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。

为什么邀您请参加这项研究？

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？

Ma H, *et al. BMJ Open* 2022; 12:e064761. doi: 10.1136/bmjopen-2022-064761

本项研究将持续 12 个月。

参加本研究受试者的风险和不良反应？

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，研究过程中无任何风险和不良反应。

参加本研究可能的获益是什么？

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，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。

如果不参加此研究，有没有其他备选治疗方案？

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。

参加该项研究的费用和补偿

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。

发生研究相关伤害的处理？

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，不会发生研究相关伤害。

我的信息会得到保密吗？

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，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。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、任何机构透露此信息。

是否一定要参加并完成本项研究？

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。您可以在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。

是否愿意参加未来研究？

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研究人员以书面文件形式退出研究。

如果有问题或困难，该与谁联系？

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：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****。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（签署页），一式两份，您和医院各保留一份签署的文件。

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：

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

INFORMED CONSENT

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

Why do this research?

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.

Why are you invited to participate in this study?

Because you (as an interventional cardiologist) have the ability to have annual PCI volume ≥ 200, annual left main (LM)-PCI volume ≥ 25, and is capable of chronic total occlusion (CTO)-PCI; or (as a cardiac surgeon) have total CABG volume ≥ 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.

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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.

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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?

With your consent, we wish to retain your data during the study period. Your anonymous research data will continue to be used for subsequent approved cardiovascular-related medical research. If you do not agree, after the completion of this research, your research data will be kept for a specified period of time in accordance with national regulations and will be kept strictly confidential. Participating in future research will not increase your additional risk and financial burden. All future research samples and materials will be properly stored in FuwaiHospital, Chinese Academy of Medical Sciences and will be kept strictly confidential. You may voluntarily choose to participate in future research and to withdraw from research at any time in writing by contacting the researcher.

Who should I contact with questions or difficulties?

Please contact the researchers at 010-8839**** . If you have any questions about your rights, please contact the Ethics Committee of Fuwai Hospital, Tel: 010-8839****.

Thank you for taking time to read this informed consent form. If you agree to participate in this clinical trial after due consideration, I hope you can complete this clinical trial in accordance with the requirements of the researchers. Before participating in this trial, please complete and sign the last page (signature page) of this document together with your investigator in duplicate, with 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:

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