Version 3 (12.10.2021)
Patient version Participant No.:_____

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Department of Anaesthesia and Intensive Care
The Chinese University of Hong Kong

Title of Study
Effect of a patient education video and prehabilitation on the quality of preoperative person-centred coordinated care experience: a randomized controlled trial

Background
Multimodal prehabilitation includes individualized structured exercises, nutrition counselling and supplementation, and psychological support through standardized multimedia patient education. The goal of multimodal prehabilitation is to optimize your health status in the 4 to 8 weeks before surgery to better cope with the stress of your upcoming surgery. However, there are no local 'prehabilitation videos' available for patients like yourself to help you understand the benefits of and process of prehabilitation as part of the psychological component of prehabilitation.

Multimodal prehabilitation requires a high level of coordination between anaesthetists, surgeons, nurses, physiotherapists and dieticians with patients to provide quality care while you wait for your surgery. Therefore, you are invited to participate in this study to help assess whether the level of patient-centred coordinated prehabilitation care is higher than standard care (no prehabilitation) before surgery.

The objective of this study
1. To evaluate the effect of prehabilitation (patient education video and multimodal prehabilitation) on the preoperative patient-centred coordinated care experience
2. To assess the effect of prehabilitation on preoperative anxiety and depression levels, quality of recovery and DAH_{30} (days alive and at home within 30 days after surgery)

Procedures

The research assistants/research investigators/nurse will explain the risks and benefits of the study to you before surgery. Written informed consent will be obtained from you.

If you agree to participate, you will be randomized (this means you will have an equal chance of being in one or other of the groups) to either:

- Group 1 (patient education by a 10-minute video and prehabilitation program) or
- Group 2 (the current standard of care).

This means that you will have a 1 in 2 chance of receiving formal patient education by video and joining the prehabilitation program. If you are assigned to Group 1, the video education will take place (you will be watching the video while waiting on your pre-operative assessment clinic at the Day Surgery Center) before the prehabilitation program that will take place during the 4-8 weeks before your surgery. The prehabilitation program will take place 4-8 weeks before your surgery, depending on your availabilities, current clinical schedule and needs assessment made by physiotherapists and dieticians. The research staff will also collect information already entered into your medical record.

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Before being allocated to either Group 1 or Group 2, you will be asked to complete a valid and reliable questionnaire "Hospital Anxiety and Depression Score" (HADS) to assess your baseline anxiety and depression levels. This will take about 5 to 10 minutes to do.

On the day before surgery, you will be asked to complete an 11-item validated and reliable questionnaire "Person-Centred Coordinated Care Experience questionnaire (P3CEQ)" to assess the quality of your preoperative healthcare experience. You will also be asked to repeat the HADS questionnaire so that we can measure a change, if any, of your anxiety and depression levels. In total, this will take about 15 to 20 minutes to do.

On the third day after surgery, you will be invited to complete a 15-item valid and reliable questionnaire "Quality of Recovery" (QoR-15) to measure your pain, physical comfort, physical independence, psychological support and emotional state. This assessment can be deferred if you are unwell or unavailable. This will take about 10 minutes to do.

Benefits
There will be no direct benefits to you from participating in the study. The results of this study may highlight aspects of multimodal prehabilitation that may be deficient, for targeting quality health services improvement in future patients undergoing major elective surgery.

Risks
There is no additional risk if you participate in the study.

Ethical Approval
This study has been approved by the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (NTEC-CUHK Cluster REC/IRB) (phone: 3505-3935).

Confidentiality
All information obtained in this study will be considered confidential and used only for research purposes. Your identity will be kept confidential in so far as the law allows. NTEC-CUHK Cluster REC/IRB is one of the authorized parties to access your records related to the study for ethics review purpose. All electronic data will be deleted 7 years after publication of research papers.

Questions
The researcher has discussed with you and offered to answer your questions. If you have further questions, you can contact research nurse Ms Floria NG (project co-coordinator) or Professor Anna LEE (principle investigator) on 3505 2735.

Right to refuse or withdraw
You understand that to participate or not in the study is voluntary, and will not affect the medical management you will receive. You also understand you have the right to withdraw from the study anytime, if you wish to do so.

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香港中文大學
麻醉及深切治療學系

病人參與研究同意書

研究主題

一項隨機對照以病人教育短片及手術前復健計劃對術前以人為中心的協調護理體驗質量影響的試驗

研究背景

手術前多模式復健計劃是提供標準多元化的病人教育，項目包括個人化的鍛煉計劃、營養輔導、營養補充和心理支援。手術前多模式復健的目標是利用手術前 4 至 8 週的時間改善您的健康狀況，以應付未來手術的壓力。但是，手術前復健的心理因素部份上，現時仍未有本地的“復健短片”提供給您這類手術的病人，讓你們理解手術前復健的好處及過程。

在您等待手術期間，能提供優質護理服務的多模式復健計劃需要麻醉科醫生、外科醫生、護士、物理治療師和營養師與患者之間的高度協調。因此，我們邀請您參與本研究，以幫助評估以病人為中心的協調護理復健計劃水平是否高於沒有復健訓練的標準護理。

研究目標

1. 評估復健訓練（病人教育短片和多模式復健訓練）對術前以病人為中心的協調護理體驗的影響
2. 評估復健訓練對術前焦慮和抑鬱水平、恢復質量以及 DAH30（術後 30 天內在家存活日數)的影響

程序

研究人員/研究助理/護士將在手術前向您解釋研究的風險和益處並將獲得您的書面知情同意書。

如果您同意參與，您將被隨機分配（即您有同等機會）進入以下兩組中的其中一組：

- 第 1 組（一個 10 分鐘的病人教育短片和術前復健計劃）或
- 第 2 組（一般的標準護理服務）。

這意味您將有二分之一的機會接受我們提供的病人教育，包括短片和參加術前復健計劃。如果您被分配到第 1 組，手術前的 4-8 週期間您首先會觀看教育短片（您將在日間手術中心等待術前評估時觀看短片）然後才進行術前復健計劃。術前復健計劃將於您手術前 4 至 8 週進行，具體取決於您的當前時間表以及物理治療師和營養師所做的需求評估。研究人員還會收集您的醫療記錄。

被分配到第 1 組或第 2 組之前，您需要完成一份“醫院焦慮和抑鬱評分”（HADS）問卷，以評估您的基線焦慮和抑鬱水平。這需要大約 5 到 10 分鐘完成。

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手術前一天，您需要完成一份 "以人為中心的協調護理之體驗水平"（P3CEQ）問卷，以評估您的術前醫療體驗質量。您仍需要重複 HADS 問卷，以便我們可以衡量您的焦慮和抑鬱水平變化的可能。這總共需要大約 15 到 20 分鐘完成。

手術後第三天，您需要完成另一份"恢復質量"（QoR-15）問卷，以衡量您的疼痛、身體舒適度、身體獨立性、心理支持和情緒狀態。這需要約 10 分鐘完成。如果您身體不適或沒法填寫，此評估可以推遲。

利益
您不會因為參與這項研究而得到任何直接益處。這項研究的結果可能突顯現時手術前多模式復健過程中存在的不足，使我們可改善醫療服務的質量，讓將來接受擇期手術的病人受惠。

風險
上述的評估和問卷調查不會有任何額外的風險。

倫理審核
此項研究已獲得香港中文大學-新界東醫院聯網臨床研究倫理聯席委員會批准(電話: 3505-3935)。

保密
由此項研究獲取的所有資料將被視為機密，只作研究用途。我們會依據法律保障保密處理您的個人資料。 香港中文大學 - 新界東醫院聯網臨床倫理聯席委員會是其中一個部門有權以倫理審查為用途而接觸您有關這項研究的紀錄。所有電子數據將在研究論文發表 7 年後刪除。

問題
研究員已和您討論並回答您的問題。若有其它疑問，您可致電 3505-2735 聯絡 Ms.Floria Ng (研究協調員)或李煥坤教授(研究負責人)。您亦可以選擇致電 3505-3935 聯絡香港中文大學 - 新界東醫院聯網臨床研究倫理聯席委員會查詢您在這項研究的權利。

拒絕參加及退出的權利
參加與否純屬自願，任何決定也不會影響您將獲得的醫療服務。您有權隨時退出此研究。

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Consent
I agree to participate in this study. I have read the information provided and understand the explanation that has been given to me.

同意書
我已閱讀所提供資料，並瞭解一切向我所說明的解釋，我同意參加這項研究。

…… ……

Name of participant
參加者姓名

Name of research assistant/investigator/nurse
研究助理/研究員/護士 姓名

…… ……
參加者簽署
signature of participant

研究助理/研究員/護士 簽署
signature of research assistant/investigator/nurse

…… ……
Date 日期

Date 日期

Patient Details (Gum Label)