography images of the current  
22  
23 77 hospitalization. Eligible cases will be randomly selected from a prospective registry of  
24  
25 78 consecutive patients who underwent coronary angiography between August 2016 and August  
26  
27 79 2017.  
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81 **Supplementary Figures**

82 **Online Figure 1. Specialist Enrollment Flowchart**

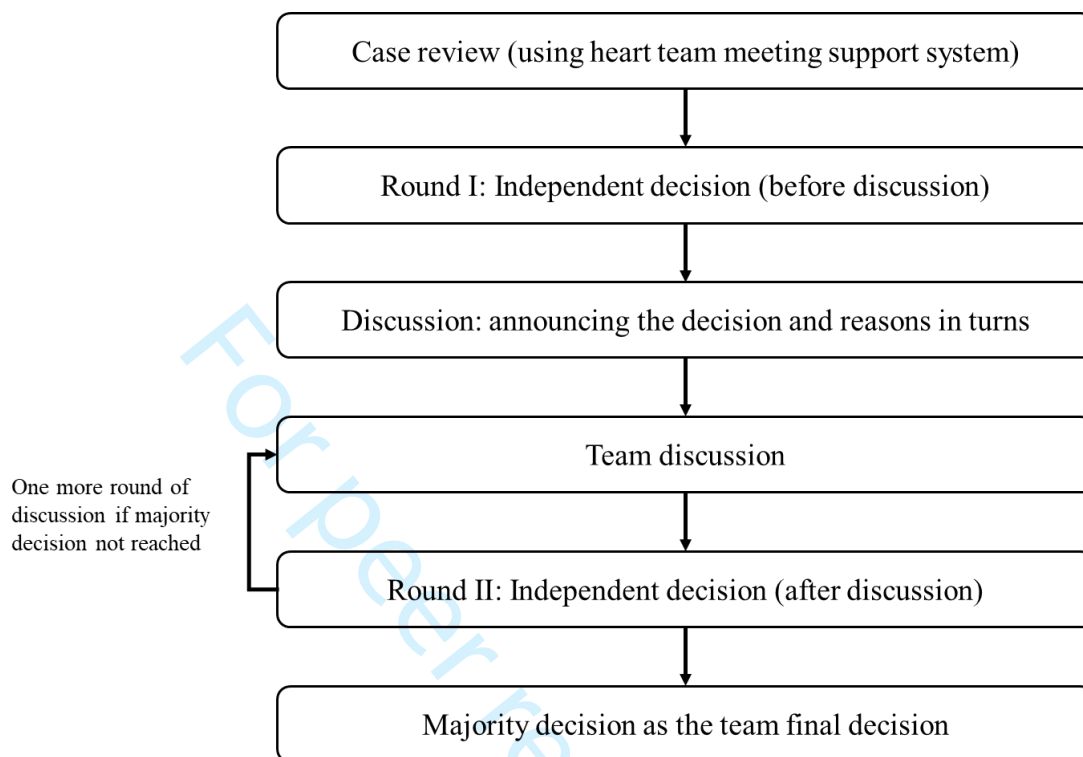


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84 **Online Figure 2. Patient Enrollment Flowchart**

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86 3VD indicates 3-vessel disease; CTnI, cardiac troponin I, LM, left main; MI, myocardial infarction;

87 PCI, percutaneous coronary intervention.

88 **Online Figure 3. Standard heart team meeting procedure**

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90

91 **Supplementary Tables**92 **Online Table 1. Structured patient information**93 **Heart Team Patient Information Sheet**94 **A. Demographics**95 Patient ID: \_\_\_\_\_ Gender:  Male  female Age: \_\_\_\_\_ y BMI : \_\_\_\_\_ kg/m<sup>2</sup>96 **B. Medical history and risk factors**

<b>Diabetes</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>History of myocardial infarction</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	Time: _____
<b>History of heart failure</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	EF value: _____%
<b>History of stroke</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>renal insufficiency</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	Creatinine: _____ umol/L (44-133) Creatinine clearance: _____ ml/min
<b>Chronic obstructive pulmonary disease</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>Other comorbidities:</b> <i>congenital mitral valve prolapse, hypertension, post-operative hypothyroidism, kidney stones</i>		

97 **C. Coronary heart disease symptoms**

<b>Coronary heart disease symptoms</b>	<input type="checkbox"/> Unstable Angina <input type="checkbox"/> stable angina <input type="checkbox"/> Asymptomatic
<b>Home antianginal medication</b>	<input type="checkbox"/> Long-acting nitrates <input type="checkbox"/> $\beta$ -blockers <input type="checkbox"/> Ca <sup>2+</sup> channel blockers
<b>CCS classification (stable angina)</b>	<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Asymptomatic
<b>NYHA classification</b>	<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV

98 **D. Laboratory test**

Hemoglobin: _____g/L	White blood cells:_____ *10 <sup>9</sup> /L	Platelets:_____ *10 <sup>9</sup> /L
PT: _____s (11.5-14.5)	APTT: _____s (28.5-43.5)	INR: _____(0.8-1.2)
Troponin I: _____ng/ml (ll_____:ul_____)		

99 **E. Preoperative non-invasive examination**

	Result
<b>Admission ECG</b>	<i>Sinus bradycardia 58 beats/min</i>
<b>Echocardiography</b>	<i>Mitral valve posterior leaflet prolapse, mitral valve regurgitation</i>
<b>Stress Testing and Nuclear Medicine</b>	
<b>Coronary CTA</b>	
<b>Cardiac MRI</b>	

100 **F. Invasive coronary examination**

Aniography	FFR:	IVUS:	OCT:
QFR	LM (left main artery): _____		LAD (left anterior descending artery): _____
	LCX (left circumflex artery): _____		RCA (right coronary artery): _____
	Obtuse marginal: _____		Diagonal: _____
	Posterior descending artery: _____		Left posterior artery: _____
	Ramus medianus: _____		

101 **G. Clinical risk scores**

SYNTAX	Score: _____
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S YNTAX II	PCI Score: <u>30.0(9.8%)</u>	CABG Score: <u>32.5(10.2%)</u>	Recommended: /
SYNTAX II 2020	PCI score: <u>9.8%</u>	CABG Score: <u>10.2%</u>	
EuroScore II	Mortality: <u>0.7%</u>		
SinoScore II	Mortality: <u>0.7%</u>		
STS Score	Mortality: <u>0.49%</u>	Mortality and complication rate: <u>9.95%</u>	
	Renal failure rate: <u>0.39%</u>	Stroke rate: <u>1.27%</u>	
	Prolonged ventilation rate: <u>5.8%</u>	Deep sternum infection rate: <u>0.36%</u>	
	Reoperation rate: <u>2.37%</u>	Extended hospital stay rate: <u>4.34%</u>	

102 \* Guidelines recommend STSscore mortality >2% with higher surgical risk

103 **H. Decision result (single choice)**

<b>Independent decision before discussion</b>	<input type="checkbox"/> PCI <input type="checkbox"/> CABG <input type="checkbox"/> PCI /CABG <input type="checkbox"/> Drugs <input type="checkbox"/> Further inspection
<b>Independent decision after discussion</b>	<input type="checkbox"/> PCI <input type="checkbox"/> CABG <input type="checkbox"/> PCI /CABG <input type="checkbox"/> Drugs <input type="checkbox"/> Further inspection

104

105

106 **Online Table 2. Ten-Item Personality Inventory in China (TIPI-C)**

Question No.*	Original items (Gosling et al., 2003)	Rating Scale						
		Absolutely disagree	Quite disagree	Almost disagree	Uncertain	Almost agree	Quite agree	Absolutely agree
		1	2	3	4	5	6	7
1	Extraverted, enthusiastic							
2	Critical, quarrelsome							
3	Dependable, self-disciplined							
4	Anxious, easily upset							
5	Open to new experience, complex							
6	Reserved, quiet							
7	Sympathetic, warm							
8	Disorganized, careless							

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9	Calm, emotionally stable							
10	Conventional, uncreative							

107 \*Scale scoring (“R” denotes reverse-scored items): Extraversion: 1, 6R; Agreeableness: 2R, 7; Conscientiousness: 3,  
 108 8R; Emotional Stability: 4R, 9; Openness to Experiences: 5, 10R.

For peer review only

109 **Online Table 3. Tabular analysis of inter-team agreement**

Case ID	Interventional group			Guideline group		
	Hear team 1 decision	Hear team 2 decision	agreement	Hear team 1' decision	Hear team 2' decision	agreement
001	CABG	CABG	Yes	PCI	CABG	No
002	CABG	PCI	No	PCI	PCI	Yes
003	Medication	PCI	No	Further testing	PCI	No
...	...	...	...	...	...	...
...	...	...	...	...	...	...
480	PCI	PCI	Yes	PCI	Medication	No

110 **Online Table 3. Tabular analysis of inter-team agreement.** Each case will be discussed by two assigned heart teams. The pairwise  
 111 comparison between the heart team's decision on each case provides data on the agreement. CABG indicates coronary artery bypass  
 112 grafting; PCI, percutaneous coronary intervention.

# BMJ Open

## Effect of a Standardized Heart Team Protocol versus Guideline-based Protocol on Revascularization Decisions Stability in Stable Complex Coronary Artery Disease: Rationale and Design of a Randomized Trial

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<b>Primary Subject Heading</b>:	Cardiovascular medicine
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Keywords:	Coronary heart disease < CARDIOLOGY, Coronary intervention < CARDIOLOGY, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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4 **Title page**  
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9 **Title:** Effect of a Standardized Heart Team Protocol versus Guideline-based Protocol on  
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11 Revascularization Decisions Stability in Stable Complex Coronary Artery Disease: Rationale and  
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13 Design of a Randomized Trial  
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34 **Word Count:** 4673 words.  
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## ABSTRACT

### Introduction

The multidisciplinary heart team approach has been recommended by revascularization guidelines, but how to organize and implement the heart team standardly has not been validated. Inter- and intra-team decision instability existed in guideline-based heart team protocol, and our standardized heart team protocol based on a mixed-method study may improve the decision stability. The objective of this study is to evaluate the effect of a standardized heart team protocol versus the guideline-based protocol on decision-making stability in stable complex coronary artery disease (CAD).

### Methods and analysis

Eighty-four eligible interventional cardiologists, cardiac surgeons, or non-interventional cardiologists from 26 hospitals in China have been enrolled. They will be randomized to a standardized heart team protocol group or a guideline-based protocol group to make revascularization decisions for 480 historic cases with stable complex CAD. In the standardized group, we will establish 12 heart teams based on an evidence-based protocol, including specialist selection, specialist training, team composition, team training, and a standardized meeting process. In the guideline-based group, we will organize 12 heart teams according to the guideline principles, including team composition and standardized meeting process. The primary outcome is the overall percent agreement (OPA) in revascularization decisions between heart teams within a group. To demonstrate the clinical implication of decision-making stability, we will further analyze the association between decision stability and 1-year all-cause death, myocardial infarction, stroke, repeated revascularization, and re-hospitalization due to ischemic symptoms.



## Ethics and dissemination

The study was approved by the Institutional Review Board (IRB) of Fuwai hospital (No. 2019-1303).

All participants have provided informed consent for enrollment. The results of this trial will be reported to the participating specialists, disseminated through scientific conferences and journals, reported on <https://ClinicalTrials.gov>, and published in full in peer-reviewed journals.

## Trial registrations:

ClinicalTrials.gov, NCT05039567. Registered on 09/08/2021, <https://register.clinicaltrials.gov/>

## Strengths and limitations of this study

1. The study is a randomized controlled trial testing an evidence-based standardized heart team protocol covering the whole heart team organization process with up-to-date information provision against an approach following guideline basic recommendations.
2. Randomization is used in three aspects: stratified randomization in group allocation, randomization in heart team membership, and randomization in case allocation, which controls the social factors that may have negative implications for true group decision-making and ensures relatively heart team exposure to case complexity.
3. Trial procedures will be carried out remotely, and all heart team meetings will be held via video conference using an online system, enabling full involvement and eliminating the risk of viral spreading in COVID-19.

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4 4. The cases discussed are retrospectively instead of prospectively selected, and the study does not  
5  
6 investigate the impact of the standardized heart team protocol on true treatment decisions and  
7  
8 clinical outcomes in routine clinical care, which is the next step to be tested.  
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11 5. The intervention in the standardized protocol group is an integrated approach, and the potential  
12  
13 differential outcomes associated with its use cannot be attributed to a single point of the process.  
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## 17 **KEYWORDS**

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21 Heart team; standardized protocol; decision-making stability  
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## INTRODUCTION

The heart team approach has received a Class 1C/1B recommendation in European and American guidelines on myocardial revascularization in patients with complex coronary artery disease (CAD) to optimize the treatment strategies and may lead to better outcomes.<sup>1-5</sup> Clinical guidelines recommend that a heart team, consisting of clinical/non-interventional cardiologists, interventional cardiologists, and cardiac surgeons, should take sufficient time to assess all available information on complex cases. However, there are relatively limited data on the heart team implementation in detail, such as the ideal composition, meeting frequency, the timing of decision-making, and outcomes, potentially leading to suboptimal decision-making quality.

Prior efforts have noted insufficient inter-specialist consistency, intra-team reproducibility, and inter-team agreement in heart team decision-making. Denvir et al. found poor agreement existed between cardiac clinical specialists (kappa 0.26)<sup>6</sup>. Several studies reported that on re-discussion of the same patient data 9-12 months later, nearly 20% to 24% of decisions differed from the original heart team recommendations.<sup>7 8</sup> In our previous work, the agreement between heart teams for revascularization decision-making was just moderate (kappa 0.58)<sup>9</sup>.

Clinical guidelines and previous practice experience from different centers have summarized several critical principles in heart team implementation.<sup>10-12</sup> Guidelines recommend the composition should be at least a cardiac surgeon, a interventional cardiologist, and a non-interventional cardiologist.<sup>1 5</sup> Sanchez et al. summed up the experience of the heart team implementation from their single center, including team composition, data collection, and meeting process. The British Cardiovascular Society (BCS), Society for Cardiothoracic Surgery in Great Britain and Ireland

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4 (SCTS), and British Cardiovascular Intervention Society (BCIS) set out the principles for the  
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6 functioning of the heart team across United Kingdom, including composition, frequency, and the  
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8 type of cases discussed.<sup>12</sup> Although these works provided essential experiences for heart team  
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10 implementation, the protocols were not evidence-based, and data regarding how these protocols  
11  
12 impact decision-making stability were scarce.<sup>12</sup>  
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17 To determine the potential factors influencing heart team decision-making comprehensively and  
18  
19 explore an evidence-based heart team protocol, we conducted a sequential explanatory mixed method  
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21 study and summarized three themes (specialist quality, team composition, and meeting process) and  
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23 ten subthemes of potential factors. In addition, nine recommendations for heart team implementation  
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25 were derived based on qualitative and quantitative data, and a standardized heart team protocol was  
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27 developed based on the previous experience, recommendations, and guidelines, covering the whole  
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29 procedure of heart team implementation.  
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35 However, the practical effect of the standardized protocol versus the guideline-based protocol on  
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37 decision-making stability and clinical outcomes remains unknown, and a randomized trial for  
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39 validation is warranted. Therefore, we designed this pivotal randomized trial.  
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## 44 **METHODS AND ANALYSIS**

### 45 **Study design overview**

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49 The current study is a randomized, controlled, 2-arm trial involving 84 cardiac specialists from 26  
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51 hospitals in China. Eligible specialists have been randomized to a standardized implementation  
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53 protocol group or a guideline-based group to establish 24 heart teams and make revascularization  
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55 decisions for 480 stable complex CAD cases retrospectively enrolled. We will evaluate the decision-  
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4 making stability. (**Figure 1**) SPIRIT<sup>13</sup>, CONSORT<sup>14</sup>, and TIDieR<sup>15</sup> checklists are in **Supplemental**  
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6 **File 1**. All procedures have been approved by the Institutional Review Board (IRB) of Fuwai  
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8 hospital (2 August 2021). The study start date is 4 January 2022, and the anticipated end date is 31  
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10 January 2023.  
11

## 12 13 14 15 **Objective and hypothesis**

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17  
18 The primary objective of this study is to evaluate the effect of the standardized heart team protocol  
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20 versus the guideline-based protocol on the stability of decision-making in stable complex CAD. The  
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22 primary hypothesis is that heart teams organized on the standardized protocol will result in better  
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24 decision-making consistency compared with those based on guideline principles. The secondary  
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26 objectives of this study are to (1) evaluate the association between decision-making stability and 1-  
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28 year composite of death, myocardial infarction (MI), stroke, repeated revascularization, and re-  
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30 hospitalization due to ischemic symptoms; (2) assess the appropriateness of heart team decision-  
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32 making.  
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## 40 41 **Participants and recruitment**

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44 To have access to enough experienced specialists, we will enroll eligible specialists from hospitals  
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46 with (1) annual volume of percutaneous coronary intervention (PCI)  $\geq 500$ ; (2) annual volume of  
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48 coronary artery bypass grafting (CABG)  $\geq 200$ <sup>1</sup>; (3) have at least two interventional cardiologists,  
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50 two cardiac surgeons and one non-interventional cardiologist meeting the inclusion criteria and  
51  
52 agreeing to participate in the study. The inclusion criteria for the heart team specialists differ from  
53  
54 specialties and require specified operator volumes and experience (**Table 1**). The interventional  
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56 cardiologist is required to have an annual PCI volume  $\geq 200$ <sup>16</sup>, an annual left main (LM)-PCI volume  
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4  $\geq 25^1$ , and is capable of chronic total occlusion (CTO)-PCI. The cardiac surgeon must have a total  
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6 CABG volume  $\geq 200^{17}$  and be proficient in both on-pump and off-pump CABG. We have contacted  
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8  
9 all the potential participants via e-mails or telephones to get their information confirmed and  
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12 obtained their content from 1 December 2021 to 10 January 2022. All participating specialists have  
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14 provided written informed consent for enrollment (**Supplemental File 2**).

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16  
17 **Table 1. Inclusion criteria for heart team specialists**

Disciplines	Inclusion Criteria
Interventional Cardiologist	1) Annual PCI volume $\geq 200^{16}$
	2) Annual LM PCI volume $\geq 25^1$
	3) CTO PCI total volume $\geq 10$
	4) Clinical researcher experience in coronary revascularization
	5) Proficient in clinical guidelines
Cardiac Surgeon	1) CABG total volume $\geq 200^{17}$
	2) Proficient in both on-pump and off-pump CABG
	3) Clinical researcher experience in coronary revascularization
	4) Proficient in clinical guidelines
Non-interventional Cardiologist	1) Proficient in clinical guidelines

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43 CABG indicates coronary artery bypass grafting; CTO, chronic total occlusion; LM, left main; PCI,  
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45 percutaneous coronary intervention.

#### 46 47 48 49 **Randomization**

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53 Randomization is stratified by specialties and conducted by a data manager using random number  
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55 generation in SAS. We have randomized 36 cardiac surgeons and 36 interventional cardiologists in a  
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57 2:1 ratio to the standardized protocol group (24 surgeons and 24 interventional cardiologists) or the  
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4 guideline-based group (12 surgeons and 12 interventional cardiologists). Twelve non-interventional  
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6 cardiologists have been randomly selected and allocated to the guideline-based group. After the  
7  
8 randomization, each group of specialists will be randomly assigned to 12 heart teams and perform  
9  
10 heart team meetings according to corresponding protocols. Research staff will be informed of the  
11  
12 randomization and organize the allocated specialists to establish heart teams. Participating specialists  
13  
14 are unaware of the implementation conditions. **(Online Figure 1)**

## 20 **Case selection and preparation**

### 23 *Selection of cases to be discussed*

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27 Adult cases with stable CAD according to the National Cardiovascular Data Registry (NCDR)  
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29 CathPCI criteria<sup>18</sup> (stable angina, no or silent myocardial ischemia) and angiographically confirmed  
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31 3-vessel disease or left main (3VD/LM) disease are eligible for inclusion in the study. We have  
32  
33 randomly selected eligible cases from a prospective registry of consecutive patients who underwent  
34  
35 coronary angiography between August 2016 and August 2017 **(Online Figure 2)**.<sup>19</sup> All cases  
36  
37 provided written informed consent at the time of registration and agreed to use their data for  
38  
39 subsequent approved cardiovascular-related medical research. Definitions and inclusion/exclusion  
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41 criteria of cases can be seen in **Supplemental methods**.

### 48 *Structured patient information*

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52 Patient data will be presented in a structured information form on an electronic meeting support  
53  
54 system by non-clinical coordinators **(Online Table 1)**. The structured information includes (a)  
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56 demographics; (b) medical histories and clinical risk factors; (c) medical treatment histories and CVD  
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4 symptoms of the index hospitalization; (d) laboratory results; (e) noninvasive testing results (e.g.,  
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6 electrocardiogram, echocardiogram, stress testing results); (f) diagnostic angiogram images and  
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8 quantitative flow ratio (QFR)<sup>20</sup>; (g) clinical risk scores (i.e., SYNTAX (Synergy Between  
9  
10 Percutaneous Coronary Intervention With Taxus and Cardiac Surgery) score<sup>21</sup>, SYNTAX II score<sup>22</sup>,  
11  
12 SYNTAX II 2020 score<sup>23</sup>, Society of Thoracic Surgeons (STS) score<sup>24 25</sup>, the European System for  
13  
14 Cardiac Operative Risk Evaluation (EuroSCORE) II<sup>26</sup>, and sinoSCORE II<sup>27</sup>). All the clinical  
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16 information have been obtained from medical records according to the NCDR CathPCI data  
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18 definitions<sup>18</sup>. An independent angiographic core laboratory takes responsibility for all angiogram  
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20 images screening and risk scores evaluation by using a computer-based automatic calculator.  
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### 28 ***Case assignment***

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31 Four hundred and eighty cases will be randomized into 6 sets of 80 cases each, using a stratified  
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33 randomization procedure to ensure relatively equal heart team exposure to case complexity and a  
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35 similar ratio of actual treatment strategies (CABG, PCI, or medication therapy).  
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### 40 **Intervention**

#### 41 ***Standardized Heart team protocol***

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44 Eligible specialists randomized to this group will establish 12 heart teams and conduct heart team  
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46 meetings based on the standardized heart team protocol.<sup>9</sup> **(Figure 2)**  
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52 **i. Specialist selection.** All the cardiac surgeons are required personality tests by Ten-Item  
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54 Personality Inventory in China (TIPI-C)<sup>28</sup> and 24 surgeons with moderate scores will be  
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56 randomly selected. **(Online Table 2)** Twenty-four interventional cardiologists will be randomly  
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4 selected without personality selection.  
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7 **ii. Specialist training.** All heart team members must undergo unified training to achieve a  
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9 consensus on the potential factors influencing revascularization decisions. The training will be  
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11 conducted and recorded by well-prepared coordinators. Consensus view should include clinical  
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13 considerations on the essential characteristics (e.g., age, left ventricular ejection fraction  
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15 (LVEF), and body mass index (BMI)) and their weightage, interpretation of evidence (e.g.,  
16  
17 SYNTAX trial, Evaluation of XIENCE versus Coronary Artery Bypass Surgery for  
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19 Effectiveness of Left Main Revascularization (EXCEL) trial and the International Study of  
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21 Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) results).  
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23 Additionally, the latest technical advancements in PCI and CABG will be discussed, especially  
24  
25 for PCI, to narrow cognitive gaps among specialists of different expertise. The consensus view  
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27 document will be recorded and put onto the electronic meeting support system for reference at  
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29 any time. To maintain fidelity to the consensus view, we will present each bullet point of the  
30  
31 consensus view as a footnote under the corresponding variable.  
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40 **iii. Team composition.** All specialists selected will be randomly assigned to 12 heart teams  
41  
42 consisting of 2 cardiac surgeons and 2 interventional cardiologists. Non-interventional  
43  
44 cardiologist or other disciplinary specialist is not required in the routine heart team unless  
45  
46 necessary. Moreover, the technical level and administration position will be balanced in each  
47  
48 team.  
49  
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52  
53 **iv. Team training.** Before the formal heart team meeting, a pilot discussion (25-50 retrospective  
54  
55 cases) will be performed following the standard meeting procedure to reinforce the practice of  
56  
57 the former consensus view for a more solid team consensus.  
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4 **v. Standardized meeting process.** Heart team meetings will be conducted standardly in both  
5  
6 groups according to the procedure widely used in the previous studies.<sup>10-12</sup> Each heart team  
7  
8 independently evaluates a set of cases (80 cases) through the heart team assistance system using  
9  
10 structured online case presentations, with the members blinded to the other heart teams and the  
11  
12 decisions of other heart teams. All specialists are required to make decisions independently  
13  
14 among five treatment categories (PCI, CABG, PCI/CABG equipoise, medical therapy, or further  
15  
16 testing) before (round I) and after (round II) the heart team discussion. The heart team member  
17  
18 only has access to the responses of the other heart team members after all members have  
19  
20 submitted their independent decisions. The final treatment strategy is determined by a majority  
21  
22 decision.<sup>29</sup> **(Online Figure 3)**

### ***Guideline-based protocol***

31  
32  
33  
34 We will randomly assigned eligible specialists randomized to this group to 12 heart teams based on  
35  
36 the principles of guidelines **(Figure 2)**. Each heart team consists of 1 interventional cardiologist, 1  
37  
38 cardiac surgeon, and 1 non-interventional cardiologist. This group does not require pre-meeting  
39  
40 training on consensus view and pilot discussion. Formal meeting procedures follow the standardized  
41  
42 meeting process as the other group.  
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46  
47 All heart team meetings will be held through video conferencing, and a quiet environment will  
48  
49 be required. For each heart team, the frequency of meetings is one or two times per week and lasts  
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51 1.5-2h at a time.  
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### **Outcomes**

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59 The primary outcome is the overall percent agreement (OPA), defined as the proportion of patients  
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4 who received coincident decision recommendations from paired heart teams. The secondary  
5  
6 outcomes include:

- 7  
8  
9 (1) 1-year major adverse cardiovascular and cerebrovascular events (MACCEs): a composite of all-  
10  
11 cause death, MI, stroke, repeated revascularization, and re-hospitalization due to ischemic  
12  
13 symptoms;  
14  
15  
16 (2) Kappa value of heart team decision-making: Fleiss's (more than 2 raters) and Cohen's (2 raters)  
17  
18 kappa coefficients to evaluate inter-team, intra-team, inter-specialist, intra-specialist, and inter-  
19  
20 round agreement for treatment decisions. To evaluate the reproducibility, all assigned cases will  
21  
22 be re-discussed with the same clinical data but not in the same order at 1 month after the  
23  
24 completion of initial discussion, with the heart team blinded to the outcome of the initial meeting.  
25  
26  
27 (3) Inappropriate decision rate: the final heart team recommendations will be adjudicated for  
28  
29 appropriateness using the American College of Cardiology (ACC) /American Association for  
30  
31 Thoracic Surgery (AATS) /American Heart Association (AHA) 2017 Appropriate Use Criteria  
32  
33 (AUC) and the Chinese AUC for coronary revascularization for each case.<sup>30 31</sup>Two investigators  
34  
35 who do not participate in data collection will take responsibility for reviewing the team decisions  
36  
37 and adjudicating the decision appropriateness independently. Any disputes will be settled via  
38  
39 review by a third investigator, with decision by consensus.  
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### 49 **Data management and monitoring**

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52 Our IRB-approved protocol specifies plans for data entry, coding, security, and data storage on a  
53  
54 secure server. For retrospective data, all data will be double-checked or assessed by two independent  
55  
56 coordinators. For prospective data on heart team meetings, the online meeting supporting system  
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4 included several mechanisms to protect data integrity and promote data quality (e.g., warning of  
5  
6 missing values and preventing duplicate team participation). The data manager will maintain detailed  
7  
8 data management procedures. Coordinators will report to and discuss with the principal investigator  
9  
10 about the study progress, including participant recruitment, data collection and analysis, and heart  
11  
12 team meeting conductions. Any protocol modifications will be discussed with and approved by the  
13  
14 IRB. Any significant changes in methods will be reported to the project's program officer and  
15  
16 updated on the registration site <https://ClinicalTrials.gov>. This study does not need a data  
17  
18 monitoring committee because all the cases discussed are retrospectively selected. Their  
19  
20 revascularization strategies would not be influenced by heart team recommendations and will be no  
21  
22 risk for cases. As for participating specialists, heart team discussion will not interfere with their  
23  
24 routine clinical work. The Principal Investigator and approved study team members will have access  
25  
26 to the final trial datasets.  
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### 34 35 36 **Statistics**

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39 The pairwise comparison between the heart team decisions in each case provides data on the  
40  
41 agreement (**Online Table 3**). The inter-team, intra-team, inter-specialist, intra-specialist, and inter-  
42  
43 round agreements will be assessed using OPA and Cohen's  $\kappa$  coefficient, whenever applicable. Mean  
44  
45 decision time will also be calculated. Cox proportional hazards models will be used to analyze  
46  
47 whether the treatment decision adhering to the heart team recommendations is associated with better  
48  
49 outcomes. Categorical variables will be expressed as frequency and percentage. Continuous variables  
50  
51 will be expressed as mean  $\pm$  standard deviation (SD), or median and interquartile range. Categorical  
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53 variables will be analyzed with the likelihood ratio  $\chi^2$  test or Fisher exact test if more than 25% of the  
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4 cells have an expected frequency smaller than 5. Continuous variables will be computed with the 2-  
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6 sample t-test when data follow a normal distribution and will be compared with the Wilcoxon rank  
7  
8 sum test for non-normal distribution. 95% confidence intervals will be computed for all  
9  
10 measurements. All the analyses will be performed at a significance level of 2-sided 0.05. All tests  
11  
12 will be performed using SAS software, version 9.4 (SAS Institute, Cary, NC).  
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## 17 **Sample Size**

### 21 *Number of assessments necessary to evaluate decision-making agreement*

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24 The primary endpoint of this study is to compare the OPA between the standardized protocol group  
25  
26 and the guideline-based group. In our previous study, heart teams were established totally based on  
27  
28 guidelines, and it was estimated that the OPA was 66.3% (unpublished data), serving as the reference  
29  
30 rate of the controlled group in this study. We assumed that inter-team agreement is similar to or no  
31  
32 better than intra-team reproducibility rate. According to relevant literature,<sup>7 8</sup> it is estimated that the  
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34 OPA of the standardized protocol group is 76% (the minimum estimate of previous literature). Under  
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36 this circumstance, the standardized protocol group has the minor effect on improving the decision  
37  
38 consistency compared with the guideline-based group. Using a 5% level of 2-side significance and a  
39  
40 confidence level of 90%, it was estimated that a total number of 454 pairwise comparisons for each  
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42 group would be necessary to meet the study acceptance criterion. Considering the feasibility of the  
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44 study, we adjusted the sample size to 480 cases.  
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### 52 *Number of heart teams needed*

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55 Considering the feasibility of implementation and a good representation of both samples and heart  
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57 teams, it was decided that 24 heart teams are needed with 12 in each arm. Teams in each group will  
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4 be divided into 6 pairs randomly, and each pair of heart teams will evaluate the same randomly  
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6 assigned 80 cases independently to provide inter-team agreement data, generating 480 pairwise  
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8 comparisons in each group.  
9

### 10 11 ***Number of heart team specialists*** 12

13  
14 The heart team in the standardized group consists of 2 interventional cardiologists and 2 cardiac  
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16 surgeons, and that in the guideline-based group consists of 1 interventional cardiologist, 1 cardiac  
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18 surgeon, and 1 non-interventional cardiologist. With 12 heart teams in each group, a minimum of 36  
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20 cardiac surgeons, 36 interventional cardiologists, and 12 non-interventional cardiologists are needed  
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22 in the final study in total.  
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### 26 27 28 **Subgroup analysis** 29

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31 The primary and secondary outcomes will be analyzed in pre-specified subgroups, including  
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33 specialties and professional status. The analysis will also be conducted according to different cases  
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35 stratified by age, left ventricular ejection fraction (LVEF), body mass index (BMI), degree of the  
36  
37 stenosis, calcified lesion, stenosis severity, tandem and bending/tortuous lesion, LM, SYNTAX  
38  
39 stratification, SYNTAX II recommendations, and SinoSCORE stratification. The comparisons in  
40  
41 these analyses may be not powered for hypothesis testing but are descriptive in nature.  
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### 48 **Patient and Public Involvement statement** 49

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51 None.  
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### 54 55 **Current status** 56

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58 Thirty-six cardiac surgeons, 36 interventional cardiologists, and 12 non-interventional cardiologists  
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4 from 26 eligible hospitals have agreed to participate in this study and provided informed consent.  
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6 Four hundred and eighty cases with stable complex CAD have been randomly selected for  
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8  
9 discussion. Specialist and patient baselines are shown in **Table 2** and **Table 3**.  
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1 **TABLE 2. Specialist baseline characteristics**

Characteristics	Overall (n=84)	Cardiac Surgeon (n=36)	Interventional Cardiologist (n=36)	Non-interventional Cardiologist (n=12)
Male	71 (84.5)	35 (97.2)	34 (94.4)	2 (16.7)
Status				
Chief specialist	46 (54.8)	21 (58.3)	19 (52.8)	6 (50.0)
Associate specialist	34 (40.5)	15 (41.7)	13 (36.1)	6 (50.0)
Attending specialist	4 (4.8)	0 (0.0)	4 (11.1)	0 (0.0)
Personality (TIPI)*	5.20 (4.80-5.70)	5.20 (4.90-5.50)	5.20 (4.60-5.80)	5.45 (4.80-5.60)
Extraversion	4.50 (4.00-5.00)	4.50 (4.00-5.50)	4.50 (4.00-5.00)	4.50 (4.00-5.00)
Agreeableness	5.50 (4.50-6.00)	5.00 (4.50-5.50)	5.75 (4.50-6.50)	5.75 (5.00-6.00)
Conscientiousness	5.50 (5.00-6.50)	6.00 (5.00-6.50)	5.50 (5.00-6.50)	5.75 (5.00-6.00)
Emotional Stability	5.00 (5.00-6.00)	5.00 (5.00-5.50)	5.00 (4.50-6.00)	6.00 (5.00-6.00)
Openness to Experiences	5.00 (4.50-5.50)	5.00 (4.50-5.50)	5.00 (5.00-5.50)	4.75 (4.50-5.50)

2 TIPI indicates the ten-item personality inventory.<sup>28</sup>Data presented as n (%) and median (interquartile range).\*Personality was  
3 evaluated by the TIPI scale in Chinese.

4



5 **TABLE 3. Demographic and clinical characteristics of retrospective patients**

Characteristics	Patients for discussion (n=480)	Characteristics	Patients for discussion (n=480)
<b>Demographics</b>		Silent ischemia (after medical therapy)	90 (18.8)
Age, y	62.0 (55.0-67.5)	Non-ischemia symptom	20 (4.2)
Male (%)	363 (75.6)	Stable angina	370 (77.1)
<b>Risk Factors</b>		CCS I-II	325 (87.8)
Hypertension	334 (69.6)	CCS III-IV	45 (12.2)
Hyperlipidemia	429 (89.4)	Number of anti-anginal medications	
Diabetes	185 (38.5)	0	118 (24.6)
Cerebrovascular disease	102 (21.3)	1	154 (32.1)
COPD	7 (1.5)	2	149 (31.0)
Chronic renal disease	14 (2.9)	3	59 (12.3)
Smoker	226 (47.1)	Extent of coronary disease	
Body mass index, kg/m <sup>2</sup>	25.6 (23.7-27.5)	3-vessel disease	451 (94.0)
Ccr <60 mL/min/1.73m <sup>2</sup>	7 (1.5)	Left main disease	129 (26.9)
<b>Cardiovascular Characteristics</b>		<b>Risk Classification</b>	
Previous MI	49 (10.2)	SYNTAX score	22.5 (16.5-29.5)
Previous heart failure	10 (2.1)	SYNTAX score tertiles	
Peripheral vascular disease	46 (9.6)	Low risk (0-22)	237 (49.4)
Ejection fraction, %	63.0 (59.0-65.0)	Intermediate risk (23-32)	157 (32.7)
Ejection fraction ≤40%	23 (4.8)	High risk (≥33)	86 (17.9)
CAD symptoms		SYNTAX score II recommendation	

Characteristics	Patients for discussion (n=480)	Characteristics	Patients for discussion (n=480)
PCI	11 (2.3)	Reoperation (%)	1.72 (1.46-2.07)
CABG	153 (31.9)	Renal failure (%)	0.43 (0.32-0.61)
Equipoise	316 (65.8)	Stroke (%)	0.96 (0.73-1.36)
SYNTAX score II 2020 10-year mortality (%)		Prolonged ventilation (%)	3.20 (2.62-3.98)
CABG	14.8 (9.1-24.7)	DSWI (%)	0.10 (0.08-0.14)
PCI	19.4 (11.6-32.2)	Prolonged hospitalization (%)	1.79 (1.33-2.53)
EuroSCORE II mortality (%)	0.80 (0.58-1.06)	<b>Treatment Strategy in Real World</b>	
SinoSCORE II mortality (%)	0.82 (0.47-1.18)	PCI	287 (59.8)
STS score (incidence of postoperative events)		CABG	116 (24.2)
Mortality (%)	0.49 (0.36-0.70)	Medical therapy	77 (16.0)
Mortality or major complications (%)	5.30 (4.43-6.56)		

- 7 CABG indicates coronary artery bypass graft; CAD, coronary artery disease; Ccr, creatinine clearance rate; CCS, Canadian  
 8 Cardiovascular Society; COPD, chronic obstructive pulmonary disease; DSWI, deep sternal wound infection; MI, myocardial  
 9 infarction; PCI, percutaneous coronary intervention; SD, standard deviation; STS, Society of Thoracic Surgeons; and SYNTAX,  
 10 Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery.  
 11 Data presented as median (interquartile range, IQR) and n (%).

## 12 **ETHICS AND DISSEMINATION**

### 13 **Ethics**

14 The study was reviewed and approved by the Ethics Review Committees of Fuwai hospital  
15 (2019-1303) on 2 August 2021; subsequent amendments have been approved. All the  
16 participants have provided informed consents.

### 17 **Safety**

18 All the eligible cases were retrospectively selected and underwent coronary angiography  
19 between August 2016 and August 2017. Heart team decisions do not effect on patients' actual  
20 treatments. There will be no adverse event or serious adverse event relating to this study.

### 21 **Dissemination**

22 Results of this trial will be reported to the participating specialists, disseminated through  
23 scientific conferences and journals, reported on <https://ClinicalTrials.gov>, and published in full in  
24 peer-reviewed journals.

## 25 **DISCUSSION**

26 The optimization of heart team implementation including team composition, operation,  
27 distribution of responsibilities, and other issues still lacks verification by evidence-based trials.  
28 The present study is the first trial focusing on the heart team implementation quality assessment  
29 and improvement by evaluating the effect of the standardized heart team protocol compared to

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4 30 the guideline-based protocol on decision-making stability for stable complex CAD.  
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6 31 Stability is a potential metric of decision-making quality. As the expertise of individual  
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9 32 specialists is specific to their professional training and experience, cardiologists and surgeons  
10  
11 33 prefer PCI or CABG, respectively.<sup>10</sup> Prior data showed that 18.1% of the overall decision-  
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14 34 making for stable angina patients was classified as inappropriate based on a single disciplinary  
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17 35 decision, especially among patients undergoing PCI<sup>32</sup>. The heart team, a medium of  
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20 36 communication to integrate the input of numerous specialists, can help to minimize fragmented  
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22 37 communication between specialists and eliminate specialist bias in the decision-making process.  
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24  
25 38 It was reported that heart team recommendations differed from those of the original treating  
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27 39 interventional cardiologist in approximately one-third of cases.<sup>33</sup> Sanchez et al convened 301  
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29  
30 40 heart team meetings for complex CAD from 2012 to 2015 and reported the concordance of the  
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32 41 heart team to appropriate use criteria was up to a 99.3% appropriate primary indication for  
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35 42 coronary revascularization.<sup>34</sup> Therefore, qualified heart teams perform more evidence-based and  
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38 43 neutral in revascularization decision-making. The success of the heart team approach is apparent  
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41 44 in a growing number of optimal revascularization decisions made according to professional  
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43 45 guidelines.

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45 46 Notably, a dedicated and structured heart team has a potential benefit for patient survival.  
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48 47 Peyman et al reported patients treated for mitral valve disease based on a dedicated heart team  
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51 48 decision have significantly higher survival than a general heart team, which illustrated the  
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53 49 establishment of a dedicated heart team consisting of experienced specialists with adequate  
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56 50 procedure volume benefits patient survival<sup>35</sup>. In addition, appropriate revascularization is  
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4 51 associated with improved 1-year outcomes in patients with appropriate indications and has no  
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6 52 benefit in those with uncertain or inappropriate indications.<sup>19</sup> Thus, we assume that  
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9 53 revascularization recommendations of dedicated heart teams organized by the standardized heart  
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11 54 team protocol would be more stable and appropriate compared with those of general heart teams  
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14 55 based on guideline principles, which leads to better clinical outcomes.  
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17 56 Making the heart team approach well-structured and efficient contributes to a better quality  
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19 57 of cardiovascular care. The current study is essential to answer the following questions: (1) Is it  
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21 58 feasible to establish and organize heart team meetings with the guidance of the standardized  
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24 59 heart team protocol? (2) Will the standardized heart team protocol improve the decision-making  
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27 60 stability in patients with stable complex CAD compared with the fundamental principles of heart  
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30 61 team organizing in guidelines? Moreover, it will enhance educational opportunities for all team  
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33 62 members involved and provide experience in the practice of heart team meetings in prospective  
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35 63 clinical scenarios.  
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38 64 Several novel designs underlie the strength of this study. Firstly, we use a randomized  
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40 65 controlled design to demonstrate the structure and effect of an evidence-based standardized heart  
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43 66 team protocol on decision-making stability against the controlled approach based on guideline  
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46 67 principles, which fills the gap with no randomized data currently available in optimal heart team  
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48 68 implementation<sup>12 33</sup>. Secondly, the study applies randomization three times. Eligible specialists  
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51 69 are first randomly selected and assigned to different arms by stratification randomization. Then  
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54 70 we establish heart teams with randomized membership to reduce social factors that may have  
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56 71 negative implications on individual decision-making<sup>36</sup>. Cases are also randomized into 6 sets of  
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4 72 80 cases each to ensure relatively equal heart team exposure to case complexity. Thirdly, all  
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6 73 heart team training and meetings are held via video conference using an online decision-making  
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9 74 support system, which makes it possible to involve specialists from multiple hospitals, reduce the  
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12 75 negative influence of a few influential individuals on face-to-face decision-making, and  
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14 76 eliminate the risk of viral spreading in COVID-19.<sup>37</sup> Fourthly, we provide the most up-to-date  
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17 77 risk scores (such as SYNTAX II 2020 score<sup>23</sup>, sinoSCORE II<sup>27</sup>) and QFR<sup>20</sup>, a novel  
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20 78 angiography-derived physiological assessment approach, in structured information for the  
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23 79 specialists to adjudicate the optimal treatment strategy.

24  
25 80 The study has several limitations. First, cases discussed are retrospectively selected rather  
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28 81 than prospectively enrolled. All cases have already been treated from August 2016 to August  
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31 82 2017 in the original hospitalization, thus it is unable to reveal the true impact and benefits of  
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34 83 heart team meetings on real-world decision-making and outcomes in routine clinical practice.  
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37 84 Prospective design is needed for the next step. Second, the intervention in the standardized  
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40 85 protocol group is an integrated approach and the potential differential outcomes associated with  
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43 86 its use cannot be attributed to a single point of the process. Additional quantitative and  
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46 87 qualitative analysis is needed to find out which steps work on the decision-making stability.  
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49 88 Third, heart team decisions will be made independently of patient preferences, while in real-  
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52 89 world clinical practice, patient preference is an important factor for the final treatment decision.  
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55 90 Patient involvement in shared decision-making should be considered in future trials.  
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4 91 **DECLARATIONS**

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7  
8 92 **Consent for publication**

9  
10 93 Not applicable.

11  
12  
13 94 **Competing interests**

14  
15  
16 95 The authors declare that they have no competing interests.

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28  
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31 101 of results. The authors report no financial conflicts of interest.

32  
33  
34 102 **Contributors**

35  
36 103 ZZ contributed to study conception, funding obtaining, administration, and technical material  
37  
38  
39 104 support. HPM, SL, XL, BX, and ZZ contributed to the study design. HPM and SL drafted the  
40  
41  
42 105 manuscript. XL and YW contributed to statistical consultation. HPM, SL, and BX contributed to  
43  
44 106 data collection and interpretation. All authors revised the manuscript for important intellectual  
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46  
47 107 content and approved the final version.

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6 244 **FIGURE LEGENDS**  
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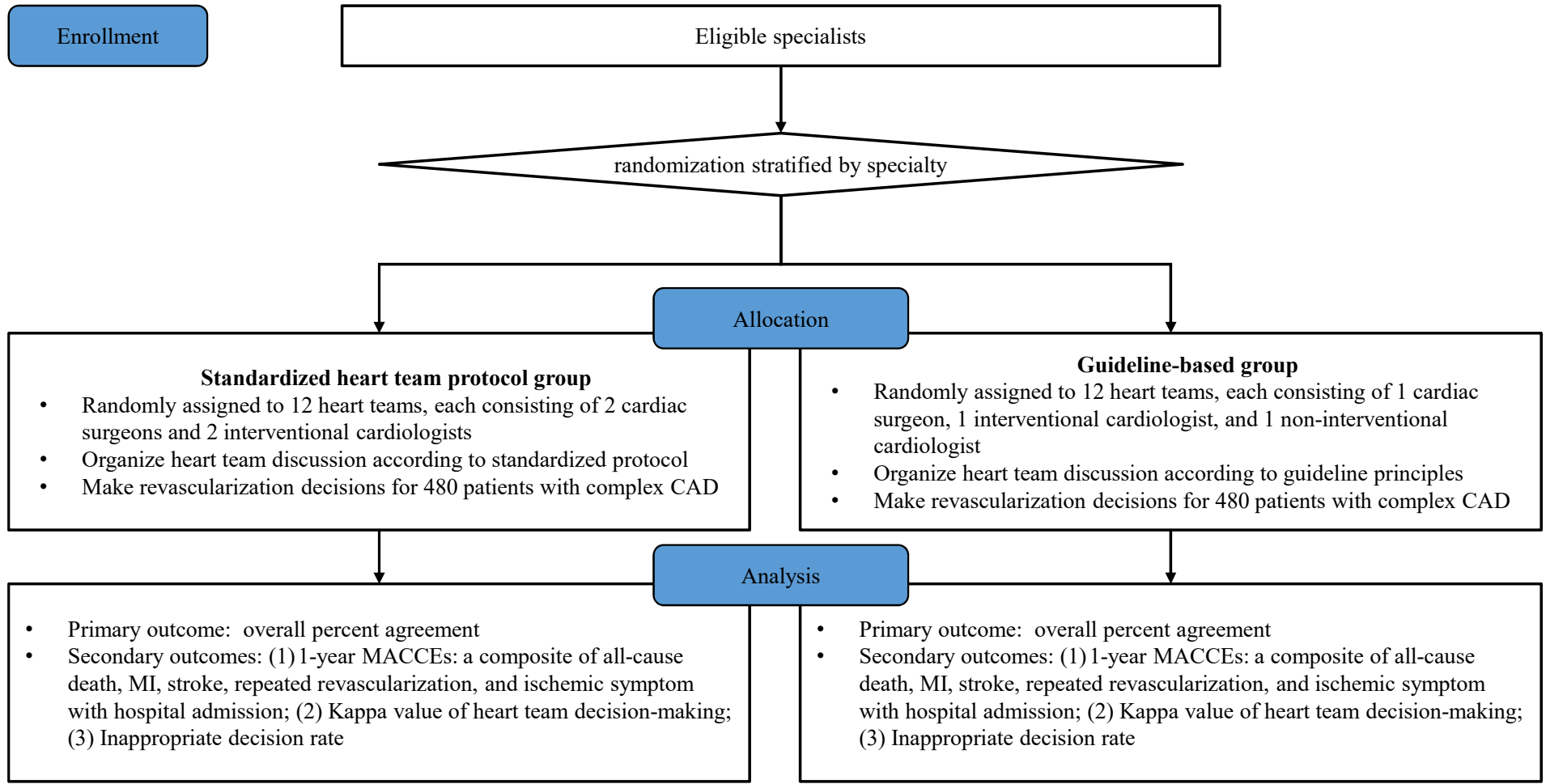
10 245 **Figure 1. Flow chart**

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12 246 Eligible specialists will be randomized to a standardized heart team protocol group or  
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15 247 guideline-based group and established 12 heart teams in each group to make  
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18 248 revascularization decisions for 480 historic cases with stable complex CAD. CAD  
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20 249 indicates coronary artery disease; MACCE, major adverse cardiovascular and  
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23 250 cerebrovascular event.  
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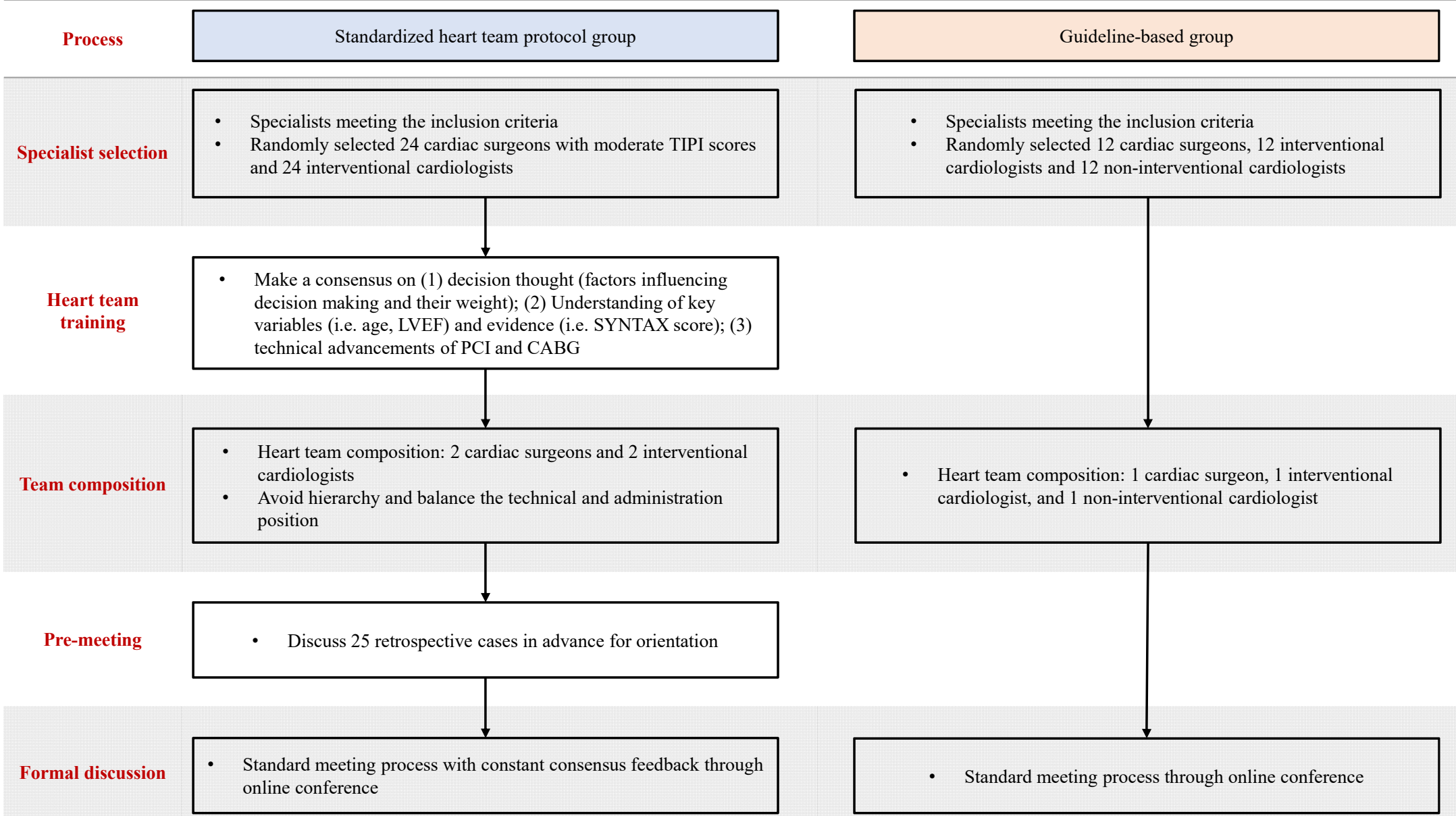
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28 252 **Figure 2. Implementation strategies for the standardized protocol group and**  
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31 253 **guideline-based group**

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33 254 In the standardized protocol group, the heart team will be implemented based on an  
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36 255 evidence-based protocol including specialist selection, specialist training, team  
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39 256 composition, team training, and a standardized meeting process. In the guideline-  
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42 257 based group, the heart team will be implemented according to the key principles  
43  
44 258 mentioned in clinical guidelines, including team composition and standardized  
45  
46 259 meeting process. TIPI indicates a ten-item personality inventory; LVEF, left  
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49 260 ventricular ejection fraction; CABG, coronary artery bypass grafting; PCI,  
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52 261 percutaneous coronary intervention; SYNTAX, Synergy Between Percutaneous  
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54 262 Coronary Intervention with Taxus and Cardiac Surgery.  
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## SUPPLEMENTAL MATERIALS

### Effect of a Standardized Heart Team Protocol versus Guideline-based Protocol on Revascularization Decisions Stability in Stable Complex Coronary Artery Disease: Rationale and Design of a Randomized Trial

#### Contents

#### Supplemental method

Full Definitions of key variables

Inclusion and exclusion criteria of cases to be discussed

#### Supplementary Figures

Online Figure 1. Specialist Enrollment Flowchart

Online Figure 2. Patient Enrollment Flowchart

Online Figure 3. Standard heart team meeting flow

#### Supplementary Tables

Online Table 1. Structured patient information

Online Table 2. Ten-Item Personality Inventory in China (TIPI-C)

Online Table 3. Tabular analysis of inter-team agreement

## 17 Supplemental Methods

### 18 *Full Definitions of key variables and clinical endpoints*

- 19 **1. Three-vessel disease:** three lesions with a percent diameter stenosis (DS%) between 50%-  
20 99% or total occlusion in a coronary artery with a  $\geq 2.5$  mm reference vessel diameter by  
21 visual assessment.
- 22 **2. Left main disease:** left main coronary artery is visually assessed DS%  $\geq 50\%$ .
- 23 **3. Major adverse cardiovascular and cerebrovascular events (MACCEs):** a composite of  
24 death, myocardial infarction, stroke, repeated revascularization, and rehospitalization due to  
25 ischemic symptoms.
- 26 **4. Death:** death from any cause. The cause of death will be adjudicated as being due to cardiac  
27 death or non-cardiac death.
- 28 **5. Myocardial infarction (MI)**
  - 29 **(1) In-hospital MI:** Defined as the occurrence during hospitalization after PCI, CABG or  
30 coronary angiography meeting at least 1 of the following criteria:
    - 31 1) The rise in cardiac troponin I (cTnI) is  $\geq 70$  times the 99th percentile URL (where  
32 the baseline is lower than the URL, elevated and stable, or falling).
    - 33 2) If cTnI was not available, MI was defined with at least one of the following:
      - 34 i. New ischaemic ECG changes;
      - 35 ii. Development of new pathological Q waves;
      - 36 iii. Imaging evidence of loss of viable myocardium that is presumed to be new and  
37 in a pattern consistent with an ischaemic etiology;

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4 38 iv. Angiographic findings consistent with a procedural flow-limiting complication  
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6 39 such as coronary dissection, occlusion of a major epicardial artery or graft,  
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9 40 side-branch occlusion-thrombus, disruption of collateral flow or distal  
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11  
12 41 embolization.

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14 42 **(2) Spontaneous MI:** Defined as detection of a rise and/or fall of cTn values with at least  
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17 43 one value above the 99th percentile URL after discharge and with at least one of the  
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19  
20 44 following:

- 21  
22 45 1) Symptoms of acute myocardial ischemia;  
23  
24  
25 46 2) New ischaemic ECG changes;  
26  
27  
28 47 3) Development of pathological Q waves;  
29  
30 48 4) Imaging evidence of new loss of viable myocardium or new regional wall motion  
31  
32  
33 49 abnormality in a pattern consistent with an ischaemic etiology;  
34  
35 50 5) Identification of a coronary thrombus by angiography including intracoronary  
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37  
38 51 imaging or by autopsy.

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40 52 **6. Stroke** was confirmed by a neurologist on the basis of imaging studies and was defined as  
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43 53 follows:

- 44  
45 54 1) A focal neurologic deficit of central origin lasting >72 hours, or  
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48 55 2) A focal neurologic deficit of central origin lasting >24 hours, with imaging evidence of  
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51 56 cerebral infarction or intracerebral hemorrhage, or  
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54 57 3) A non-focal encephalopathy lasting >24 hours with imaging evidence of cerebral  
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56 58 infarction or hemorrhage adequate to account for the clinical state.  
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4 59 **7. Repeat revascularization** was defined as any repeat coronary artery bypass graft (CABG)

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6  
7 60 or PCI.

8  
9 61 1) Target Lesion: Lesions were revascularized in the index procedure (or during a planned  
10  
11 or provisional staged procedure).

12 62  
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14 63 2) Non-Target Vessel: Lesions were not treated by either PCI or CABG at the index  
15  
16 procedure.  
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19 65 **8. Rehospitalization due to ischemic symptoms:** rehospitalization because of ischemic  
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21 discomfort (angina or symptoms thought to be equivalent).  
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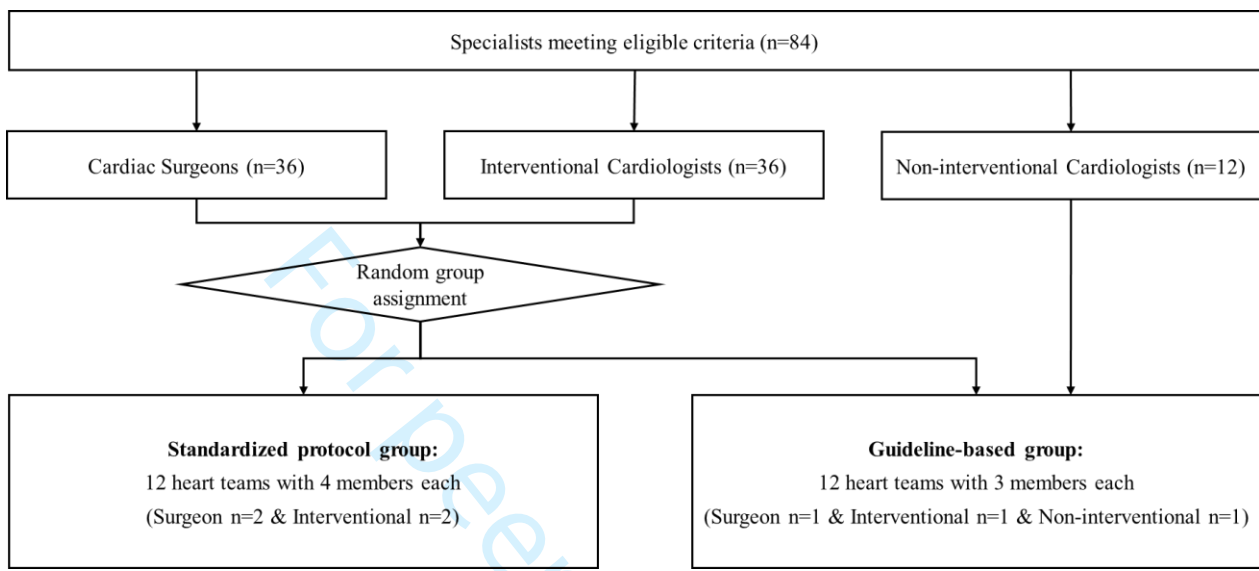
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4 68 ***Inclusion and exclusion criteria of cases to be discussed***  
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7 69 Adult patients with stable CAD according to the National Cardiovascular Data Registry (NCDR)  
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9 70 CathPCI criteria (stable angina, no or silent myocardial ischemia) and angiographically  
10  
11 71 confirmed 3-vessel disease or left main (3VD/LM) disease will be eligible for inclusion in the  
12  
13 72 study. The exclusion criteria included: (1) prior coronary artery bypass grafting (CABG); (2)  
14  
15 73 cardiac troponin I (CTnI) greater than the local laboratory upper limit of normal or recent  
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17 74 myocardial infarction with CTnI levels still elevated; (3) concomitant severe valvular disease,  
18  
19 75 macrovascular disease, or huge ventricular aneurysm requiring surgery; (4) concomitant atrial  
20  
21 76 fibrillation or severe arrhythmia; or (5) unavailable de novo angiography images of the current  
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23 77 hospitalization. Eligible cases will be randomly selected from a prospective registry of  
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25 78 consecutive patients who underwent coronary angiography between August 2016 and August  
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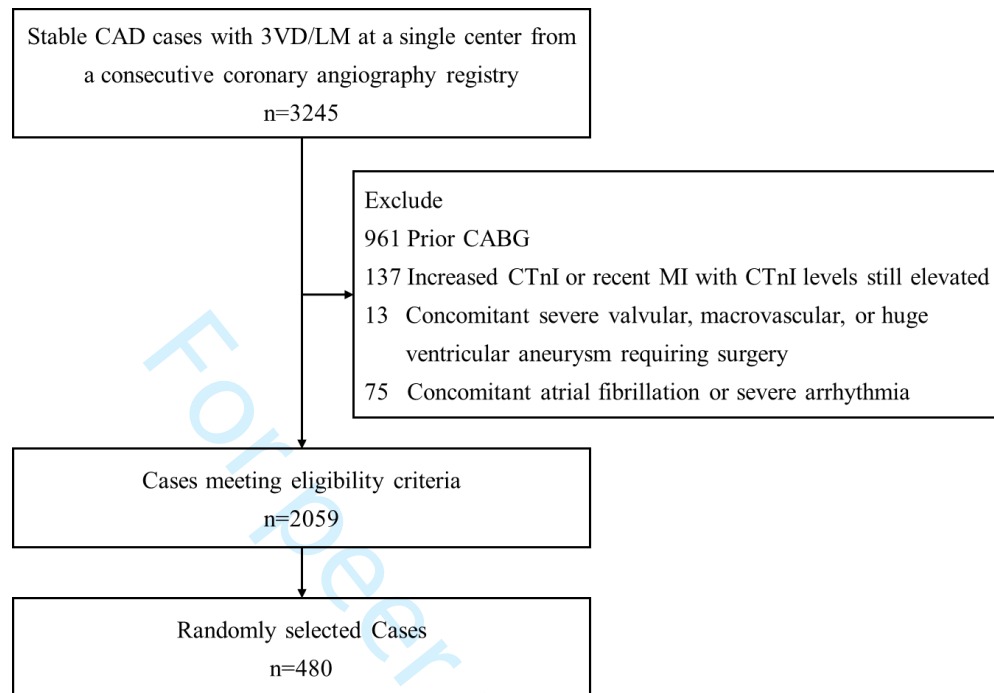
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81 **Supplementary Figures**

82 **Online Figure 1. Specialist Enrollment Flowchart**



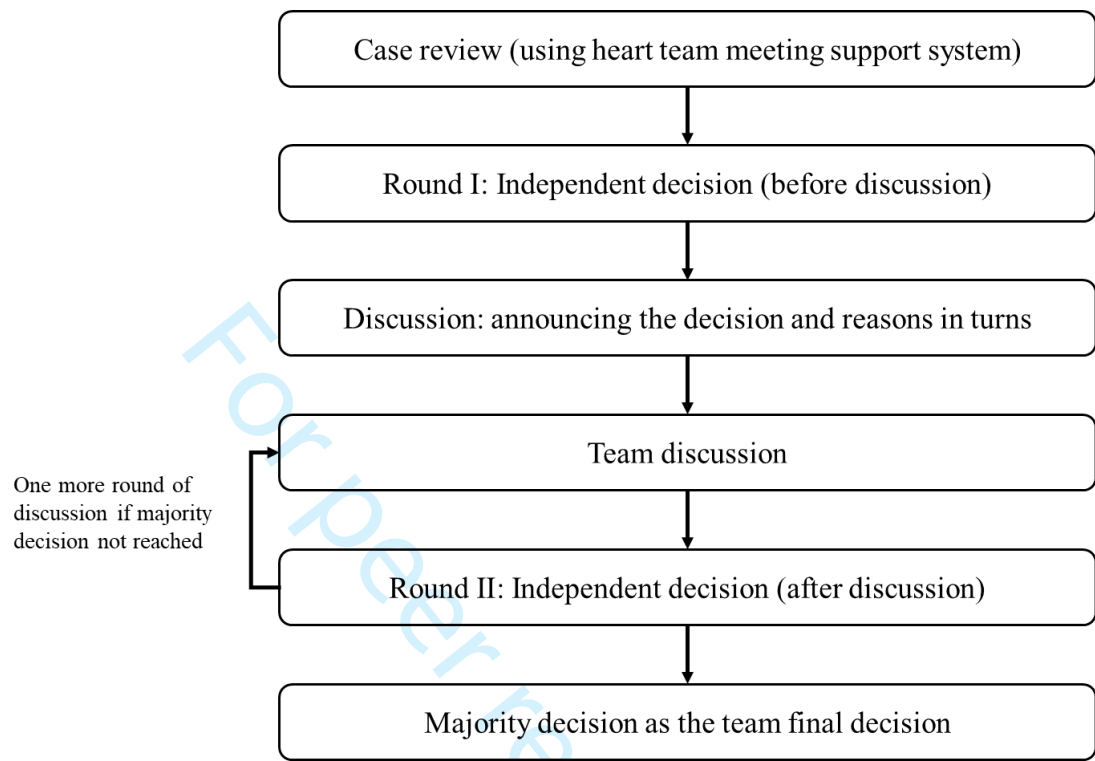
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84 **Online Figure 2. Cases Selection Flowchart**

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86 3VD indicates 3-vessel disease; CTnI, cardiac troponin I, LM, left main; MI, myocardial infarction;  
87 PCI, percutaneous coronary intervention.

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88 **Online Figure 3. Standard heart team meeting procedure**



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91 **Supplementary Tables**92 **Online Table 1. Structured patient information**93 **Heart Team Patient Information Sheet**94 **A. Demographics**95 Patient ID: \_\_\_\_\_ Gender:  Male  female Age: \_\_\_\_\_ y BMI : \_\_\_\_\_ kg/m<sup>2</sup>96 **B. Medical history and risk factors**

<b>Diabetes</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>History of myocardial infarction</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	Time: _____
<b>History of heart failure</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	EF value: _____%
<b>History of stroke</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>renal insufficiency</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	Creatinine: _____ umol/L (44-133) Creatinine clearance: _____ ml/min
<b>Chronic obstructive pulmonary disease</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>Other comorbidities:</b> <i>congenital mitral valve prolapse, hypertension, post-operative hypothyroidism, kidney stones</i>		

97 **C. Coronary heart disease symptoms**

<b>Coronary heart disease symptoms</b>	<input type="checkbox"/> Unstable Angina <input type="checkbox"/> stable angina <input type="checkbox"/> Asymptomatic
<b>Home antianginal medication</b>	<input type="checkbox"/> Long-acting nitrates <input type="checkbox"/> $\beta$ -blockers <input type="checkbox"/> Ca <sup>2+</sup> channel blockers
<b>CCS classification (stable angina)</b>	<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Asymptomatic
<b>NYHA classification</b>	<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV

98 **D. Laboratory test**

Hemoglobin: _____g/L	White blood cells:_____ *10 <sup>9</sup> /L	Platelets:_____ *10 <sup>9</sup> /L
PT: _____s (11.5-14.5)	APTT: _____s (28.5-43.5)	INR: _____(0.8-1.2)
Troponin I: _____ng/ml (ll_____:ul_____)		

99 **E. Preoperative non-invasive examination**

	Result
<b>Admission ECG</b>	<i>Sinus bradycardia 58 beats/min</i>
<b>Echocardiography</b>	<i>Mitral valve posterior leaflet prolapse, mitral valve regurgitation</i>
<b>Stress Testing and Nuclear Medicine</b>	
<b>Coronary CTA</b>	
<b>Cardiac MRI</b>	

100 **F. Invasive coronary examination**

Aniography	FFR:	IVUS:	OCT:
QFR	LM (left main artery): _____		LAD (left anterior descending artery): _____
	LCX (left circumflex artery): _____		RCA (right coronary artery): _____
	Obtuse marginal: _____		Diagonal: _____
	Posterior descending artery: _____		Left posterior artery: _____
	Ramus medianus: _____		

101 **G. Clinical risk scores**

SYNTAX	Score: _____
--------	--------------

S YNTAX II	PCI Score: <u>30.0(9.8%)</u>	CABG Score: <u>32.5(10.2%)</u>	Recommended: /
SYNTAX II 2020	PCI score: <u>9.8%</u>	CABG Score: <u>10.2%</u>	
EuroScore II	Mortality: <u>0.7%</u>		
SinoScore II	Mortality: <u>0.7%</u>		
STS Score	Mortality: <u>0.49%</u>	Mortality and complication rate: <u>9.95%</u>	
	Renal failure rate: <u>0.39%</u>	Stroke rate: <u>1.27%</u>	
	Prolonged ventilation rate: <u>5.8%</u>	Deep sternum infection rate: <u>0.36%</u>	
	Reoperation rate: <u>2.37%</u>	Extended hospital stay rate: <u>4.34%</u>	

102 \* Guidelines recommend STSscore mortality >2% with higher surgical risk

103 **H. Decision result (single choice)**

<b>Independent decision before discussion</b>	<input type="checkbox"/> PCI <input type="checkbox"/> CABG <input type="checkbox"/> PCI /CABG <input type="checkbox"/> Drugs <input type="checkbox"/> Further inspection
<b>Independent decision after discussion</b>	<input type="checkbox"/> PCI <input type="checkbox"/> CABG <input type="checkbox"/> PCI /CABG <input type="checkbox"/> Drugs <input type="checkbox"/> Further inspection

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106 **Online Table 2. Ten-Item Personality Inventory in China (TIPI-C)**

Question No.*	Original items (Gosling et al., 2003)	Rating Scale						
		Absolutely disagree	Quite disagree	Almost disagree	Uncertain	Almost agree	Quite agree	Absolutely agree
		1	2	3	4	5	6	7
1	Extraverted, enthusiastic							
2	Critical, quarrelsome							
3	Dependable, self-disciplined							
4	Anxious, easily upset							
5	Open to new experience, complex							
6	Reserved, quiet							
7	Sympathetic, warm							
8	Disorganized, careless							

9	Calm, emotionally stable							
10	Conventional, uncreative							

107 \*Scale scoring (“R” denotes reverse-scored items): Extraversion: 1, 6R; Agreeableness: 2R, 7; Conscientiousness: 3,  
 108 8R; Emotional Stability: 4R, 9; Openness to Experiences: 5, 10R.

109 **Online Table 3. Tabular analysis of inter-team agreement**

Case ID	Interventional group			Guideline group		
	Hear team 1 decision	Hear team 2 decision	agreement	Hear team 1' decision	Hear team 2' decision	agreement
001	CABG	CABG	Yes	PCI	CABG	No
002	CABG	PCI	No	PCI	PCI	Yes
003	Medication	PCI	No	Further testing	PCI	No
...	...	...	...	...	...	...
...	...	...	...	...	...	...
480	PCI	PCI	Yes	PCI	Medication	No

110 **Online Table 3. Tabular analysis of inter-team agreement.** Each case will be discussed by two assigned heart teams. The pairwise  
 111 comparison between the heart team's decision on each case provides data on the agreement. CABG indicates coronary artery bypass  
 112 grafting; PCI, percutaneous coronary intervention.



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	Addressed on page number
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
	2b	All items from the World Health Organization Trial Registration Data Set	see clinicaltrials.gov
Protocol version	3	Date and version identifier	8
Funding	4	Sources and types of financial, material, and other support	27
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1-2, 27
	5b	Name and contact information for the trial sponsor	see clinicaltrials.gov
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	27
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	15-16

1	<b>Introduction</b>			
2				
3	Background and	6a	Description of research question and justification for undertaking the trial, including summary of relevant	6-7
4	rationale		studies (published and unpublished) examining benefits and harms for each intervention	
5				
6		6b	Explanation for choice of comparators	6-7
7				
8	Objectives	7	Specific objectives or hypotheses	8
9				
10	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group),	7-8
11			allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	
12				
13				
14	<b>Methods: Participants, interventions, and outcomes</b>			
15				
16	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will	7-8
17			be collected. Reference to where list of study sites can be obtained	
18				
19	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and	7-8
20			individuals who will perform the interventions (eg, surgeons, psychotherapists)	
21				
22	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be	8-10
23			administered	
24				
25		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose	NA
26			change in response to harms, participant request, or improving/worsening disease)	
27				
28		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence	13
29			(eg, drug tablet return, laboratory tests)	
30				
31		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
32				
33	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood	14-15
34			pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg,	
35			median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen	
36			efficacy and harm outcomes is strongly recommended	
37				
38	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for	see
39			participants. A schematic diagram is highly recommended (see Figure)	clinicaltrials.gov
40				
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1	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	17-18
2				
3				
4	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9
5				
6				
7	<b>Methods: Assignment of interventions (for controlled trials)</b>			
8	Allocation:			
9				
10	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10
11				
12				
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15				
16	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	NA
17				
18				
19				
20	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8-14
21				
22				
23				
24	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10
25				
26				
27		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
28				
29				
30				
31	<b>Methods: Data collection, management, and analysis</b>			
32				
33	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10-11,16-17
34				
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39		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA
40				
41				
42				

1	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15-16
2				
3				
4				
5	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16-17
6				
7				
8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18
9				
10		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	NA
11				
12				
13				
14	<b>Methods: Monitoring</b>			
15				
16	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	15-16
17				
18				
19				
20				
21				
22		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
23				
24				
25	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
26				
27				
28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	15-16
29				
30				
31				
32	<b>Ethics and dissemination</b>			
33				
34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	23
35				
36				
37	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	23
38				
39				
40				
41				
42				

1	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9, 11
2				
3				
4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
5				
6				
7	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15-16
8				
9				
10	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	27
11				
12				
13	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	23
14				
15				
16	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
17				
18				
19				
20	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	23
21				
22				
23				
24		31b	Authorship eligibility guidelines and any intended use of professional writers	27
25				
26		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	27
27				
28				
29	<b>Appendices</b>			
30				
31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplemental file 2
32				
33				
34	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA
35				
36				

\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons [“Attribution-NonCommercial-NoDerivs 3.0 Unported”](https://creativecommons.org/licenses/by-nc-nd/3.0/) license.



## CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3-4
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	6-7
	2b	Specific objectives or hypotheses	8
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7-8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	7-8
	4b	Settings and locations where the data were collected	7-8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	12-14
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	14-15
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	17-18
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
<b>Randomisation:</b>			
Sequence generation	8a	Method used to generate the random allocation sequence	10
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	10
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	10

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	14
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	16-17
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	18
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	10
	13b	For each group, losses and exclusions after randomisation, together with reasons	NA
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8-9
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	20-22
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	NA
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	NA
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
<b>Discussion</b>			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	NA
<b>Other information</b>			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	See ClinicalTrials.gov
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	27

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).



**The TIDieR (Template for Intervention Description and Replication) Checklist\*:**  
Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	<b>BRIEF NAME</b>		
1.	Provide the name or a phrase that describes the intervention.	12-14	
	<b>WHY</b>		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	12-14	Ma H, Lin S, Li X, et al. Exploring optimal heart team protocol to improve decision-making stability for complex coronary artery disease: a sequential explanatory mixed method study. Eur Heart J Qual Care Clin Outcomes 2021 doi: 10.1093/ehjqcco/qcab074 [published Online First: 2021/10/12]
	<b>WHAT</b>		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	11-12	Online table 1
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	12-14	

1	<b>WHO PROVIDED</b>	
2	5. For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise,	12-14
3	background and any specific training given.	
4	<b>HOW</b>	
5	6. Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of	13-14
6	the intervention and whether it was provided individually or in a group.	
7	<b>WHERE</b>	
8	7. Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or	13-14
9	relevant features.	
10	<b>WHEN and HOW MUCH</b>	
11	8. Describe the number of times the intervention was delivered and over what period of time including the	13-14
12	number of sessions, their schedule, and their duration, intensity or dose.	
13	<b>TAILORING</b>	
14	9. If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	N/A
15	<b>MODIFICATIONS</b>	
16	10.† If the intervention was modified during the course of the study, describe the changes (what, why, when, and	N/A
17	how).	
18	<b>HOW WELL</b>	
19	11. Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies	13
20	were used to maintain or improve fidelity, describe them.	
21	12.† Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was	N/A
22	delivered as planned.	

\*\* **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported.

1 † If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other  
2 published papers (provide citation details) or a website (provide the URL).

3 ‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

4  
5 \* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

6 \* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of  
7 studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the  
8 TIDieR checklist should be used in conjunction with the CONSORT statement (see [www.consort-statement.org](http://www.consort-statement.org)) as an extension of **Item 5 of the CONSORT 2010 Statement**.  
9 When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013**  
10 **Statement** (see [www.spirit-statement.org](http://www.spirit-statement.org)). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see [www.equator-](http://www.equator-network.org)  
11 [network.org](http://www.equator-network.org)).



# 复杂冠心病心脏团队决策一致性对比研究（随机对照试验）

## 知情同意书

我们邀请您参加由中国医学科学院阜外医院发起的一项“复杂冠心病心脏团队决策一致性对比研究”，本研究已通过中国医学科学院阜外医院伦理委员会审批（电话 010-88396281）。请仔细阅读说明，了解您在研究中的权利和义务，明确研究性质和风险。参加研究属完全自愿。当研究人员向您说明和讨论知情同意书时，您可以随时提问并让研究人员向您解释您不明白的地方。若您目前正参加其他临床研究，请告知研究人员。本项研究的项目负责人是郑哲（中国医学科学院阜外医院），本项研究的资助方是中国医学科学院阜外医院。

### 为什么进行这项研究？

当前复杂冠心病心脏团队实践流程存在标准不统一及决策一致性欠佳的问题。前期的一项序贯解释性混合方法研究探索出了一套优化流程的标准化心脏团队实践方案，其对改善心脏团队决策一致性的效果有待验证。本研究拟通过随机对照设计，评价标准化心脏团队实践方案改善复杂冠心病心脏团队决策一致性的效果。

### 为什么邀请您参加这项研究？

因为您（作为介入医生）具备年介入手术量至少 200 例、左主干病变介入年手术量至少 25 例，且可独立完成慢性完全性闭塞病变的介入手术的能力；或（作为心脏外科医生）具备总搭桥手术量至少 200 例，且可熟练完成体外循环和非体外循环搭桥手术的能力；或（作为非介入手术医生）具备副主任医师及以上的技术资格。此外，您还需具备相关临床研究经验及循证医学素养。因此，我们邀请您参加本项研究。是否最终入选由研究者根据您的实际情况来判断。

### 多少人将参与这项研究？

本研究计划在内外科合作良好的医院中最终招募 84 位心血管病医生，其中包含介入医生 36 位、心外科医生 36 位及非介入手术医生 12 位。

### 参加本项研究，需要您做什么？

您需要在项目组的引导下，学习使用心脏团队会议系统、接受会议培训，并参与心脏团队会议讨论，为回顾性病例提供最优诊疗决策推荐。同时，需对项目组为您提供的任何形式的包括但不限于研究方案、病例基本临床信息、心电图图片、超声心动图报告、造影图像、未公开发表的临床文件或其他保密信息进行保密，不得通过拍照、录音、录像、截图等形式泄露、告知、公开、发布、出版、传授、转让或其他任何方式使任何第三方知悉项目提供的数据或利用项目组数据分析的成果数据。

### 本项研究会持续多久？

1  
2  
3  
4 本项研究将持续 12 个月。

#### 5 **参加本研究受试者的风险和不良反应？**

6  
7 本研究仅邀请您参与心脏团队并进行既往病例会议讨论。研究不会干预您正常的临床诊疗工作，研究  
8  
9 过程中无任何风险和不良反应。

#### 10 **参加本研究可能的获益是什么？**

11  
12 您不会因参加本项研究有直接获益，您的参与有助于促进心脏内科与心脏外科医生的学科和技术交流，  
13  
14 为真实世界优化和完善心脏团队实践流程提供宝贵资料和经验。

#### 15 **如果不参加此研究，有没有其他备选治疗方案？**

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17 您可以选择不参加本项研究，这对您正常的临床诊疗工作不会产生任何影响。

#### 18 **参加该项研究的费用和补偿**

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20 本研究仅邀请您参与心脏团队并进行既往病例会议讨论，不涉及正常诊疗工作，无相关费用和补偿。

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23 本研究仅邀请您参与心脏团队并进行既往病例会议讨论，不影响您正常的临床工作，不会发生研究相  
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25 关伤害。

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28 是的，您的信息在研究中将严格保密。本试验中使用您的研究数据时，您的个人信息都是保密的，您  
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30 的所有信息资料将得到妥善保存并仅供研究使用。研究数据库中的信息会严格脱敏消除个人身份识别特征，  
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38 息。

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41 是否参加本项研究是自愿的，您可以自由决定参加或拒绝参加此项研究。无论您是否同意参与此项研  
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53 用您的试验数据，但在您退出前已匿名化采集的数据将无法删除或撤回。

#### 54 **是否愿意参加未来研究？**

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4 如果您同意，我们希望保留您在研究期间的资料和数据。您的匿名研究数据将继续用于后续经审批的  
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7 保存于中国医学科学院阜外医院并严格保密。您可以自愿选择是否参加未来研究，并可以在任何时间联系  
8 研究人员以书面文件形式退出研究。  
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### 13 如果有问题或困难，该与谁联系？

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15 您可以在任何时间提出有关本项试验的任何问题，并得到相应的解答，请联系研究人员，电话：  
16 010-88398027。如果您对自己的权益有任何疑问，请联系阜外医院伦理委员会，电话：010-88396281。  
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19 感谢您花时间阅读本知情同意书。如果您通过充分考虑之后同意参加本临床试验，希望您能按照研究  
20 人员的要求完成本次临床试验。参加本试验前，请与您的研究人员共同完成并签署此文件最后一页（签署  
21 页），一式两份，您和医院各保留一份签署的文件。  
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### 签署页

我已经认真阅读、理解并同意本知情同意书全部条款。

我已被告知此项研究/临床试验的试验目的、内容、程序，研究/试验可能有的不良反应，研究补偿，以及我的权益等；我有足够的时间和机会进行提问，并得到了令我满意答复。

我承诺我提供的信息是真实的；如提供了虚假信息，我承诺对其后果负责。

我确认签名处所留联系方式为我本人有效联系方式，如变更联系方式应及时告知你院，否则，我愿意承担无法联系及无法收到通知的相应后果。

我知道我可以随时退出此项试验，并不影响我正常临床工作。

我将得到这份知情同意书的正本，上面包含我和研究者的签名。

**我同意参加本项研究。**

**是否同意参与未来研究**  同意  不同意（请您选择）研究数据用于未来研究，授权研究者及相关医学研究项目的共同研究单位在被批准的心血管相关医学研究中使用并且处理我本人的匿名数据。

受试者姓名

签名：

日期：

研究者

签名：

日期：

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3 **A comparative study on the stability of heart team decision-making in**  
4 **complex coronary artery disease (a randomized controlled trial)**  
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6  
7 **INFORMED CONSENT**  
8

9 We invite you to participate in a " comparative study on the stability of heart team  
10 decision-making in complex coronary artery disease (a randomized controlled trial)" initiated by  
11 Fuwai Hospital, Chinese Academy of Medical Sciences. This study has been approved by the  
12 Ethics Committee of Fuwai Hospital, Chinese Academy of Medical Sciences (Tel: 010-88396281).  
13 Please read the instructions carefully to understand your rights and obligations in the research and  
14 to clarify the nature and risks of the research. Participation in research is entirely voluntary. When  
15 the researcher explains and discusses the informed consent form to you, you can always ask  
16 questions and ask the researcher to explain to you what you don't understand. If you are currently  
17 participating in other clinical studies, please inform the investigators. The project leader of this  
18 research is Zheng Zhe (Fuwai Hospital, Chinese Academy of Medical Sciences), and the sponsor  
19 of this research is Fuwai Hospital, Chinese Academy of Medical Sciences.  
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30 **Why do this research?**  
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32 The current practice processes of coronary revascularization heart team have problems with  
33 inconsistent standards and poor consistency of decision-making. A previous sequential explanatory  
34 mixed methods study explored a standardized heart team implementation protocol to optimize the  
35 process, and its effect on improving the consistency of heart team decision-making remains to be  
36 verified. This randomized controlled trial aims to evaluate the effect of a standardized heart team  
37 implementation protocol on improving decision-making consistency in complex coronary artery  
38 disease.  
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46 **Why are you invited to participate in this study?**  
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48 Because you (as an interventional cardiologist) have the ability to have annual PCI volume  $\geq$   
49 200, annual left main (LM)-PCI volume  $\geq$  25, and is capable of chronic total occlusion (CTO)-PCI;  
50 or (as a cardiac surgeon) have total CABG volume  $\geq$  200, and is proficient in both on-pump and  
51 off-pump CABG; or (as a non-interventional surgeon) have the technical qualifications of associate  
52 chief physician or above. In addition, you need to have relevant clinical research experience and  
53 evidence-based medicine literacy. Therefore, we invite you to participate in this study. Whether  
54 you are finally selected or not will be judged by the researcher based on the actual situation.  
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### **How many people will be involved in this study?**

This study plans to eventually recruit 84 specialists from hospitals with good cooperation in internal medicine and surgery, including 36 interventional cardiologists, 36 cardiac surgeons, and 12 non-interventional cardiologists.

### **What do you need to do to participate in this study?**

Under the guidance of the project team, you need to learn to use the heart team meeting system, receive team training, and participate in the heart team meeting discussions to provide optimal treatment decisions for retrospective cases. At the same time, it is necessary to keep confidential of any form of information provided to you, including but not limited to research protocols, basic clinical information of cases, electrocardiogram pictures, echocardiography reports, angiography images, unpublished clinical documents or other confidential information. Any means (photographing, audio recording, video recording, screenshots, etc.) to make any third party aware of the data provided by the project or the results of data analysis by the project team is forbidden.

### **How long will this study last?**

The study will last for 12 months.

### **Risks and adverse effects of participants in this study?**

This study only invites you to participate in the heart team and make decisions for retrospective cases. The study will not interfere with your normal clinical practice, and there will be no risks and adverse effects during the process.

### **What are the possible benefits of participating in this study?**

You will not directly benefit from participating in this study, but your participation will help promote the exchange of disciplines and techniques between cardiologists and cardiac surgeons, and provide valuable information and experience for real-world optimization and improvement of heart team practice.

### **If not participating in this study, are there other options?**

You can choose not to participate in this study, which will not have any impact on your normal clinical work.

### **Fees and Compensation for Participation in the Study**

This study only invites you to participate in the heart team and make decisions for retrospective cases, and there is no related cost and compensation.



### **What happens to research-related injuries?**

This study only invites you to participate in the heart team and make decisions for retrospective cases, which will not interfere with your normal clinical work and will not cause research-related injuries.

### **Will my information be kept private?**

Yes, your information will be kept strictly confidential during the study. When your research data is used in this trial, your personal information is kept confidential, and all your information will be kept securely and used for research purposes only. The information in the research database will be strictly desensitized to eliminate personally identifiable characteristics, and information that may identify you will not be disclosed to anyone other than the researcher without your permission. Without violating the principle of confidentiality and relevant regulations, the reviewers of the ethics committee can consult the original medical records of the subjects to verify the process and data of the clinical trial. If the research results are published publicly, your personal information will not appear in any publications, and we will not disclose this information to anyone or any institution.

### **Do I have to participate in and complete this study?**

Participation in this study is voluntary, and you are free to decide to participate or refuse to participate in this study. Whether you agree to participate in this research or not will not affect your normal clinical work. If you want to participate in this research, you need to read this informed consent form carefully and sign this informed consent form after confirming that you fully understand the relevant issues. You will not lose any legal rights conferred on you by law by signing this document. You may refuse to participate at any time or have the right to withdraw from the research at any time during the research period without any reason, without discrimination or retaliation, and the corresponding rights will not be affected. If you want to withdraw from the research project during the participation, please notify the researcher, complete the relevant procedures before withdrawal as required by the researcher, and complete the relevant withdrawal procedures in writing as required; after withdrawal, the researcher will no longer continue to collect and use your trial data, but data collected anonymized prior to your opt-out cannot be deleted or withdrawn.

### **Would you like to participate in future research?**

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4 With your consent, we wish to retain your data during the study period. Your anonymous  
5 research data will continue to be used for subsequent approved cardiovascular-related medical  
6 research. If you do not agree, after the completion of this research, your research data will be kept  
7 for a specified period of time in accordance with national regulations and will be kept strictly  
8 confidential. Participating in future research will not increase your additional risk and financial  
9 burden. All future research samples and materials will be properly stored in FuwaiHospital,  
10 Chinese Academy of Medical Sciences and will be kept strictly confidential. You may voluntarily  
11 choose to participate in future research and to withdraw from research at any time in writing by  
12 contacting the researcher.  
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### 21 **Who should I contact with questions or difficulties?**

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23 Please contact the researchers at 010-88398027 . If you have any questions about your rights,  
24 please contact the Ethics Committee of Fuwai Hospital, Tel: 010-88396281.  
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27 Thank you for taking time to read this informed consent form. If you agree to participate in  
28 this clinical trial after due consideration, I hope you can complete this clinical trial in accordance  
29 with the requirements of the researchers. Before participating in this trial, please complete and sign  
30 the last page (signature page) of this document together with your investigator in duplicate, with  
31 one signed document each for you and the hospital.  
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**SIGN PAGE**

I have carefully read, understood and agreed to all the terms of this informed consent form.

I have been informed of the purpose, content, procedures of this research/clinical trial, possible adverse effects of the research/trial, research compensation, and my rights and interests; I have enough time and opportunity to ask questions, and have received satisfactory answers.

I promise that the information I provide is true; if false information is provided, I promise to be responsible for the consequences.

I confirm that the contact information left in the signature office is my valid contact information. If I change the contact information, I should inform your hospital in time. Otherwise, I am willing to bear the corresponding consequences of not being able to contact and not being notified.

I know that I can withdraw from this trial at any time without affecting my normal clinical work.

I will get the original copy of this informed consent form, signed by me and the researcher.

**I agree to participate in this study.**

**I agree to participate in the future study.**  Agree  Disagree

SUBJECT'S NAME	sign:
	date:
RESEARCHER	sign:
	date:

# BMJ Open

**Effect of a standardized heart team protocol versus a guideline-based protocol on revascularization decision stability in stable complex coronary artery disease: rationale and design of a randomized trial of cardiology specialists using historic cases**

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-064761.R2
Article Type:	Protocol
Date Submitted by the Author:	02-Nov-2022
Complete List of Authors:	Ma, Hanping; Chinese Academy of Medical Sciences & Peking Union Medical College Fuwai Hospital Lin, Shen; Chinese Academy of Medical Sciences & Peking Union Medical College Fuwai Hospital, Department of Cardiovascular Surgery Li, Xi; Chinese Academy of Medical Sciences & Peking Union Medical College Fuwai Hospital, National Clinical Research Center for Cardiovascular Diseases, NHC Key Laboratory of Clinical Research for Cardiovascular Medications, State Key Laboratory of Cardiovascular Disease, National Center for Cardiovascular Diseases Yang, Wang; Chinese Academy of Medical Sciences & Peking Union Medical College Fuwai Hospital Xu, Bo; Chinese Academy of Medical Sciences & Peking Union Medical College Fuwai Hospital, Catheterization Laboratories Zheng, Zhe; Chinese Academy of Medical Sciences & Peking Union Medical College Fuwai Hospital
<b>Primary Subject Heading</b>:	Cardiovascular medicine
Secondary Subject Heading:	Evidence based practice
Keywords:	Coronary heart disease < CARDIOLOGY, Coronary intervention < CARDIOLOGY, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Manuscripts

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4 1 **Effect of a standardized heart team protocol versus a guideline-based protocol on**  
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6 2 **revascularization decision stability in stable complex coronary artery disease: rationale and**  
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9 3 **design of a randomized trial of cardiology specialists using historic cases**  
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14 5 Hanping Ma<sup>1\*</sup>, PhD; Shen Lin<sup>1,2\*</sup>, MD, PhD; Xi Li<sup>1,3</sup>, PhD; Yang Wang<sup>4</sup>, PhD; Bo Xu<sup>5</sup>, MBBS; Zhe  
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17 6 Zheng<sup>1,2,6</sup>, MD, PhD

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19 7 \*Drs. Ma and Lin contributed equally to this work.  
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9 3 Cardiovascular Diseases, Zhengzhou, China  
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## 1 2 3 4 1 **ABSTRACT**

### 5 6 7 2 **Introduction**

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11 3 A multidisciplinary heart team approach has been recommended by revascularization guidelines, but  
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13 4 how to organize and implement the heart team in a standardized way has not been validated. Inter-  
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16 5 and intra-team decision instability existed in the guideline-based heart team protocol, and our  
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19 6 standardized heart team protocol based on a mixed-method study may improve decision stability.  
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21 7 The objective of this study is to evaluate the effect of the standardized heart team protocol versus the  
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24 8 guideline-based protocol on decision-making stability in stable complex coronary artery disease  
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27 9 (CAD).

### 28 29 30 10 **Methods and analysis**

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34 11 Eighty-four eligible interventional cardiologists, cardiac surgeons, or non-interventional cardiologists  
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36 12 from 26 hospitals in China have been enrolled. They will be randomized to a standardized heart team  
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39 13 protocol group or a guideline-based protocol group to make revascularization decisions for 480  
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42 14 historic cases (from a prospective registry) with stable complex CAD. In the standardized group, we  
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44 15 will establish 12 heart teams based on an evidence-based protocol, including specialist selection,  
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47 16 specialist training, team composition, team training, and a standardized meeting process. In the  
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49 17 guideline-based group, we will organize 12 heart teams according to the guideline principles,  
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52 18 including team composition and standardized meeting process. The primary outcome is the overall  
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55 19 percent agreement (OPA) in revascularization decisions between heart teams within a group. To  
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57 20 demonstrate the clinical implication of decision-making stability, we will further explore the  
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60 21 association between decision stability and 1-year clinical outcomes.

## 1 **Ethics and dissemination**

2 The study was approved by the Institutional Review Board (IRB) of Fuwai hospital (No. 2019-1303).  
3 All participants have provided informed consent and all patients included as historic cases provided  
4 written informed consent at the time of entry to the prospective registry. The results of this trial will  
5 be disseminated through manuscript publication and national/international conferences, and reported  
6 in the trial registry entry.

## 7 **Trial registration number**

8 ClinicalTrials.gov, NCT05039567.  
9

## 10 **Strengths and limitations of this study**

- 11 ⇒ The study is a randomized controlled trial testing an evidence-based standardized heart team  
12 protocol covering the whole heart team organization process with up-to-date information  
13 provision against an approach following guideline basic recommendations.
- 14 ⇒ Randomization is used in three aspects, stratified randomization in group allocation,  
15 randomization in heart team membership, and randomization in case allocation, which controls  
16 the social factors that may have negative implications for true group decision-making and  
17 ensures relatively heart team exposure to case complexity.
- 18 ⇒ Trial procedures will be carried out remotely, and all heart team meetings will be held via video  
19 conference using an online system, enabling full involvement and eliminating the risk of  
20 spreading COVID-19.

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- 1 ⇒ The cases discussed are retrospectively instead of prospectively selected, and the study does not  
investigate the impact of the standardized heart team protocol on true treatment decisions and  
clinical outcomes in routine clinical care, which is the next step to be tested.
- 4 ⇒ The intervention in the standardized protocol group is an integrated approach, and the potential  
differential outcomes associated with its use cannot be attributed to a single point of the process.

## 6 **KEYWORDS**

7 Heart team; standardized protocol; decision-making stability

For peer review only

## 1 INTRODUCTION

2 The heart team approach has received a Class 1C/1B recommendation in European and American  
3 guidelines on myocardial revascularization in patients with complex coronary artery disease (CAD)  
4 to optimize the treatment strategies and may lead to better outcomes.<sup>1-5</sup> Clinical guidelines  
5 recommend that a heart team, consisting of clinical/non-interventional cardiologists, interventional  
6 cardiologists, and cardiac surgeons, should take sufficient time to assess all available information on  
7 complex cases. However, there are relatively limited data on the heart team implementation in detail,  
8 such as the ideal composition, meeting frequency, the timing of decision-making, and outcomes,  
9 potentially leading to suboptimal decision-making quality.

10 Prior efforts have noted insufficient inter-specialist consistency, intra-team reproducibility, and  
11 inter-team agreement in heart team decision-making. Denvir et al. found poor agreement existed  
12 between cardiac clinical specialists (kappa 0.26)<sup>6</sup>. Several studies reported that on re-discussion of  
13 the same patient data 9-12 months later, nearly 20% to 24% of decisions differed from the original  
14 heart team recommendations.<sup>7 8</sup> In our previous work, the agreement between heart teams for  
15 revascularization decision-making was just moderate (kappa 0.58)<sup>9</sup>.

16 Clinical guidelines and previous practice experience from different centers have summarized  
17 several critical principles in heart team implementation.<sup>10-12</sup> Guidelines recommend the composition  
18 should be at least a cardiac surgeon, an interventional cardiologist, and a non-interventional  
19 cardiologist.<sup>1 5</sup> Sanchez et al. summed up the experience of the heart team implementation from their  
20 single center, including team composition, data collection, and meeting process. The British  
21 Cardiovascular Society (BCS), Society for Cardiothoracic Surgery in Great Britain and Ireland



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4 1 (SCTS), and British Cardiovascular Intervention Society (BCIS) set out the principles for the  
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6 2 functioning of the heart team across the United Kingdom, including composition, frequency, and the  
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9 3 type of cases discussed.<sup>12</sup> Although these works provided essential experiences for heart team  
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11 4 implementation, the protocols were not evidence-based, and data regarding how these protocols  
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14 5 impact decision-making stability were scarce.<sup>12</sup>  
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17 6 To determine the potential factors influencing heart team decision-making comprehensively and  
18  
19 7 explore an evidence-based heart team protocol, we conducted a sequential explanatory mixed method  
20  
21 8 study and summarized three themes (specialist quality, team composition, and meeting process) and  
22  
23 9 ten subthemes of potential factors. In addition, nine recommendations for heart team implementation  
24  
25 10 were derived based on qualitative and quantitative data, and a standardized heart team protocol was  
26  
27 11 developed based on the previous experience, recommendations, and guidelines, covering the whole  
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29 12 procedure of heart team implementation.  
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35 13 However, the practical effect of the standardized protocol versus the guideline-based protocol on  
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37 14 decision-making stability and clinical outcomes remains unknown, and a randomized trial for  
38  
39 15 validation is warranted. Therefore, we designed this pivotal randomized trial.  
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## 45 16 **METHODS AND ANALYSIS**

### 46 47 48 17 **Study design**

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52 18 The current study is a randomized, controlled, two-arm trial involving 84 cardiac specialists from 26  
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54 19 hospitals in China. Eligible specialists have been randomized to a standardized implementation  
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56 20 protocol group or a guideline-based group to establish 24 heart teams and make revascularization  
57  
58 21 decisions for 480 stable complex CAD cases retrospectively enrolled. We will evaluate the decision-  
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4 1 making stability (**Figure 1**). SPIRIT<sup>13</sup>, CONSORT<sup>14</sup>, and TIDieR<sup>15</sup> checklists are in **Supplemental**  
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6  
7 2 **File 1**. All procedures have been approved by the Institutional Review Board (IRB) of Fuwai  
8  
9 3 hospital (2 August 2021). The study start date is 4 January 2022, and the anticipated end date is 31  
10  
11  
12 4 January 2023.

### 5 **Objective and hypothesis**

6 The primary objective of this study is to evaluate the effect of the standardized heart team protocol  
7 versus the guideline-based protocol on the stability of decision-making in stable complex CAD. The  
8 primary hypothesis is that heart teams organized on the standardized protocol will result in better  
9 decision-making consistency compared with those based on guideline principles. The secondary  
10 objectives of this study are to (1) evaluate the association between decision-making stability and 1-  
11 year composite of death, myocardial infarction (MI), stroke, repeated revascularization, and re-  
12 hospitalization due to ischemic symptoms; (2) assess the appropriateness of heart team decision-  
13 making.

### 14 **Participants and recruitment**

15 To have access to enough experienced specialists, we will enroll eligible specialists from hospitals  
16 with (1) annual volume of percutaneous coronary intervention (PCI)  $\geq 500$ ; (2) annual volume of  
17 coronary artery bypass grafting (CABG)  $\geq 200$ <sup>1</sup>; (3) have at least two interventional cardiologists,  
18 two cardiac surgeons and one non-interventional cardiologist meeting the inclusion criteria and  
19 agreeing to participate in the study. The inclusion criteria for the heart team specialists differ from  
20 specialties and require specified operator volumes and experience (**Table 1**). The interventional  
21 cardiologist is required to have an annual PCI volume  $\geq 200$ <sup>16</sup>, an annual left main (LM)-PCI volume

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4 1  $\geq 25^1$ , and is capable of chronic total occlusion (CTO)-PCI. The cardiac surgeon must have a total  
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6 2 CABG volume  $\geq 200^{17}$  and be proficient in both on-pump and off-pump CABG. We have contacted  
7  
8  
9 3 all the potential participants via e-mails or telephones to get their information confirmed and  
10  
11  
12 4 obtained their content from 1 December 2021 to 10 January 2022. All participating specialists have  
13  
14 5 provided written informed consent for enrollment (**Supplemental File 2**).

17 6 **Table 1. Inclusion criteria for heart team specialists**

Disciplines	Inclusion Criteria
Interventional Cardiologist	1) Annual PCI volume $\geq 200^{16}$
	2) Annual LM PCI volume $\geq 25^1$
	3) CTO PCI total volume $\geq 10$
	4) Clinical researcher experience in coronary revascularization
	5) Proficient in clinical guidelines
Cardiac Surgeon	1) CABG total volume $\geq 200^{17}$
	2) Proficient in both on-pump and off-pump CABG
	3) Clinical researcher experience in coronary revascularization
	4) Proficient in clinical guidelines
Non-interventional Cardiologist	1) Proficient in clinical guidelines

43 7 CABG indicates coronary artery bypass grafting; CTO, chronic total occlusion; LM, left main; PCI,  
44  
45  
46 8 percutaneous coronary intervention.

49 9 **Randomization**

52  
53 10 Randomization is stratified by specialties and conducted by a data manager using random number  
54  
55 11 generation in SAS. We have randomized 36 cardiac surgeons and 36 interventional cardiologists in a  
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57  
58 12 2:1 ratio to the standardized protocol group (24 surgeons and 24 interventional cardiologists) or the  
59  
60

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3  
4 1 guideline-based group (12 surgeons and 12 interventional cardiologists). Twelve non-interventional  
5  
6 2 cardiologists have been randomly selected and allocated to the guideline-based group. After the  
7  
8  
9 3 randomization, each group of specialists will be randomly assigned to 12 heart teams and perform  
10  
11 4 heart team meetings according to corresponding protocols. Research staff will be informed of the  
12  
13  
14 5 randomization and organize the allocated specialists to establish heart teams. Participating specialists  
15  
16  
17 6 are unaware of the implementation conditions (**Supplementary Figure 1**).

## 7 **Case selection and preparation**

### 8 *Selection of cases to be discussed*

9 Adult cases with stable CAD according to the National Cardiovascular Data Registry (NCDR)  
10 CathPCI criteria<sup>18</sup> (stable angina, no or silent myocardial ischemia) and angiographically confirmed  
11 3-vessel disease or left main (3VD/LM) disease are eligible for inclusion in the study. We have  
12 randomly selected eligible cases from a prospective registry of consecutive patients who underwent  
13 coronary angiography between August 2016 and August 2017 (**Supplementary Figure 2**).<sup>19</sup> All  
14 cases provided written informed consent at the time of registration and agreed to use their data for  
15 subsequent approved cardiovascular-related medical research. Definitions and inclusion/exclusion  
16 criteria of cases can be seen in **Supplemental methods**.

### 17 *Structured patient information*

18 Patient data will be presented in a structured information form on an electronic meeting support  
19 system by non-clinical coordinators (**Supplementary Table 1**). The structured information includes  
20 (a) demographics; (b) medical histories and clinical risk factors; (c) medical treatment histories and

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4 1 CVD symptoms of the index hospitalization; (d) laboratory results; (e) noninvasive testing results  
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6  
7 2 (e.g., electrocardiogram, echocardiogram, stress testing results); (f) diagnostic angiogram images and  
8  
9 3 quantitative flow ratio (QFR)<sup>20</sup>; (g) clinical risk scores (i.e., SYNTAX (Synergy Between  
10  
11  
12 4 Percutaneous Coronary Intervention With Taxus and Cardiac Surgery) score<sup>21</sup>, SYNTAX II score<sup>22</sup>,  
13  
14 5 SYNTAX II 2020 score<sup>23</sup>, Society of Thoracic Surgeons (STS) score<sup>24 25</sup>, the European System for  
15  
16  
17 6 Cardiac Operative Risk Evaluation (EuroSCORE) II<sup>26</sup>, and sinoSCORE II<sup>27</sup>). All the clinical  
18  
19  
20 7 information has been obtained from medical records according to the NCDR CathPCI data  
21  
22 8 definitions<sup>18</sup>. An independent angiographic core laboratory takes responsibility for all angiogram  
23  
24  
25 9 image screening and risk score evaluation by using a computer-based automatic calculator.  
26  
27

### 28 10 ***Case assignment***

29  
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31  
32 11 Four hundred and eighty cases will be randomized into 6 sets of 80 cases each, using a stratified  
33  
34  
35 12 randomization procedure to ensure relatively equal heart team exposure to case complexity and a  
36  
37 13 similar ratio of actual treatment strategies (CABG, PCI, or medication therapy).  
38  
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### 40 14 **Intervention**

#### 41 15 ***Standardized heart team protocol***

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47 16 Eligible specialists randomized to this group will establish 12 heart teams and conduct heart team  
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49  
50 17 meetings based on the standardized heart team protocol<sup>9</sup> (**Figure 2**).

- 51  
52  
53 18 **i. Specialist selection.** All the cardiac surgeons are required personality tests by Ten-Item  
54  
55 19 Personality Inventory in China (TIPI-C)<sup>28</sup> and 24 surgeons with moderate scores will be  
56  
57  
58 20 randomly selected (**Supplementary Table 2**). Twenty-four interventional cardiologists will be  
59  
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4 1 randomly selected without personality selection.

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6 2 **ii. Specialist training.** All heart team members must undergo unified training to achieve a  
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8  
9 3 consensus on the potential factors influencing revascularization decisions. The training will be  
10  
11  
12 4 conducted and recorded by well-prepared coordinators. Consensus view should include clinical  
13  
14 5 considerations on the essential characteristics (e.g., age, left ventricular ejection fraction  
15  
16  
17 6 (LVEF), and body mass index (BMI)) and their weightage, interpretation of evidence (e.g.,  
18  
19  
20 7 SYNTAX trial, Evaluation of XIENCE versus Coronary Artery Bypass Surgery for  
21  
22 8 Effectiveness of Left Main Revascularization (EXCEL) trial and the International Study of  
23  
24  
25 9 Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) results).  
26  
27 10 Additionally, the latest technical advancements in PCI and CABG will be discussed, especially  
28  
29  
30 11 for PCI, to narrow cognitive gaps among specialists of different expertise. The consensus view  
31  
32  
33 12 document will be recorded and put onto the electronic meeting support system for reference at  
34  
35 13 any time. To maintain fidelity to the consensus view, we will present each bullet point of the  
36  
37  
38 14 consensus view as a footnote under the corresponding variable.

39  
40 15 **iii. Team composition.** All specialists selected will be randomly assigned to 12 heart teams  
41  
42  
43 16 consisting of 2 cardiac surgeons and 2 interventional cardiologists. Non-interventional  
44  
45  
46 17 cardiologist or other disciplinary specialist is not required in the routine heart team unless  
47  
48  
49 18 necessary. Moreover, the technical level and administration position will be balanced in each  
50  
51 19 team.

52  
53 20 **iv. Team training.** Before the formal heart team meeting, a pilot discussion (25-50 retrospective  
54  
55  
56 21 cases) will be performed following the standard meeting procedure to reinforce the practice of  
57  
58  
59 22 the former consensus view for a more solid team consensus.  
60

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4 1 **v. Standardized meeting process.** Heart team meetings will be conducted standardly in both  
5  
6 2 groups according to the procedure widely used in the previous studies.<sup>10-12</sup> Each heart team  
7  
8 3 independently evaluates a set of cases (80 cases) through the heart team assistance system using  
9  
10 4 structured online case presentations, with the members blinded to the other heart teams and the  
11  
12 5 decisions of other heart teams. All specialists are required to make decisions independently  
13  
14 6 among five treatment categories (PCI, CABG, PCI/CABG equipoise, medical therapy, or further  
15  
16 7 testing) before (round I) and after (round II) the heart team discussion. The heart team member  
17  
18 8 only has access to the responses of the other heart team members after all members have  
19  
20 9 submitted their independent decisions. The final treatment strategy is determined by a majority  
21  
22 10 decision<sup>29</sup> (**Supplementary Figure 3**).

### 31 ***Guideline-based protocol***

32  
33  
34 12 We will randomly assign eligible specialists randomized to this group to 12 heart teams based on the  
35  
36 13 principles of guidelines (**Figure 2**). Each heart team consists of 1 interventional cardiologist, 1  
37  
38 14 cardiac surgeon, and 1 non-interventional cardiologist. This group does not require pre-meeting  
39  
40 15 training on consensus view and pilot discussion. Formal meeting procedures follow the standardized  
41  
42 16 meeting process as the other group.

43  
44  
45  
46  
47 17 All heart team meetings will be held through video conferencing, and a quiet environment will  
48  
49 18 be required. For each heart team, the frequency of meetings is one or two times per week and lasts  
50  
51 19 1.5-2h at a time.

### 56 20 **Outcomes**

57  
58  
59 21 The primary outcome is the overall percent agreement (OPA), defined as the proportion of patients

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4 1 who received coincident decision recommendations from paired heart teams. The secondary  
5  
6 2 outcomes include:

- 7  
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9 3 (1) 1-year major adverse cardiovascular and cerebrovascular events (MACCEs): a composite of all-  
10  
11 4 cause death, MI, stroke, repeated revascularization, and re-hospitalization due to ischemic  
12  
13  
14 5 symptoms;
- 15  
16  
17 6 (2) Kappa value of heart team decision-making: Fleiss's (more than 2 raters) and Cohen's (2 raters)  
18  
19 7 kappa coefficients to evaluate inter-team, intra-team, inter-specialist, intra-specialist, and inter-  
20  
21  
22 8 round agreement for treatment decisions. To evaluate the reproducibility, all assigned cases will  
23  
24  
25 9 be re-discussed with the same clinical data but not in the same order 1 month after the completion  
26  
27 10 of the initial discussion, with the heart team blinded to the outcome of the initial meeting.
- 28  
29  
30 11 (3) Inappropriate decision rate: the final heart team recommendations will be adjudicated for  
31  
32  
33 12 appropriateness using the American College of Cardiology (ACC) /American Association for  
34  
35 13 Thoracic Surgery (AATS) /American Heart Association (AHA) 2017 Appropriate Use Criteria  
36  
37  
38 14 (AUC) and the Chinese AUC for coronary revascularization for each case.<sup>30 31</sup>Two investigators  
39  
40 15 who do not participate in data collection will take responsibility for reviewing the team decisions  
41  
42  
43 16 and adjudicating the decision appropriateness independently. Any disputes will be settled via  
44  
45  
46 17 review by a third investigator, with a decision by consensus.

### 47 48 49 18 **Data management and monitoring**

50  
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53 19 Our IRB-approved protocol specifies plans for data entry, coding, security, and data storage on a  
54  
55 20 secure server. For retrospective data, all data will be double-checked or assessed by two independent  
56  
57  
58 21 coordinators. For prospective data on heart team meetings, the online meeting supporting system  
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4 1 included several mechanisms to protect data integrity and promote data quality (e.g., warning of  
5  
6 2 missing values and preventing duplicate team participation). The data manager will maintain detailed  
7  
8  
9 3 data management procedures. Coordinators will report to and discuss with the principal investigator  
10  
11 4 about the study progress, including participant recruitment, data collection and analysis, and heart  
12  
13  
14 5 team meeting conceptions. Any protocol modifications will be discussed with and approved by the  
15  
16  
17 6 IRB. Any significant changes in methods will be reported to the project's program officer and  
18  
19  
20 7 updated on the registration site <https://ClinicalTrials.gov>. This study does not need a data monitoring  
21  
22 8 committee because all the cases discussed are retrospectively selected. Their revascularization  
23  
24  
25 9 strategies would not be influenced by heart team recommendations and will be no risk for cases. As  
26  
27  
28 10 for participating specialists, heart team discussion will not interfere with their routine clinical work.  
29  
30 11 The Principal Investigator and approved study team members will have access to the final trial  
31  
32  
33 12 datasets.

### 36 13 **Statistical analysis**

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39 14 The pairwise comparison between the heart team decisions in each case provides data on the  
40  
41  
42 15 agreement (**Supplementary Table 3**). The inter-team, intra-team, inter-specialist, intra-specialist,  
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44  
45 16 and inter-round agreements will be assessed using OPA and Cohen's  $\kappa$  coefficient, whenever  
46  
47  
48 17 applicable. Mean decision time will also be calculated. Cox proportional hazards models will be used  
49  
50 18 to analyze whether the treatment decision adhering to the heart team recommendations is associated  
51  
52  
53 19 with better outcomes. Categorical variables will be expressed as frequency and percentage.  
54  
55 20 Continuous variables will be expressed as mean  $\pm$  standard deviation (SD), or median and  
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57  
58 21 interquartile range. Categorical variables will be analyzed with the likelihood ratio  $\chi^2$  test or Fisher  
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4 1 exact test if more than 25% of the cells have an expected frequency smaller than 5. Continuous  
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6 2 variables will be computed with the 2-sample t-test when data follow a normal distribution and will  
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8  
9 3 be compared with the Wilcoxon rank sum test for non-normal distribution. 95% confidence intervals  
10  
11  
12 4 will be computed for all measurements. All the analyses will be performed at a significance level of  
13  
14 5 2-sided 0.05. All tests will be performed using SAS software, version 9.4 (SAS Institute, Cary, NC).  
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16

## 17 18 6 **Sample size**

### 19 20 21 7 *Number of assessments necessary to evaluate decision-making agreement*

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23  
24 8 The primary endpoint of this study is to compare the OPA between the standardized protocol group  
25  
26 9 and the guideline-based group. In our previous study, heart teams were established based on  
27  
28  
29 10 guidelines, and it was estimated that the OPA was 66.3% (unpublished data), serving as the reference  
30  
31  
32 11 rate of the controlled group in this study. We assumed that inter-team agreement is similar to or no  
33  
34 12 better than intra-team reproducibility rate. According to relevant literature,<sup>7 8</sup> it is estimated that the  
35  
36  
37 13 OPA of the standardized protocol group is 76% (the minimum estimate of previous literature). Under  
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39  
40 14 this circumstance, the standardized protocol group has a minor effect on improving decision  
41  
42 15 consistency compared with the guideline-based group. Using a 5% level of 2-side significance and a  
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44  
45 16 confidence level of 90%, it was estimated that a total number of 454 pairwise comparisons for each  
46  
47  
48 17 group would be necessary to meet the study acceptance criterion. For the convenience of case  
49  
50 18 assignment, we adjusted the sample size to 480 cases.

### 51 52 19 *Number of heart teams needed*

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54  
55 20 Considering the feasibility of implementation and a good representation of both samples and heart  
56  
57  
58 21 teams, it was decided that 24 heart teams are needed with 12 in each arm. Teams in each group will  
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4 1 be divided into 6 pairs randomly, and each pair of heart teams will evaluate the same randomly  
5  
6 2 assigned 80 cases independently to provide inter-team agreement data, generating 480 pairwise  
7  
8  
9 3 comparisons in each group.

#### 4 ***Number of heart team specialists***

5 The heart team in the standardized group consists of 2 interventional cardiologists and 2 cardiac  
6  
7 surgeons, and that in the guideline-based group consists of 1 interventional cardiologist, 1 cardiac  
8  
9 surgeon, and 1 non-interventional cardiologist. With 12 heart teams in each group, a minimum of 36  
10  
11 cardiac surgeons, 36 interventional cardiologists, and 12 non-interventional cardiologists are needed  
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25 9 in the final study in total.

#### 10 **Subgroup analysis**

11 The primary and secondary outcomes will be analyzed in pre-specified subgroups, including  
12  
13 specialties and professional status. The analysis will also be conducted according to different cases  
14  
15 stratified by age, left ventricular ejection fraction (LVEF), body mass index (BMI), degree of the  
16  
17 stenosis, calcified lesion, stenosis severity, tandem and bending/tortuous lesion, LM, SYNTAX  
18  
19 stratification, SYNTAX II recommendations, and SinoSCORE stratification. The comparisons in  
20  
21 these analyses may be not powered for hypothesis testing but are descriptive in nature.

#### 17 **Current status**

18 Thirty-six cardiac surgeons, 36 interventional cardiologists, and 12 non-interventional cardiologists  
19  
20 from 26 eligible hospitals agreed to participate in this study and have provided informed consent.  
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22 Four hundred and eighty cases with stable complex CAD have been randomly selected for  
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60 21 discussion. Specialist and patient baseline data are shown in **Table 2** and **Table 3**. The study start

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4 1 date is 4 January 2022, and the anticipated end date is 31 January 2023.  
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8 2 **Patient and public involvement**  
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11 3 None.  
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For peer review only

4 **Table 2. Specialist baseline characteristics**

Characteristics	Overall (n=84)	Cardiac Surgeon (n=36)	Interventional Cardiologist (n=36)	Non-interventional Cardiologist (n=12)
Male	71 (84.5)	35 (97.2)	34 (94.4)	2 (16.7)
Status				
Chief specialist	46 (54.8)	21 (58.3)	19 (52.8)	6 (50.0)
Associate specialist	34 (40.5)	15 (41.7)	13 (36.1)	6 (50.0)
Attending specialist	4 (4.8)	0 (0.0)	4 (11.1)	0 (0.0)
Personality (TIPI)*	5.20 (4.80-5.70)	5.20 (4.90-5.50)	5.20 (4.60-5.80)	5.45 (4.80-5.60)
Extraversion	4.50 (4.00-5.00)	4.50 (4.00-5.50)	4.50 (4.00-5.00)	4.50 (4.00-5.00)
Agreeableness	5.50 (4.50-6.00)	5.00 (4.50-5.50)	5.75 (4.50-6.50)	5.75 (5.00-6.00)
Conscientiousness	5.50 (5.00-6.50)	6.00 (5.00-6.50)	5.50 (5.00-6.50)	5.75 (5.00-6.00)
Emotional Stability	5.00 (5.00-6.00)	5.00 (5.00-5.50)	5.00 (4.50-6.00)	6.00 (5.00-6.00)
Openness to Experiences	5.00 (4.50-5.50)	5.00 (4.50-5.50)	5.00 (5.00-5.50)	4.75 (4.50-5.50)

5 TIPI indicates the ten-item personality inventory.<sup>28</sup>Data presented as n (%) and median (interquartile range).\*Personality was  
6 evaluated by the TIPI scale in Chinese.

7

8 **Table 3. Demographic and clinical characteristics of retrospective patients**

Characteristics	Patients for discussion (n=480)	Characteristics	Patients for discussion (n=480)
<b>Demographics</b>		Silent ischemia (after medical therapy)	90 (18.8)
Age, y	62.0 (55.0-67.5)	Non-ischemia symptom	20 (4.2)
Male (%)	363 (75.6)	Stable angina	370 (77.1)
<b>Risk Factors</b>		CCS I-II	325 (87.8)
Hypertension	334 (69.6)	CCS III-IV	45 (12.2)
Hyperlipidemia	429 (89.4)	Number of anti-anginal medications	
Diabetes	185 (38.5)	0	118 (24.6)
Cerebrovascular disease	102 (21.3)	1	154 (32.1)
COPD	7 (1.5)	2	149 (31.0)
Chronic renal disease	14 (2.9)	3	59 (12.3)
Smoker	226 (47.1)	Extent of coronary disease	
Body mass index, kg/m <sup>2</sup>	25.6 (23.7-27.5)	3-vessel disease	451 (94.0)
Ccr <60 mL/min/1.73m <sup>2</sup>	7 (1.5)	Left main disease	129 (26.9)
<b>Cardiovascular Characteristics</b>		<b>Risk Classification</b>	
Previous MI	49 (10.2)	SYNTAX score	22.5 (16.5-29.5)
Previous heart failure	10 (2.1)	SYNTAX score tertiles	
Peripheral vascular disease	46 (9.6)	Low risk (0-22)	237 (49.4)
Ejection fraction, %	63.0 (59.0-65.0)	Intermediate risk (23-32)	157 (32.7)
Ejection fraction ≤40%	23 (4.8)	High risk (≥33)	86 (17.9)
CAD symptoms		SYNTAX score II recommendation	

<b>Characteristics</b>	<b>Patients for discussion (n=480)</b>	<b>Characteristics</b>	<b>Patients for discussion (n=480)</b>
PCI	11 (2.3)	Reoperation (%)	1.72 (1.46-2.07)
CABG	153 (31.9)	Renal failure (%)	0.43 (0.32-0.61)
Equipoise	316 (65.8)	Stroke (%)	0.96 (0.73-1.36)
SYNTAX score II 2020 10-year mortality (%)		Prolonged ventilation (%)	3.20 (2.62-3.98)
CABG	14.8 (9.1-24.7)	DSWI (%)	0.10 (0.08-0.14)
PCI	19.4 (11.6-32.2)	Prolonged hospitalization (%)	1.79 (1.33-2.53)
EuroSCORE II mortality (%)	0.80 (0.58-1.06)	<b>Treatment Strategy in Real World</b>	
SinoSCORE II mortality (%)	0.82 (0.47-1.18)	PCI	287 (59.8)
STS score (incidence of postoperative events)		CABG	116 (24.2)
Mortality (%)	0.49 (0.36-0.70)	Medical therapy	77 (16.0)
Mortality or major complications (%)	5.30 (4.43-6.56)		

- 10 CABG indicates coronary artery bypass graft; CAD, coronary artery disease; Ccr, creatinine clearance rate; CCS, Canadian  
 11 Cardiovascular Society; COPD, chronic obstructive pulmonary disease; DSWI, deep sternal wound infection; MI, myocardial  
 12 infarction; PCI, percutaneous coronary intervention; SD, standard deviation; STS, Society of Thoracic Surgeons; and SYNTAX,  
 13 Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery.  
 14 Data presented as median (interquartile range, IQR) and n (%).

## 15 **ETHICS AND DISSEMINATION**

### 16 **Ethics**

17 The study was reviewed and approved by the Ethics Review Committees of Fuwai hospital  
18 (2019-1303) on 2 August 2021; subsequent amendments have been approved. All participants  
19 have provided informed consent and all patients included as historic cases provided written  
20 informed consent at the time of entry to the prospective registry.

### 21 **Safety**

22 All the eligible cases were retrospectively selected and underwent coronary angiography  
23 between August 2016 and August 2017. Heart team decisions do not affect patients' actual  
24 treatments. There will be no adverse event or serious adverse event relating to this study.

### 25 **Dissemination**

26 The results of this trial will be reported to the participating specialists, disseminated through  
27 manuscript publication and national/international conferences, and reported in the trial registry  
28 entry.

## 29 **DISCUSSION**

30 The optimization of heart team implementation including team composition, operation,  
31 distribution of responsibilities, and other issues still lacks verification by evidence-based trials.

32 The present study is the first trial focusing on the heart team implementation quality assessment



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4 33 and improvement by evaluating the effect of the standardized heart team protocol compared to  
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6 34 the guideline-based protocol on decision-making stability for stable complex CAD.  
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9 35 Stability is a potential metric of decision-making quality. As the expertise of individual  
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11 36 specialists is specific to their professional training and experience, cardiologists and surgeons  
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13  
14 37 prefer PCI or CABG, respectively.<sup>10</sup> Prior data showed that 18.1% of the overall decision-  
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17 38 making for stable angina patients was classified as inappropriate based on a single disciplinary  
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19 39 decision, especially among patients undergoing PCI<sup>32</sup>. The heart team, a medium of  
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22 40 communication to integrate the input of numerous specialists, can help to minimize fragmented  
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25 41 communication between specialists and eliminate specialist bias in the decision-making process.  
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28 42 It was reported that heart team recommendations differed from those of the original treating  
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30 43 interventional cardiologist in approximately one-third of cases.<sup>33</sup> Sanchez et al convened 301  
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33 44 heart team meetings for complex CAD from 2012 to 2015 and reported the concordance of the  
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35 45 heart team to appropriate use criteria was up to a 99.3% appropriate primary indication for  
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38 46 coronary revascularization.<sup>34</sup> Therefore, qualified heart teams perform more evidence-based and  
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41 47 neutral in revascularization decision-making. The success of the heart team approach is apparent  
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43 48 in a growing number of optimal revascularization decisions made according to professional  
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46 49 guidelines.

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48 50 Notably, a dedicated and structured heart team has a potential benefit for patient survival.  
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51 51 Peyman et al reported patients treated for mitral valve disease based on a dedicated heart team  
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54 52 decision have significantly higher survival than a general heart team, which illustrated the  
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56 53 establishment of a dedicated heart team consisting of experienced specialists with adequate  
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4 54 procedure volume benefits patient survival<sup>35</sup>. In addition, appropriate revascularization is  
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6 55 associated with improved 1-year outcomes in patients with appropriate indications and has no  
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9 56 benefit in those with uncertain or inappropriate indications.<sup>19</sup> Thus, we assume that  
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11 57 revascularization recommendations of dedicated heart teams organized by the standardized heart  
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14 58 team protocol would be more stable and appropriate compared with those of general heart teams  
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17 59 based on guideline principles, which leads to better clinical outcomes.

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19 60 Making the heart team approach well-structured and efficient contributes to a better quality  
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22 61 of cardiovascular care. The current study is essential to answer the following questions: (1) Is it  
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25 62 feasible to establish and organize heart team meetings with the guidance of the standardized  
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28 63 heart team protocol? (2) Will the standardized heart team protocol improve the decision-making  
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31 64 stability in patients with stable complex CAD compared with the fundamental principles of heart  
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34 65 team organizing in guidelines? Moreover, it will enhance educational opportunities for all team  
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37 66 members involved and provide experience in the practice of heart team meetings in prospective  
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40 67 clinical scenarios.

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43 68 Several novel designs underlie the strength of this study. Firstly, we use a randomized  
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46 69 controlled design to demonstrate the structure and effect of an evidence-based standardized heart  
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49 70 team protocol on decision-making stability against the controlled approach based on guideline  
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52 71 principles, which fills the gap with no randomized data currently available in optimal heart team  
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55 72 implementation<sup>12 33</sup>. Secondly, the study applies randomization three times. Eligible specialists  
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58 73 are first randomly selected and assigned to different arms by stratification randomization. Then  
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60 74 we establish heart teams with randomized membership to reduce social factors that may have

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4 75 negative implications on individual decision-making<sup>36</sup>. Cases are also randomized into 6 sets of  
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6 76 80 cases each to ensure relatively equal heart team exposure to case complexity. Thirdly, all  
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9 77 heart team training and meetings are held via video conference using an online decision-making  
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11 78 support system, which makes it possible to involve specialists from multiple hospitals, reduce the  
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14 79 negative influence of a few influential individuals on face-to-face decision-making, and  
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17 80 eliminate the risk of viral spreading in COVID-19.<sup>37</sup> Fourthly, we provide the most up-to-date  
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20 81 risk scores (such as SYNTAX II 2020 score<sup>23</sup>, sinoSCORE II<sup>27</sup>) and QFR<sup>20</sup>, a novel  
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22 82 angiography-derived physiological assessment approach, in structured information for the  
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25 83 specialists to adjudicate the optimal treatment strategy.

26  
27 84 The study has several limitations. First, cases discussed are retrospectively selected rather  
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30 85 than prospectively enrolled. All cases have already been treated from August 2016 to August  
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33 86 2017 in the original hospitalization, thus it is unable to reveal the causal link between heart team  
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36 87 meetings and real-world decision-making and outcomes in routine clinical practice. Prospective  
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39 88 design is needed for the next step. Second, the intervention in the standardized protocol group is  
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42 89 an integrated approach and the potential differential outcomes associated with its use cannot be  
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45 90 attributed to a single point of the process. Additional quantitative and qualitative analysis is  
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48 91 needed to find out which steps work on the decision-making stability. Third, heart team decisions  
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51 92 will be made independently of patient preferences, while in real-world clinical practice, patient  
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54 93 preference is an important factor for the final treatment decision. Patient involvement in shared  
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57 94 decision-making should be considered in future trials.

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4 95 **DECLARATIONS**  
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7

8 96 **Consent for publication**  
9

10 97 Not applicable.  
11  
12

13 98 **Competing interests**  
14

15 99 The authors declare that they have no competing interests.  
16  
17

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19

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28 104 study design and will not have any role in the execution, analysis, interpretation, or presentation  
29  
30  
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32  
33

34 106 **Contributors**  
35

36 107 ZZ contributed to study conception, funding obtaining, administration, and technical material  
37  
38  
39 108 support. HPM, SL, XL, BX, and ZZ contributed to the study design. HPM and SL drafted the  
40  
41 109 manuscript. XL and YW contributed to statistical consultation. HPM, SL, and BX contributed to  
42  
43  
44 110 data collection and interpretation. All authors revised the manuscript for important intellectual  
45  
46  
47 111 content and approved the final version.  
48

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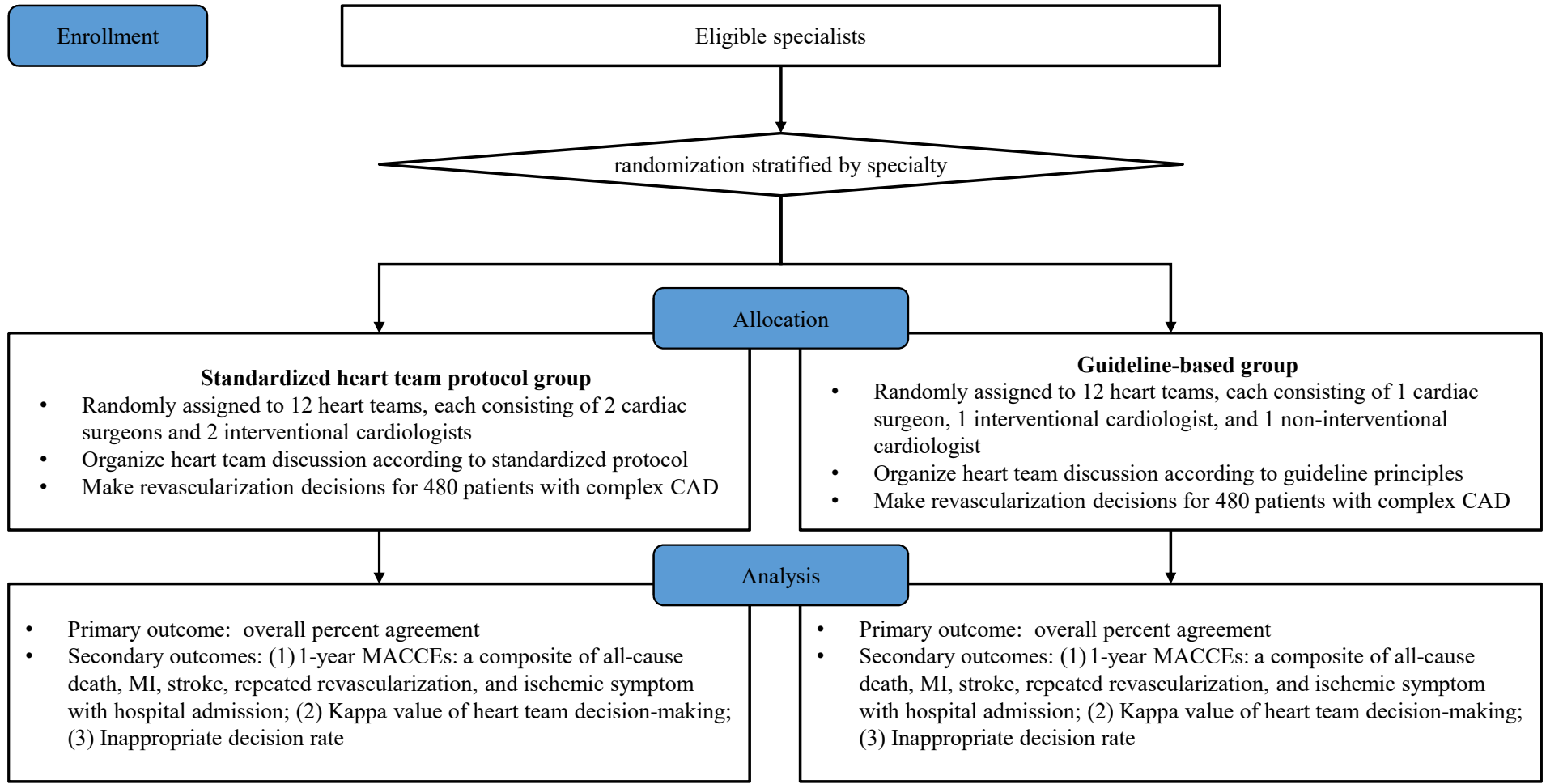
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6 247 **FIGURE TITLES AND LEGENDS**  
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10 248 **Figure 1. Study flowchart**

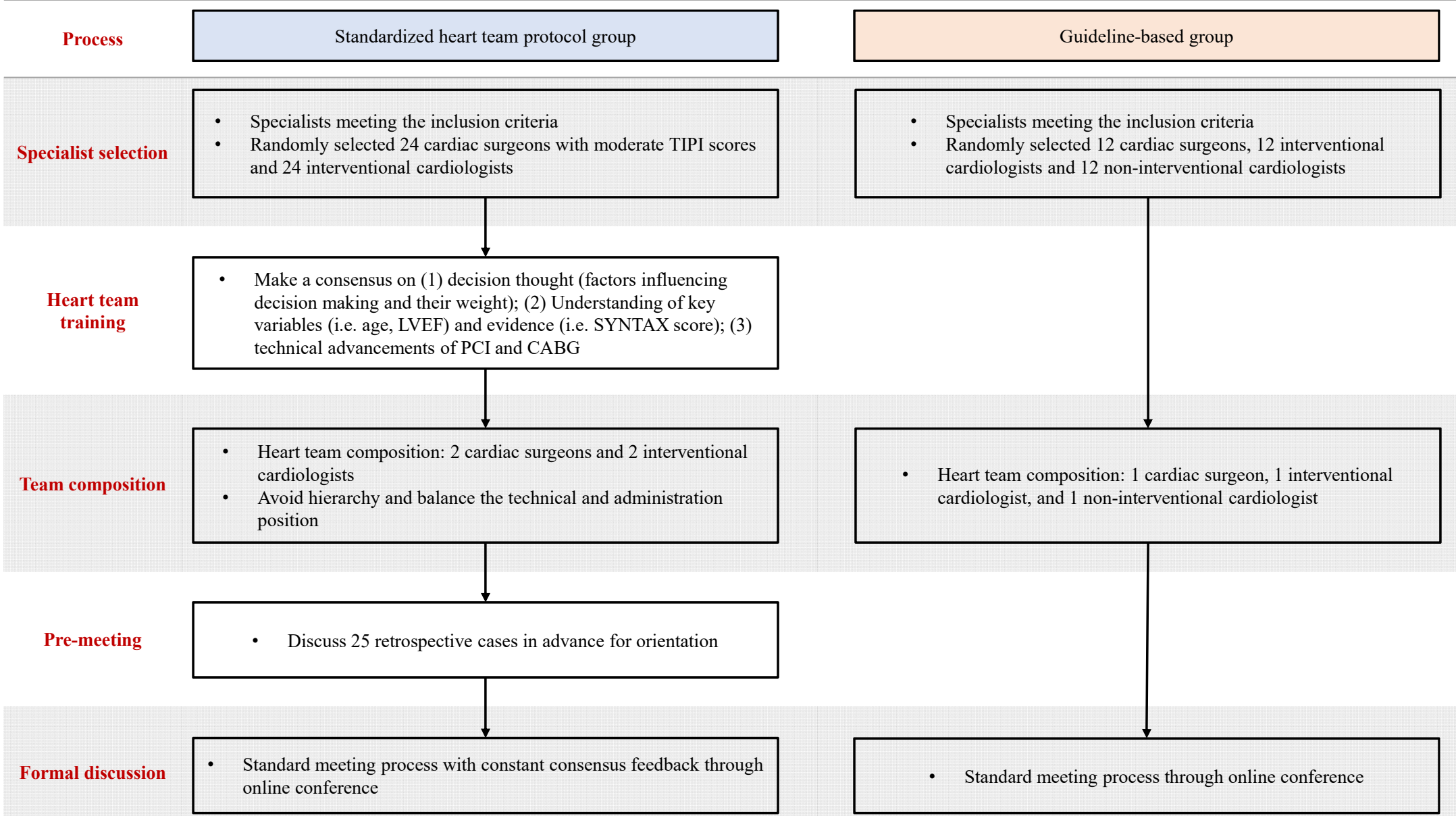
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12 249 Eligible specialists will be randomized to a standardized heart team protocol group or  
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15 250 a guideline-based group and established 12 heart teams in each group to make  
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18 251 revascularization decisions for 480 historic cases (from a prospective registry) with  
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20 252 stable complex CAD. CAD indicates coronary artery disease; MACCE, major adverse  
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23 253 cardiovascular and cerebrovascular event.  
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28 255 **Figure 2. Implementation strategies for the standardized protocol group and**  
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30 256 **guideline-based group**

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33 257 In the standardized protocol group, the heart team will be implemented based on an  
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36 258 evidence-based protocol including specialist selection, specialist training, team  
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39 259 composition, team training, and a standardized meeting process. In the guideline-  
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41 260 based group, the heart team will be implemented according to the key principles  
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44 261 mentioned in clinical guidelines, including team composition and standardized  
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46 262 meeting process. TIPI indicates a ten-item personality inventory; LVEF, left  
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49 263 ventricular ejection fraction; CABG, coronary artery bypass grafting; PCI,  
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51 264 percutaneous coronary intervention; SYNTAX, Synergy Between Percutaneous  
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54 265 Coronary Intervention with Taxus and Cardiac Surgery.  
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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	Addressed on page number
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	4
	2b	All items from the World Health Organization Trial Registration Data Set	see clinicaltrials.gov
Protocol version	3	Date and version identifier	8
Funding	4	Sources and types of financial, material, and other support	27
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1-2, 27
	5b	Name and contact information for the trial sponsor	see clinicaltrials.gov
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	27
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	15-16

1	<b>Introduction</b>			
2				
3	Background and	6a	Description of research question and justification for undertaking the trial, including summary of relevant	6-7
4	rationale		studies (published and unpublished) examining benefits and harms for each intervention	
5				
6		6b	Explanation for choice of comparators	6-7
7				
8	Objectives	7	Specific objectives or hypotheses	8
9				
10	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group),	7-8
11			allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	
12				
13				
14	<b>Methods: Participants, interventions, and outcomes</b>			
15				
16	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will	7-8
17			be collected. Reference to where list of study sites can be obtained	
18				
19	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and	7-8
20			individuals who will perform the interventions (eg, surgeons, psychotherapists)	
21				
22	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be	8-10
23			administered	
24				
25		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose	NA
26			change in response to harms, participant request, or improving/worsening disease)	
27				
28		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence	13
29			(eg, drug tablet return, laboratory tests)	
30				
31		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
32				
33	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood	14-15
34			pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg,	
35			median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen	
36			efficacy and harm outcomes is strongly recommended	
37				
38	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for	see
39			participants. A schematic diagram is highly recommended (see Figure)	clinicaltrials.gov
40				
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1	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	17-18
2				
3				
4	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9
5				
6				
7	<b>Methods: Assignment of interventions (for controlled trials)</b>			
8	Allocation:			
9				
10	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10
11				
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16	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	NA
17				
18				
19				
20	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8-14
21				
22				
23				
24	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10
25				
26				
27		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
28				
29				
30				
31	<b>Methods: Data collection, management, and analysis</b>			
32				
33	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10-11,16-17
34				
35				
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39		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA
40				
41				
42				



1	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15-16
2				
3				
4				
5	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16-17
6				
7				
8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18
9				
10		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	NA
11				
12				
13				
14	<b>Methods: Monitoring</b>			
15				
16	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	15-16
17				
18				
19				
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21				
22		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
23				
24				
25	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
26				
27				
28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	15-16
29				
30				
31				
32	<b>Ethics and dissemination</b>			
33				
34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	23
35				
36				
37	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	23
38				
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40				
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42				

1	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9, 11
2				
3				
4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
5				
6				
7	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15-16
8				
9				
10	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	27
11				
12				
13	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	23
14				
15				
16	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
17				
18				
19				
20	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	23
21				
22				
23				
24		31b	Authorship eligibility guidelines and any intended use of professional writers	27
25				
26		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	27
27				
28				
29	<b>Appendices</b>			
30				
31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplemental file 2
32				
33				
34	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA
35				
36				

\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons [“Attribution-NonCommercial-NoDerivs 3.0 Unported”](https://creativecommons.org/licenses/by-nc-nd/3.0/) license.



## CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3-4
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	6-7
	2b	Specific objectives or hypotheses	8
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7-8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	7-8
	4b	Settings and locations where the data were collected	7-8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	12-14
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	14-15
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	17-18
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
<b>Randomisation:</b>			
Sequence generation	8a	Method used to generate the random allocation sequence	10
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	10
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	10

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	14
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	16-17
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	18
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	10
	13b	For each group, losses and exclusions after randomisation, together with reasons	NA
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8-9
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	20-22
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	NA
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	NA
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
<b>Discussion</b>			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	NA
<b>Other information</b>			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	See ClinicalTrials.gov
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	27

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).



**The TIDieR (Template for Intervention Description and Replication) Checklist\*:**  
Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	<b>BRIEF NAME</b>		
1.	Provide the name or a phrase that describes the intervention.	12-14	
	<b>WHY</b>		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	12-14	Ma H, Lin S, Li X, et al. Optimal Heart Team Protocol to Improve Revascularization Decisions in Patients with Complex Coronary Artery Disease: A Sequential Mixed Method Study. Eur Heart J Qual Care Clin Outcomes 2022; 8(7):739-749. doi: 10.1093/ehjqcco/qcab074
	<b>WHAT</b>		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	11-12	Online table 1
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	12-14	
	<b>WHO PROVIDED</b>		

1	5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	12-14
2			
3			
4		<b>HOW</b>	
5	6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	13-14
6			
7			
8		<b>WHERE</b>	
9	7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	13-14
10			
11			
12			
13			
14		<b>WHEN and HOW MUCH</b>	
15	8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	13-14
16			
17			
18			
19		<b>TAILORING</b>	
20	9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	N/A
21			
22			
23		<b>MODIFICATIONS</b>	
24	10.†	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A
25			
26			
27		<b>HOW WELL</b>	
28	11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	13
29			
30			
31			
32	12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A
33			
34			
35			

\*\* **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

- 1 \* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.
- 2 \* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of
- 3 studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the
- 4 TIDieR checklist should be used in conjunction with the CONSORT statement (see [www.consort-statement.org](http://www.consort-statement.org)) as an extension of **Item 5 of the CONSORT 2010 Statement**.
- 5
- 6 When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013**
- 7 **Statement** (see [www.spirit-statement.org](http://www.spirit-statement.org)). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see [www.equator-](http://www.equator-network.org)
- 8 [network.org](http://www.equator-network.org)).
- 9

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For peer review only

# 复杂冠心病心脏团队决策一致性对比研究（随机对照试验）

## 知情同意书

我们邀请您参加由中国医学科学院阜外医院发起的一项“复杂冠心病心脏团队决策一致性对比研究”，本研究已通过中国医学科学院阜外医院伦理委员会审批（电话 010-8839\*\*\*\*）。请仔细阅读说明，了解您在研究中的权利和义务，明确研究性质和风险。参加研究属完全自愿。当研究人员向您说明和讨论知情同意书时，您可以随时提问并让研究人员向您解释您不明白的地方。若您目前正参加其他临床研究，请告知研究人员。本项研究的项目负责人是郑\*\*（中国医学科学院阜外医院），本项研究的资助方是中国医学科学院阜外医院。

### 为什么进行这项研究？

当前复杂冠心病心脏团队实践流程存在标准不统一及决策一致性欠佳的问题。前期的一项序贯解释性混合方法研究探索出了一套优化流程的标准化心脏团队实践方案，其对改善心脏团队决策一致性的效果有待验证。本研究拟通过随机对照设计，评价标准化心脏团队实践方案改善复杂冠心病心脏团队决策一致性的效果。

### 为什么邀请您参加这项研究？

因为您（作为介入医生）具备年介入手术量至少 200 例、左主干病变介入年手术量至少 25 例，且可独立完成慢性完全性闭塞病变的介入手术的能力；或（作为心脏外科医生）具备总搭桥手术量至少 200 例，且可熟练完成体外循环和非体外循环搭桥手术的能力；或（作为非介入手术医生）具备副主任医师及以上的技术资格。此外，您还需具备相关临床研究经验及循证医学素养。因此，我们邀请您参加本项研究。是否最终入选由研究者根据您的实际情况来判断。

### 多少人将参与这项研究？

本研究计划在内外科合作良好的医院中最终招募 84 位心血管病医生，其中包含介入医生 36 位、心外科医生 36 位及非介入手术医生 12 位。

### 参加本项研究，需要您做什么？

您需要在项目组的引导下，学习使用心脏团队会议系统、接受会议培训，并参与心脏团队会议讨论，为回顾性病例提供最优诊疗决策推荐。同时，需对项目组为您提供的任何形式的包括但不限于研究方案、病例基本临床信息、心电图图片、超声心动图报告、造影图像、未公开发表的临床文件或其他保密信息进行保密，不得通过拍照、录音、录像、截图等形式泄露、告知、公开、发布、出版、传授、转让或其他任何方式使任何第三方知悉项目提供的数据或利用项目组数据分析的成果数据。

### 本项研究会持续多久？



1  
2  
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4 本项研究将持续 12 个月。

5 **参加本研究受试者的风险和不良反应？**

6  
7 本研究仅邀请您参与心脏团队并进行既往病例会议讨论。研究不会干预您正常的临床诊疗工作，研究  
8  
9 过程中无任何风险和不良反应。

10  
11 **参加本研究可能的获益是什么？**

12  
13 您不会因参加本项研究有直接获益，您的参与有助于促进心脏内科与心脏外科医生的学科和技术交流，  
14 为真实世界优化和完善心脏团队实践流程提供宝贵资料和经验。

15  
16 **如果不参加此研究，有没有其他备选治疗方案？**

17  
18 您可以选择不参加本项研究，这对您正常的临床诊疗工作不会产生任何影响。

19  
20 **参加该项研究的费用和补偿**

21  
22 本研究仅邀请您参与心脏团队并进行既往病例会议讨论，不涉及正常诊疗工作，无相关费用和补偿。

23  
24 **发生研究相关伤害的处理？**

25  
26 本研究仅邀请您参与心脏团队并进行既往病例会议讨论，不影响您正常的临床工作，不会发生研究相  
27  
28 关伤害。

29  
30 **我的信息会得到保密吗？**

31  
32 是的，您的信息在研究中将严格保密。本试验中使用您的研究数据时，您的个人信息都是保密的，您  
33 的所有信息资料将得到妥善保存并仅供研究使用。研究数据库中的信息会严格脱敏消除个人身份识别特征，  
34 可能识别您身份的信息将不会透露给研究人员以外任何人，除非获得您的许可。在不违反保密原则和相关  
35 法规的情况下，伦理委员会的检查人员可以查阅受试者的原始医学记录，以核实临床试验的过程和数据。  
36 如果研究结果公开发表，您个人信息不会出现在任何出版物中，我们也不会向任何人、任何机构透露此信  
37  
38 息。

39  
40 **是否一定要参加并完成本项研究？**

41  
42 是否参加本项研究是自愿的，您可以自由决定参加或拒绝参加此项研究。无论您是否同意参与此项研  
43  
44 究，均不会影响您的正常临床诊疗工作。如果您想参加此项研究，您需要认真阅读本知情同意书，确认充  
45  
46 分了解相关问题后签署本知情同意书。您不会因为签署本文件而失去法律赋予您的任何合法权利。您可以  
47  
48 在任何时间拒绝参加或有权在研究期间的任何阶段随时退出研究，而不需要任何理由，也不会受到歧视  
49  
50 或者报复，相应的权益均不受影响。如果您参加过程中想退出研究项目，请通知研究人员，按研究人员要  
51  
52 求完成退出前相关流程，并根据要求以书面形式完成有关退出手续；退出后研究人员将不再继续收集并使  
53  
54 用您的试验数据，但在您退出前已匿名化采集的数据将无法删除或撤回。

55  
56 **是否愿意参加未来研究？**

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4 如果您同意，我们希望保留您在研究期间的资料和数据。您的匿名研究数据将继续用于后续经审批的  
5 心血管相关医学研究。如果您不同意，在本项研究完成之后，您的研究数据将根据国家规定保存至指定年  
6 限，并严格保密。参与未来研究不会增加您额外的风险与经济负担，所有未来研究的样本及资料都将妥善  
7 保存于中国医学科学院阜外医院并严格保密。您可以自愿选择是否参加未来研究，并可以在任何时间联系  
8 研究人员以书面文件形式退出研究。  
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### 13 如果有问题或困难，该与谁联系？

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15 您可以在任何时间提出有关本项试验的任何问题，并得到相应的解答，请联系研究人员，电话：  
16 010-8839\*\*\*\*。如果您对自己的权益有任何疑问，请联系阜外医院伦理委员会，电话：010-8839\*\*\*\*。  
17  
18 感谢您花时间阅读本知情同意书。如果您通过充分考虑之后同意参加本临床试验，希望您能按照研究  
19 人员的要求完成本次临床试验。参加本试验前，请与您的研究人员共同完成并签署此文件最后一页（签署  
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21 页），一式两份，您和医院各保留一份签署的文件。  
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### 签署页

我已经认真阅读、理解并同意本知情同意书全部条款。

我已被告知此项研究/临床试验的试验目的、内容、程序，研究/试验可能有的不良反应，研究补偿，以及我的权益等；我有足够的时间和机会进行提问，并得到了令我满意答复。

我承诺我提供的信息是真实的；如提供了虚假信息，我承诺对其后果负责。

我确认签名处所留联系方式为我本人有效联系方式，如变更联系方式应及时告知你院，否则，我愿意承担无法联系及无法收到通知的相应后果。

我知道我可以随时退出此项试验，并不影响我正常临床工作。

我将得到这份知情同意书的正本，上面包含我和研究者的签名。

**我同意参加本项研究。**

**是否同意参与未来研究**  同意  不同意（请您选择）研究数据用于未来研究，授权研究者及相关医学研究项目的共同研究单位在被批准的心血管相关医学研究中使用并且处理我本人的匿名数据。

受试者姓名

签名：

日期：

研究者

签名：

日期：

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3 **A comparative study on the stability of heart team decision-making in**  
4 **complex coronary artery disease (a randomized controlled trial)**

5  
6  
7 **INFORMED CONSENT**

8  
9 We invite you to participate in a " comparative study on the stability of heart team  
10 decision-making in complex coronary artery disease (a randomized controlled trial)" initiated by  
11 Fuwai Hospital, Chinese Academy of Medical Sciences. This study has been approved by the  
12 Ethics Committee of Fuwai Hospital, Chinese Academy of Medical Sciences (Tel: 010-8839\*\*\*\*).  
13 Please read the instructions carefully to understand your rights and obligations in the research and  
14 to clarify the nature and risks of the research. Participation in research is entirely voluntary. When  
15 the researcher explains and discusses the informed consent form to you, you can always ask  
16 questions and ask the researcher to explain to you what you don't understand. If you are currently  
17 participating in other clinical studies, please inform the investigators. The project leader of this  
18 research is Zheng \*\* (Fuwai Hospital, Chinese Academy of Medical Sciences), and the sponsor of  
19 this research is Fuwai Hospital, Chinese Academy of Medical Sciences.

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22 **Why do this research?**

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The current practice processes of coronary revascularization heart team have problems with  
inconsistent standards and poor consistency of decision-making. A previous sequential explanatory  
mixed methods study explored a standardized heart team implementation protocol to optimize the  
process, and its effect on improving the consistency of heart team decision-making remains to be  
verified. This randomized controlled trial aims to evaluate the effect of a standardized heart team  
implementation protocol on improving decision-making consistency in complex coronary artery  
disease.

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**Why are you invited to participate in this study?**

Because you (as an interventional cardiologist) have the ability to have annual PCI volume  $\geq$   
200, annual left main (LM)-PCI volume  $\geq$  25, and is capable of chronic total occlusion (CTO)-PCI;  
or (as a cardiac surgeon) have total CABG volume  $\geq$  200, and is proficient in both on-pump and  
off-pump CABG; or (as a non-interventional surgeon) have the technical qualifications of associate  
chief physician or above. In addition, you need to have relevant clinical research experience and  
evidence-based medicine literacy. Therefore, we invite you to participate in this study. Whether  
you are finally selected or not will be judged by the researcher based on the actual situation.

### **How many people will be involved in this study?**

This study plans to eventually recruit 84 specialists from hospitals with good cooperation in internal medicine and surgery, including 36 interventional cardiologists, 36 cardiac surgeons, and 12 non-interventional cardiologists.

### **What do you need to do to participate in this study?**

Under the guidance of the project team, you need to learn to use the heart team meeting system, receive team training, and participate in the heart team meeting discussions to provide optimal treatment decisions for retrospective cases. At the same time, it is necessary to keep confidential of any form of information provided to you, including but not limited to research protocols, basic clinical information of cases, electrocardiogram pictures, echocardiography reports, angiography images, unpublished clinical documents or other confidential information. Any means (photographing, audio recording, video recording, screenshots, etc.) to make any third party aware of the data provided by the project or the results of data analysis by the project team is forbidden.

### **How long will this study last?**

The study will last for 12 months.

### **Risks and adverse effects of participants in this study?**

This study only invites you to participate in the heart team and make decisions for retrospective cases. The study will not interfere with your normal clinical practice, and there will be no risks and adverse effects during the process.

### **What are the possible benefits of participating in this study?**

You will not directly benefit from participating in this study, but your participation will help promote the exchange of disciplines and techniques between cardiologists and cardiac surgeons, and provide valuable information and experience for real-world optimization and improvement of heart team practice.

### **If not participating in this study, are there other options?**

You can choose not to participate in this study, which will not have any impact on your normal clinical work.

### **Fees and Compensation for Participation in the Study**

This study only invites you to participate in the heart team and make decisions for retrospective cases, and there is no related cost and compensation.

### **What happens to research-related injuries?**

This study only invites you to participate in the heart team and make decisions for retrospective cases, which will not interfere with your normal clinical work and will not cause research-related injuries.

### **Will my information be kept private?**

Yes, your information will be kept strictly confidential during the study. When your research data is used in this trial, your personal information is kept confidential, and all your information will be kept securely and used for research purposes only. The information in the research database will be strictly desensitized to eliminate personally identifiable characteristics, and information that may identify you will not be disclosed to anyone other than the researcher without your permission. Without violating the principle of confidentiality and relevant regulations, the reviewers of the ethics committee can consult the original medical records of the subjects to verify the process and data of the clinical trial. If the research results are published publicly, your personal information will not appear in any publications, and we will not disclose this information to anyone or any institution.

### **Do I have to participate in and complete this study?**

Participation in this study is voluntary, and you are free to decide to participate or refuse to participate in this study. Whether you agree to participate in this research or not will not affect your normal clinical work. If you want to participate in this research, you need to read this informed consent form carefully and sign this informed consent form after confirming that you fully understand the relevant issues. You will not lose any legal rights conferred on you by law by signing this document. You may refuse to participate at any time or have the right to withdraw from the research at any time during the research period without any reason, without discrimination or retaliation, and the corresponding rights will not be affected. If you want to withdraw from the research project during the participation, please notify the researcher, complete the relevant procedures before withdrawal as required by the researcher, and complete the relevant withdrawal procedures in writing as required; after withdrawal, the researcher will no longer continue to collect and use your trial data, but data collected anonymized prior to your opt-out cannot be deleted or withdrawn.

### **Would you like to participate in future research?**

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4 With your consent, we wish to retain your data during the study period. Your anonymous  
5 research data will continue to be used for subsequent approved cardiovascular-related medical  
6 research. If you do not agree, after the completion of this research, your research data will be kept  
7 for a specified period of time in accordance with national regulations and will be kept strictly  
8 confidential. Participating in future research will not increase your additional risk and financial  
9 burden. All future research samples and materials will be properly stored in FuwaiHospital,  
10 Chinese Academy of Medical Sciences and will be kept strictly confidential. You may voluntarily  
11 choose to participate in future research and to withdraw from research at any time in writing by  
12 contacting the researcher.  
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### 21 **Who should I contact with questions or difficulties?**

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23 Please contact the researchers at 010-8839\*\*\*\* . If you have any questions about your rights,  
24 please contact the Ethics Committee of Fuwai Hospital, Tel: 010-8839\*\*\*\*.  
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27 Thank you for taking time to read this informed consent form. If you agree to participate in  
28 this clinical trial after due consideration, I hope you can complete this clinical trial in accordance  
29 with the requirements of the researchers. Before participating in this trial, please complete and sign  
30 the last page (signature page) of this document together with your investigator in duplicate, with  
31 one signed document each for you and the hospital.  
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**SIGN PAGE**

I have carefully read, understood and agreed to all the terms of this informed consent form.

I have been informed of the purpose, content, procedures of this research/clinical trial, possible adverse effects of the research/trial, research compensation, and my rights and interests; I have enough time and opportunity to ask questions, and have received satisfactory answers.

I promise that the information I provide is true; if false information is provided, I promise to be responsible for the consequences.

I confirm that the contact information left in the signature office is my valid contact information. If I change the contact information, I should inform your hospital in time. Otherwise, I am willing to bear the corresponding consequences of not being able to contact and not being notified.

I know that I can withdraw from this trial at any time without affecting my normal clinical work.

I will get the original copy of this informed consent form, signed by me and the researcher.

**I agree to participate in this study.**

**I agree to participate in the future study.**  Agree  Disagree

SUBJECT'S NAME

sign:

date:

RESEARCHER

sign:

date:



## SUPPLEMENTAL MATERIALS

### **Effect of a standardized heart team protocol versus a guideline-based protocol on revascularization decision stability in stable complex coronary artery disease: rationale and design of a randomized trial of cardiology specialists using historic cases**

#### **Contents**

#### **Supplemental method**

Full Definitions of key variables

Inclusion and exclusion criteria of cases to be discussed

#### **Supplementary Figures**

Online Figure 1. Specialist Enrollment Flowchart

Online Figure 2. Patient Enrollment Flowchart

Online Figure 3. Standard heart team meeting flow

#### **Supplementary Tables**

Online Table 1. Structured patient information

Online Table 2. Ten-Item Personality Inventory in China (TIPI-C)

Online Table 3. Tabular analysis of inter-team agreement

## 17 Supplemental Methods

### 18 *Full Definitions of key variables and clinical endpoints*

- 19 **1. Three-vessel disease:** three lesions with a percent diameter stenosis (DS%) between 50%-  
20 99% or total occlusion in a coronary artery with a  $\geq 2.5$  mm reference vessel diameter by  
21 visual assessment.
- 22 **2. Left main disease:** left main coronary artery is visually assessed DS%  $\geq 50\%$ .
- 23 **3. Major adverse cardiovascular and cerebrovascular events (MACCEs):** a composite of  
24 death, myocardial infarction, stroke, repeated revascularization, and rehospitalization due to  
25 ischemic symptoms.
- 26 **4. Death:** death from any cause. The cause of death will be adjudicated as being due to cardiac  
27 death or non-cardiac death.
- 28 **5. Myocardial infarction (MI)**
- 29 **(1) In-hospital MI:** Defined as the occurrence during hospitalization after PCI, CABG or  
30 coronary angiography meeting at least 1 of the following criteria:
- 31 1) The rise in cardiac troponin I (cTnI) is  $\geq 70$  times the 99th percentile URL (where  
32 the baseline is lower than the URL, elevated and stable, or falling).
- 33 2) If cTnI was not available, MI was defined with at least one of the following:
- 34 i. New ischaemic ECG changes;
- 35 ii. Development of new pathological Q waves;
- 36 iii. Imaging evidence of loss of viable myocardium that is presumed to be new and  
37 in a pattern consistent with an ischaemic etiology;

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4 38 iv. Angiographic findings consistent with a procedural flow-limiting complication  
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6 39 such as coronary dissection, occlusion of a major epicardial artery or graft,  
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9 40 side-branch occlusion-thrombus, disruption of collateral flow or distal  
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12 41 embolization.

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14 42 **(2) Spontaneous MI:** Defined as detection of a rise and/or fall of cTn values with at least  
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17 43 one value above the 99th percentile URL after discharge and with at least one of the  
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20 44 following:

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22 45 1) Symptoms of acute myocardial ischemia;  
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25 46 2) New ischaemic ECG changes;  
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28 47 3) Development of pathological Q waves;  
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30 48 4) Imaging evidence of new loss of viable myocardium or new regional wall motion  
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33 49 abnormality in a pattern consistent with an ischaemic etiology;  
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35 50 5) Identification of a coronary thrombus by angiography including intracoronary  
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38 51 imaging or by autopsy.

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40 52 **6. Stroke** was confirmed by a neurologist on the basis of imaging studies and was defined as  
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43 53 follows:

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45 54 1) A focal neurologic deficit of central origin lasting >72 hours, or  
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48 55 2) A focal neurologic deficit of central origin lasting >24 hours, with imaging evidence of  
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51 56 cerebral infarction or intracerebral hemorrhage, or  
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54 57 3) A non-focal encephalopathy lasting >24 hours with imaging evidence of cerebral  
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56 58 infarction or hemorrhage adequate to account for the clinical state.  
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4 59 **7. Repeat revascularization** was defined as any repeat coronary artery bypass graft (CABG)

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7 60 or PCI.

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9 61 1) Target Lesion: Lesions were revascularized in the index procedure (or during a planned  
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11 or provisional staged procedure).  
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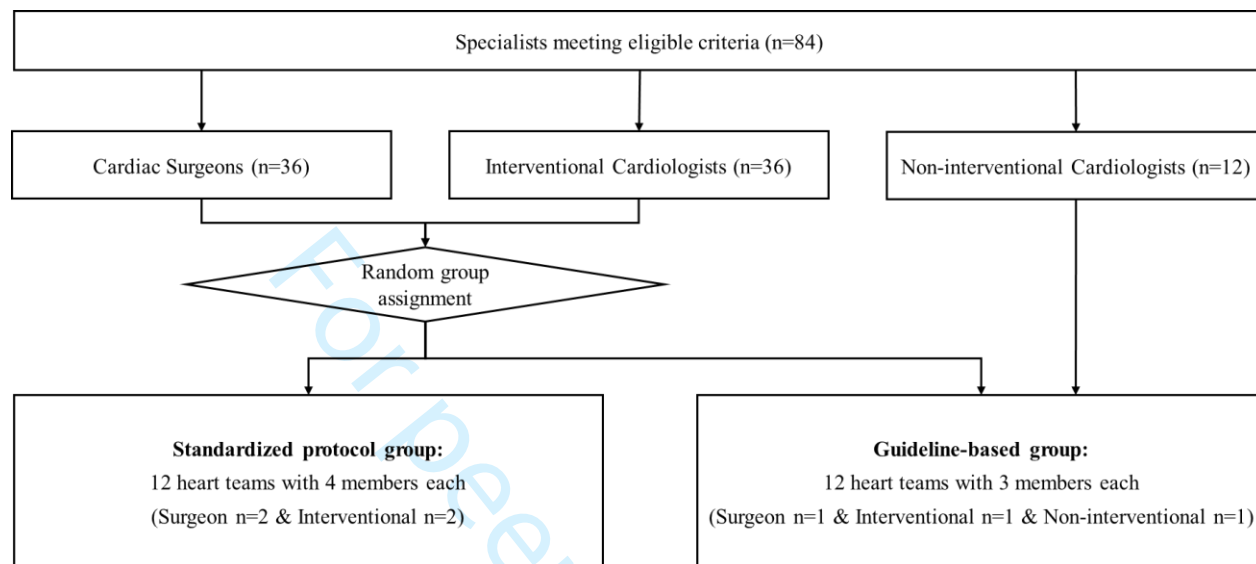
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14 63 2) Non-Target Vessel: Lesions were not treated by either PCI or CABG at the index  
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16 procedure.  
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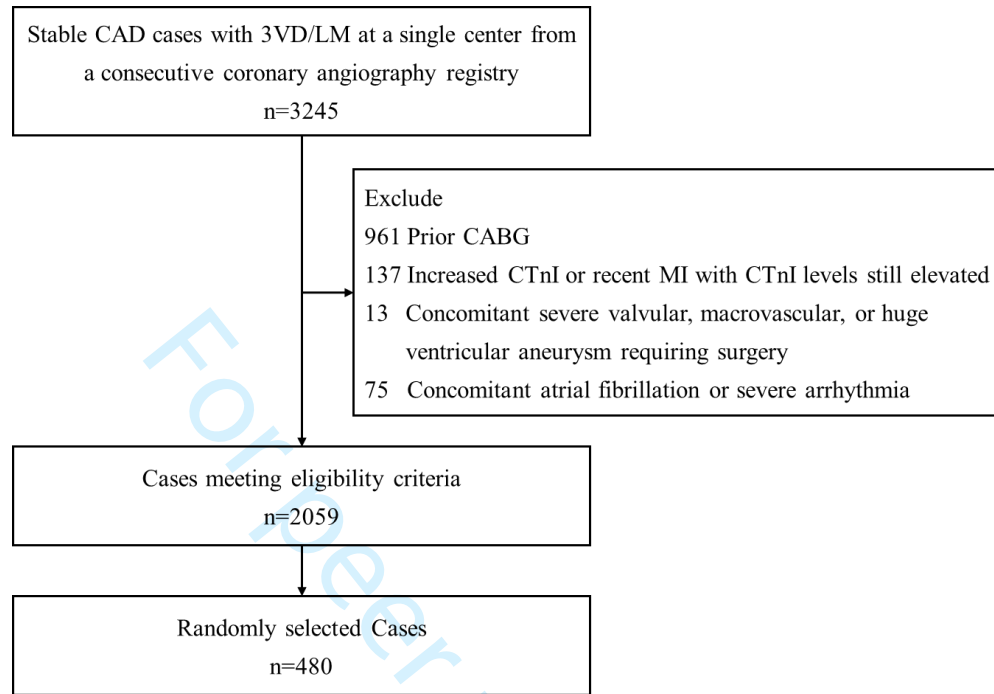
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19 65 **8. Rehospitalization due to ischemic symptoms:** rehospitalization because of ischemic  
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21 discomfort (angina or symptoms thought to be equivalent).  
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4 68 ***Inclusion and exclusion criteria of cases to be discussed***  
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7 69 Adult patients with stable CAD according to the National Cardiovascular Data Registry (NCDR)  
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9 70 CathPCI criteria (stable angina, no or silent myocardial ischemia) and angiographically  
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11 71 confirmed 3-vessel disease or left main (3VD/LM) disease will be eligible for inclusion in the  
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14 72 study. The exclusion criteria included: (1) prior coronary artery bypass grafting (CABG); (2)  
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17 73 cardiac troponin I (CTnI) greater than the local laboratory upper limit of normal or recent  
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20 74 myocardial infarction with CTnI levels still elevated; (3) concomitant severe valvular disease,  
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23 75 macrovascular disease, or huge ventricular aneurysm requiring surgery; (4) concomitant atrial  
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25 76 fibrillation or severe arrhythmia; or (5) unavailable de novo angiography images of the current  
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28 77 hospitalization. Eligible cases will be randomly selected from a prospective registry of  
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31 78 consecutive patients who underwent coronary angiography between August 2016 and August  
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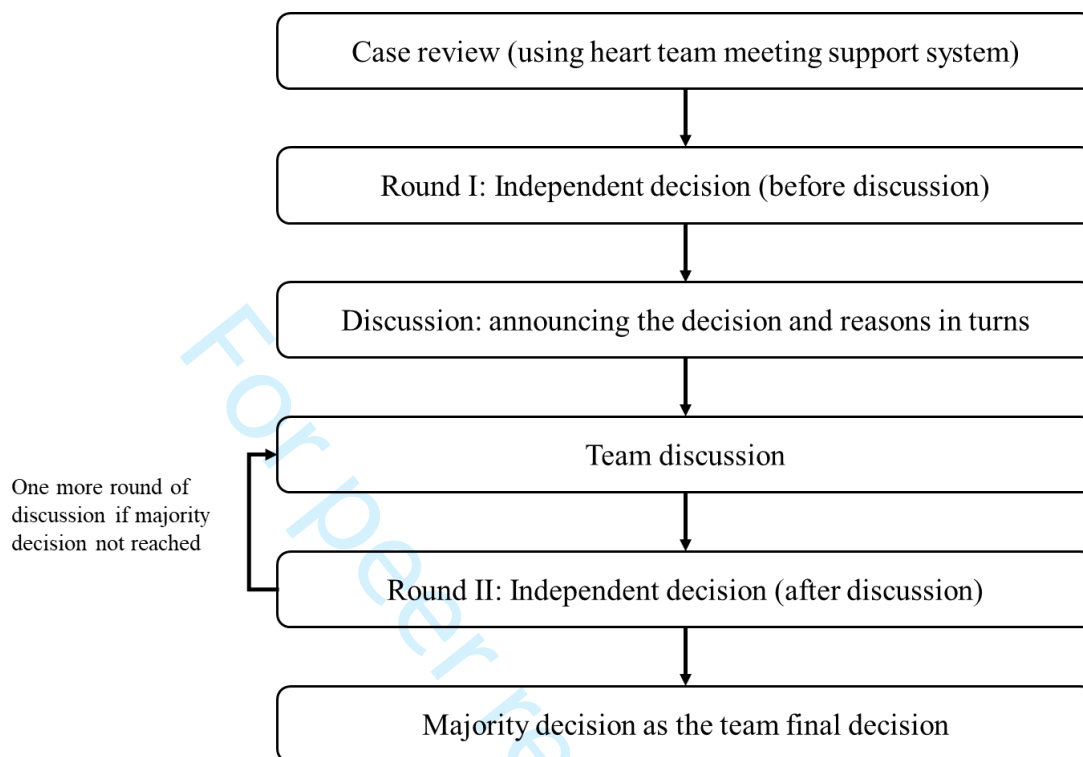
81 **Supplementary Figures**82 **Online Figure 1. Specialist Enrollment Flowchart**

84 **Online Figure 2. Cases Selection Flowchart**

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86 3VD indicates 3-vessel disease; CTnI, cardiac troponin I, LM, left main; MI, myocardial infarction;

87 PCI, percutaneous coronary intervention.

88 **Online Figure 3. Standard heart team meeting procedure**

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91 **Supplementary Tables**92 **Online Table 1. Structured patient information**93 **Heart Team Patient Information Sheet**94 **A. Demographics**95 Patient ID: \_\_\_\_\_ Gender:  Male  female Age: \_\_\_\_\_ y BMI : \_\_\_\_\_ kg/m<sup>2</sup>96 **B. Medical history and risk factors**

<b>Diabetes</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>History of myocardial infarction</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	Time: _____
<b>History of heart failure</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	EF value: _____%
<b>History of stroke</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>renal insufficiency</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	Creatinine: _____ umol/L (44-133) Creatinine clearance: _____ ml/min
<b>Chronic obstructive pulmonary disease</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>Other comorbidities:</b> <i>congenital mitral valve prolapse, hypertension, post-operative hypothyroidism, kidney stones</i>		

97 **C. Coronary heart disease symptoms**

<b>Coronary heart disease symptoms</b>	<input type="checkbox"/> Unstable Angina <input type="checkbox"/> stable angina <input type="checkbox"/> Asymptomatic
<b>Home antianginal medication</b>	<input type="checkbox"/> Long-acting nitrates <input type="checkbox"/> $\beta$ -blockers <input type="checkbox"/> Ca <sup>2+</sup> channel blockers
<b>CCS classification (stable angina)</b>	<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Asymptomatic
<b>NYHA classification</b>	<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV

98 **D. Laboratory test**

Hemoglobin: _____g/L	White blood cells:_____ *10 <sup>9</sup> /L	Platelets:_____ *10 <sup>9</sup> /L
PT: _____s (11.5-14.5)	APTT: _____s (28.5-43.5)	INR: _____(0.8-1.2)
Troponin I: _____ng/ml (ll_____:ul_____)		

99 **E. Preoperative non-invasive examination**

	Result
<b>Admission ECG</b>	<i>Sinus bradycardia 58 beats/min</i>
<b>Echocardiography</b>	<i>Mitral valve posterior leaflet prolapse, mitral valve regurgitation</i>
<b>Stress Testing and Nuclear Medicine</b>	
<b>Coronary CTA</b>	
<b>Cardiac MRI</b>	

100 **F. Invasive coronary examination**

Aniography	FFR:	IVUS:	OCT:
QFR	LM (left main artery): _____		LAD (left anterior descending artery): _____
	LCX (left circumflex artery): _____		RCA (right coronary artery): _____
	Obtuse marginal: _____		Diagonal: _____
	Posterior descending artery: _____		Left posterior artery: _____
	Ramus medianus: _____		

101 **G. Clinical risk scores**

SYNTAX	Score: _____
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S YNTAX II	PCI Score: <u>30.0(9.8%)</u>	CABG Score: <u>32.5(10.2%)</u>	Recommended: /
SYNTAX II 2020	PCI score: <u>9.8%</u>	CABG Score: <u>10.2%</u>	
EuroScore II	Mortality: <u>0.7%</u>		
SinoScore II	Mortality: <u>0.7%</u>		
STS Score	Mortality: <u>0.49%</u>	Mortality and complication rate: <u>9.95%</u>	
	Renal failure rate: <u>0.39%</u>	Stroke rate: <u>1.27%</u>	
	Prolonged ventilation rate: <u>5.8%</u>	Deep sternum infection rate: <u>0.36%</u>	
	Reoperation rate: <u>2.37%</u>	Extended hospital stay rate: <u>4.34%</u>	

102 \* Guidelines recommend STSscore mortality >2% with higher surgical risk

103 **H. Decision result (single choice)**

<b>Independent decision before discussion</b>	<input type="checkbox"/> PCI <input type="checkbox"/> CABG <input type="checkbox"/> PCI /CABG <input type="checkbox"/> Drugs <input type="checkbox"/> Further inspection
<b>Independent decision after discussion</b>	<input type="checkbox"/> PCI <input type="checkbox"/> CABG <input type="checkbox"/> PCI /CABG <input type="checkbox"/> Drugs <input type="checkbox"/> Further inspection

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106 **Online Table 2. Ten-Item Personality Inventory in China (TIPI-C)**

Question No.*	Original items (Gosling et al., 2003)	Rating Scale						
		Absolutely disagree	Quite disagree	Almost disagree	Uncertain	Almost agree	Quite agree	Absolutely agree
		1	2	3	4	5	6	7
1	Extraverted, enthusiastic							
2	Critical, quarrelsome							
3	Dependable, self-disciplined							
4	Anxious, easily upset							
5	Open to new experience, complex							
6	Reserved, quiet							
7	Sympathetic, warm							
8	Disorganized, careless							

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9	Calm, emotionally stable							
10	Conventional, uncreative							

107 \*Scale scoring (“R” denotes reverse-scored items): Extraversion: 1, 6R; Agreeableness: 2R, 7; Conscientiousness: 3,  
 108 8R; Emotional Stability: 4R, 9; Openness to Experiences: 5, 10R.

For peer review only

109 **Online Table 3. Tabular analysis of inter-team agreement**

Case ID	Interventional group			Guideline group		
	Hear team 1 decision	Hear team 2 decision	agreement	Hear team 1' decision	Hear team 2' decision	agreement
001	CABG	CABG	Yes	PCI	CABG	No
002	CABG	PCI	No	PCI	PCI	Yes
003	Medication	PCI	No	Further testing	PCI	No
...	...	...	...	...	...	...
...	...	...	...	...	...	...
480	PCI	PCI	Yes	PCI	Medication	No

110 **Online Table 3. Tabular analysis of inter-team agreement.** Each case will be discussed by two assigned heart teams. The pairwise  
 111 comparison between the heart team's decision on each case provides data on the agreement. CABG indicates coronary artery bypass  
 112 grafting; PCI, percutaneous coronary intervention.