A Video-Based Communication Intervention for Fecal Ostomy Surgery (CI-oSurg): Protocol for Open Pilot Testing

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Abstract

Background: Approximately 100,000 patients undergo fecal ostomy operations annually across the United States. This patient population experiences high surgical complication rates and poor biopsychosocial outcomes. Surgical teams are not trained to address the psychosocial needs that often arise during recovery after fecal ostomy surgery.

Objective: This study aims to refine and establish the acceptability and usability of the Communication Intervention for fecal ostomy Surgery (CI-oSurg), a web-based communication intervention aimed at reducing distress among patients recovering from ostomy surgery. Here, we describe the proposed study design, methodology, and training protocol.

Methods: We will conduct an open pilot (n=24 patients and n=8 clinicians) of video-based training to first identify the level and types of distress patients are experiencing. Next, patients will view web-based videos that address frequent challenges faced by ostomy patients considering practical management, emotional, and adaptation concerns. Exit interviews will be conducted with participants to explore acceptability and credibility of the program and refine the intervention and study procedures.

Results: This study has been approved by the MassGeneral Brigham Institutional Review Board. Study completion is anticipated by fall 2024.

Conclusions: We will refine the first web-based communication intervention focused on reducing distress after ostomy surgery. This will allow us to establish usability and acceptability of the intervention to inform a future clinical trial of CI-oSurg.

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Abstract

Background: Approximately 100,000 patients undergo fecal ostomy operations annually across the United States. This patient population experiences high surgical complication rates and poor biopsychosocial outcomes. Surgical teams are not trained to address the psychosocial needs that often arise during recovery after fecal ostomy surgery.

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Results: This study has been approved by the MassGeneral Brigham Institutional Review Board. Study completion is anticipated by fall 2024.

Conclusions: Through this study we will refine CI-oSurg, a web-based communication intervention focused on reducing distress after ostomy surgery, to improve intervention acceptability and usability. These improvements will allow us to establish usability and acceptability of the intervention prior to efficacy testing to determine the ability of this intervention to reduce distress after fecal ostomy surgery.

Introduction

Approximately 100,000 patients undergo fecal ostomy operations annually across the United States.[1] This patient population experiences high surgical complication rates (up to 37%), including surgical site infections, dehydration, and hospital readmissions.[2] Patients undergoing fecal ostomy surgery have poor biopsychosocial outcomes, including decreased quality of life and caregiver burden.[3], [4], [5], [6], [7] Surgical teams are not trained to address the psychosocial needs that often arise during recovery after fecal ostomy surgery.

Current colorectal surgery guidelines support the use of interventions to improve biopsychosocial outcomes after ostomy surgery based on expert opinion.[8] Despite these recommendations, a study by Follick *et al* highlights the lack of adequate ostomy support with 46% of ostomates reporting that they needed more information than was provided in the time after surgery with 40% indicating that their spouse needed additional information as well. [9] Of note, 45% indicated that more information would have helped them deal more effectively with the emotional effects of their ostomy. Despite this need for more and better information, enhanced recovery after surgery interventions and focus of hospital systems on increased throughput decrease the time spent in the hospital setting. This limits the time for education of patients and care-partners. There is a lack of evidence-based interventions to address distress in the postoperative period for fecal ostomy patients.

The overall goal of our work is to improve biopsychosocial outcomes of patients recovering from fecal ostomy surgery.. This study protocol is part of a larger research program to develop, refine, and establish the efficacy of a **C**ommunication **I**ntervention for fecal **o**stomy **Surg**ery (CI-oSurg), a video-based communication intervention to support patients and surgical teams during recovery from fecal ostomy surgery. The aim of this study is to elicit and systematically evaluate key stakeholder perspectives on the acceptability and usability

of a video-based communication intervention for fecal ostomy surgery, including content and procedures (e.g., recruitment and screening methods, eligibility, timing of the intervention, and intervention delivery). Our hypothesis is that iterative improvements to the intervention (i.e., CI-oSurg) will improve acceptability and usability of the intervention prior to efficacy testing.

Methods

Study Design

In this study we will perform open pilot testing of the CI-oSurg intervention with eight surgical team clinicians (i.e., surgeons who perform fecal ostomy operations, inpatient surgical nurses, outpatient surgical advanced practice practitioners and ostomy nurses) and 24 fecal ostomy patients at a single academic surgical clinic until acceptability is improved. [10], [11] Clinicians and patients will use the communication intervention to augment routine surgical care communication, see Figure 1.

The intervention prototype was developed based on qualitative interviews with patients recovering from elective ostomy surgery and focus groups of clinicians experienced in the care of this surgical patient population. The intervention includes a modified version of the NCCN Distress Management Tool[12] and video support materials. The modified distress tool includes a description of distress: an unpleasant experience of a mental, physical, social or spiritual nature that can affect the way one thinks, feels or acts. Next, a single distress thermometer question is asked to report the patient's level of distress on a scale of 0 (no distress) to 10 (extreme distress). Finally, patients complete a problem list to identify concerns they experienced over the past week across domains of physical, emotional, social, practical and spiritual/religious concerns. After completing this modified distress tool, patients are provided a list of support videos that address the most frequent areas of concern of patients recovering from ostomy surgery, see Figure 2. After exposure

to the intervention, participants will complete cognitive interviews to provide feedback on the intervention content and protocol to improve acceptability and usability in the surgical setting as well as a brief survey within 30 days of their operation.

Recruitment, Screening, and Setting

We will recruit adult patients (18 years or older) scheduled for elective surgery with a fecal ostomy from the outpatient surgical clinic at a single tertiary academic medical center. We will perform purposeful sampling to ensure that half of patients are 65 years or older to understand acceptability and usability of the intervention across the aging continuum. The potential participants will be identified by the surgical team and research assistant through medical chart review. The research assistant will then complete screening and consent procedures prior to enrollment. Eligible participants will be (1) fluent in English, (2) willing and able to participate in a live interview/surveys, and (3) undergoing an elective fecal ostomy surgery. Exclusion criteria include, severe cognitive impairment (e.g., advanced dementia, stroke, serious mental illness, or altered mental status due to septic shock) causing inability to perform teach-back for consent and the ensure meaningful participation in study interviews.[13]

We will recruit eight adult clinicians who participate in the care of patients with a fecal ostomy. Potential participants will be recruited from the same single tertiary, academic medical center via surgical team meetings and email. Potential participants will include surgeons who perform fecal ostomy operations, inpatient surgical nurses, outpatient surgical advanced practice practitioners and ostomy nurses. The research assistant will complete screening and consent procedures prior to enrollment. Clinician participants will review the CI-oSurg intervention and training module, a 30-minute in-person didactic session with role-play to ensure understanding of the intervention and study purpose.

The intervention will be provided at general and gastrointestinal surgical inpatient floors at a

Boston, tertiary care hospital where a high volume of colorectal surgery is performed. These surgical inpatient floors are staffed by nurses experienced in caring for patients with fecal ostomies who have access to onsite ostomy nursing staff during weekdays.

Study Intervention

Participating clinicians will be trained with the CI-oSurg intervention and protocol using the CI-oSurg training module. The training module will consist of a 30-minute in-person didactic session with role play of intervention components. This will occur on the inpatient surgical floor conference room to provide participants with a convenient and familiar setting where they will execute the intervention. We will provide flexible scheduling and reschedule sessions as needed to increase clinician recruitment. During this module participants will learn the potential benefits of psychological support for patients recovering from ostomy surgery and address the distress patients often experience during the recovery process. Participants will view the intervention, including intervention video content.

Twenty-four consenting patient participants will complete the CI-oSurg intervention assessment and management video series 1-3 days after fecal ostomy surgery, while admitted to the hospital. The intervention content and protocol will be refined iteratively with each group of four to six participants based on qualitative feedback from the interviews. For example, participants will be asked if: the content addresses concerns using understandable terms/images, they would like to repeat the intervention in the hospital and/ or at home via a web-based platform on a personal tablet/device. Patients might request changes to the images of the video content, size of font or speed of audio recordings.

Participants will then undergo an approximately 30- minute in-person cognitive interview prior to discharge from the hospital and within 2 weeks of surgery, using a semi-structured interview guide. Interview guide content is designed to gather feedback on the proposed CI-oSurg content and protocol. Specifically, this study is designed to gather participants'

perspectives on the following: (1) acceptability of the CI-oSurg content components, (2) acceptability of clinician training sessions, (3) useability of the intervention with the surgical team and existing clinical staff, and (4) proposed recruitment procedures for a future clinical trial.

Study Procedures: To improve credibility of results, interviews will be performed by trained qualitative researchers, audio recorded, and transcribed. Rapid data analysis will be performed to allow changes to be quickly made to the intervention to improve acceptability and feasibility in the busy inpatient surgical setting prior to in depth coding and analysis. Final study data will undergo in-depth coding and analysis to ensure credibility of findings with double coding of at least 20% of interviews to ensure consistency. A hybrid inductive-deductive approach[14] will be used for qualitative coding and a modified Framework method for thematic synthesis in final analysis.[15], [16], [17] Our team will use iterative refinement of the CI-oSurg intervention and protocol based on ongoing data collection and rapid data analysis, consistent with prior studies.[18]

Data Collection

Data from all participants will be collected using REDCap (Research electronic Data Capture; Vanderbilt University) tools hosted at MGH; a HIPAA (Health Insurance Portability and Accountability Act) approved electronic data capture system). [19] Demographic data will be obtained upon study enrollment (i.e., age, sex, race/ethnicity, education, and occupation). In addition, the World Health Organization brief quality of life evaluation[20] and Hospital anxiety and depression scale[21] data will be collected from patient participants 1 month after the surgery date to evaluate retention for future clinical trial planning. Assessment responses from the intervention will be collected by the research assistant as part of the CI-oSurg intervention. Client satisfaction questionnaire[22] will be collected within 1 month of intervention use.. In addition, we will conduct qualitative

interviews with patients and clinicians. Interviews will be 1:1 and will last approximately 30-minutes to allow adequate time for discussion. The interview will follow a semi structured interview guide with open-ended prompts and questions surrounding domains including, (1) perceptions of fecal ostomy care after surgery, (2) feedback on the CI-oSurg intervention procedures and content, and (3) ways of maximizing acceptability and usability. The interviewer will follow the guide with further probes to develop a comprehensive understanding of the participants' perspectives, see Appendix 1.

Interviews will be audio-recorded and performed by a trained research assistant with expertise in qualitative research methods. Recordings will be transcribed and reviewed with rapid data analysis using a template developed by the research team. The template will be used to inform formal coding and intervention refinement with observations within key interview domains, critical participant statements, and other important observations. The research team will work to generate information on clinical team perspectives regarding the acceptability and usability of the intervention procedures and content.

Data Analysis

Audio recordings will be transcribed and deidentified. Evaluation of deidentified data using rapid analysis will be performed in Microsoft Excel to allow rapid updates to the intervention based on participant feedback. A hybrid deductive-inductive approach to qualitative data analysis will be used guided by a modified framework method.[23], [24], [25], [26] Our deductive approach will be based on our interview guide, rapid analysis template (see Appendix 2) and codebook domains. These are influenced by our prior research on patient perspectives on challenges faced by patients undergoing fecal ostomy surgery and the findings from our clinician focus groups for prototype development. For example, we will include prompts in the interview guide that assess the perspectives of patients and clinicians in evaluating social support and adapting to life after surgery.

Transcripts will undergo rapid data analysis with summarizing data matrices to determine real-time data saturation before conducting more extensive qualitative analyses.[27] Rapid data analysis bypasses the process of in-depth coding and organizes data immediately following qualitative interviews based on interview script templates.[28] Rapid analysis will be used to enact changes to the CI-oSurg intervention and protocol until thematic saturation is reached with 32 participants anticipated based on past studies and practical considerations.[29] Discrepancies in coding or analysis will be resolved through discussions with the larger research team to ensure consistency and accuracy.

Ethics Considerations and Approval

This study was approved by the Massachusetts General Brigham Hospital Institutional Review Board, Protocol Number 2023P003564. Informed consent will be obtained verbally during enrollment and during qualitative interviews. Participant data will be de-identified and stored securely on HIPPA compliant servers. Participants will not receive compensation for participation.

Results

The study has been approved by the Massachusetts General Brigham Institutional Review Board and registered with clinicaltrials.gov. Recruitment is expected to begin in Spring 2024. Completion is anticipated by September 2024 with plans for dissemination of study findings at national surgical meetings in Spring of 2025 with peer reviewed publications to follow.

Discussion

Findings from this study will improve the acceptability and usability of a web-based communication intervention for fecal ostomy surgery to address challenges leading to distress during fecal ostomy surgery recovery. Recovery after fecal ostomy surgery requires practical management changes (i.e., changing an ostomy appliance and monitoring output)

as well as emotional adaptation to life with an ostomy. This novel intervention leverages existing technology and resources in surgical clinics to provide scalable, psychologically informed care aimed at improving biopsychosocial outcomes of patients recovering from fecal ostomy surgery.

Current colorectal surgery guidelines support the use of interventions to improve biopsychosocial outcomes after ostomy surgery based on expert opinion.[30] Communication interventions have been utilized in some surgical practices (i.e., oncology) to identify distress[31], [32] However, these interventions are not currently used in the benign surgical setting and management strategies to address ostomy patient needs are lacking. The intervention refined in this study will evaluate the level of distress, identify potential needs of patients recovering from ostomy surgery, and provide management steps. By addressing common concerns identified from patients and clinicians interviewed by our team during prototype development, we hypothesize that the intervention will reduce postoperative patient distress during future efficacy testing.

The intervention under development in this study, CI-oSurg, is novel because current surgical care models limit integration of psychologically informed care. While psychiatrists are involved in the care of select surgical patient populations (preoperative bariatric surgery screening), there is a lack of psychological support for patients facing and recovering from fecal ostomy surgery. Providing individual counseling to all fecal ostomy patients is unlikely to be feasible due to resource constraints.[33] However, screening for distress, anxiety, and depression before and after ostomy surgery is a key first step in identifying the needs of this high-risk surgical population[34], [35], [36]. Use of a distress screen in this communication intervention with a problem list to compartmentalize challenges will provide surgical teams with a better understanding of specific, individualized interventions needed to support patients during recovery after ostomy surgery.

In this study we will ensure recruitment of older adults facing fecal ostomy surgery to understand unique needs of this growing patient population. Older adults undergoing fecal ostomy surgery have poor biopsychosocial outcomes, including high rate of permanent ostomy formation, poor quality of life, and high levels of caregiver burden.[3], [4], [5], [6], [7], [37], [38], [39], [40] A study by Bosshardt et al reports high rates of mortality and permanent ostomy among patients 70 years or older.[41] Among aging adults, poor outcomes can be linked to geriatric conditions. For example, arthritis or sensory impairments can impact patients' ability to perform practical management tasks required for independent ostomy care and polypharmacy and neurocognitive function contribute to dehydration. If older adults note new challenges, such as medication management for dehydration, we will refine the intervention to address these needs prior to finalizing prototype content. This focus on older adult ostomy patients will provide key insight to improve the care of this growing surgical population.[42]

During this open pilot phase, certain barriers may arise to using this intervention in the busy inpatient surgical setting. This study will identify and address barriers to intervention acceptability, such as clinicians' limited time or unfamiliarity with distress screening strategies prior to efficacy testing.[43], [44] In addition, usability of certain intervention components might need to be modified (i.e., using hospital-provided tablets versus personal devices). Using a human-centered design approach to obtain information on these potential barriers is a critical step in intervention development to optimize the intervention acceptability prior to efficacy testing.

This study should be considered in light of important limitations. The web-based intervention content is only in English; therefore, lack of English fluency is an exclusion criterion. Future work will need to be performed to develop and evaluate the acceptability and usability of a culturally adapted intervention in diverse populations considering different

languages and ethnicity groups. Next, the study is being performed at a single institution in the Northeastern United States. Clinicians practicing in different hospital settings might find unique challenges to using the intervention with different clinical demands or patient populations.

Conclusion

Through this open pilot study, we will refine CI-oSurg, a web-based communication intervention focused on addressing biopsychosocial needs of patients recovering from ostomy surgery. Current colorectal surgery guidelines support use of interventions to improve outcomes after ostomy surgery; however, there is a paucity of evidence-based interventions to address the needs of this population. This study is the next step in establishing the usability and acceptability of the CI-oSurg intervention. Future efficacy testing will provide surgical teams with an evidence-based, scalable communication intervention that addresses the biopsychosocial needs of this large surgical patient population.

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Data Availability: Once the study is complete, the data sets generated during and/or

analyzed will be available from the corresponding author on reasonable request.

Conflicts of Interest: none

References

[1] 'WOCN Society Clinical Guideline: Management of the Adult Patient With a Fecal or Urinary Ostomy-An Executive Summary.', *J Wound Ostomy Continence Nurs*, vol. 45, no. 1, pp. 50–58, 2018, doi: 10.1097/WON.0000000000000396.

[2] K. H. Sheetz *et al.*, 'Complication rates of ostomy surgery are high and vary significantly between hospitals.', *Dis Colon Rectum*, vol. 57, no. 5, pp. 632–637, May 2014, doi: 10.1097/DCR.0000000000000038.

[3] L. Richbourg, J. M. Thorpe, and C. G. Rapp, 'Difficulties experienced by the ostomate after hospital discharge.', *J Wound Ostomy Continence Nurs*, vol. 34, no. 1, pp. 70–79, 2007, doi: 10.1097/00152192-200701000-00011.

[4] K. L. Parmar, M. Zammit, A. Smith, D. Kenyon, and N. P. Lees, 'A prospective audit of early stoma complications in colorectal cancer treatment throughout the Greater Manchester and Cheshire colorectal cancer network.', *Colorectal Dis*, vol. 13, no. 8, pp. 935–938, Aug. 2011, doi: 10.1111/j.1463-1318.2010.02325.x.

[5] S. J. Coons, Y. Chongpison, C. S. Wendel, M. Grant, and R. S. Krouse, 'Overall quality of life and difficulty paying for ostomy supplies in the Veterans Affairs ostomy health-related quality of life study: an exploratory analysis.', *Med Care*, vol. 45, no. 9, pp. 891–895, Sep. 2007, doi: 10.1097/MLR.0b013e318074ce9b.

[6] K. P. Nugent, P. Daniels, B. Stewart, R. Patankar, and C. D. Johnson, 'Quality of life in stoma patients.', *Dis Colon Rectum*, vol. 42, no. 12, pp. 1569–1574, Dec. 1999.

[7] R. S. Krouse *et al.*, 'Health-related quality of life among long-term rectal cancer survivors with an ostomy: manifestations by sex.', *J Clin Oncol*, vol. 27, no. 28, pp. 4664–4670, Oct. 2009, doi: 10.1200/JCO.2008.20.9502.

[8] M. Goldberg *et al.*, 'Management of the patient with a fecal ostomy: best practice guideline for clinicians.', *J Wound Ostomy Continence Nurs*, vol. 37, no. 6, pp. 596–598, 2010, doi: 10.1097/WON.0b013e3181f97e37.

[9] M. J. Follick, T. W. Smith, and D. C. Turk, 'Psychosocial adjustment following ostomy.', *Health Psychol*, vol. 3, no. 6, pp. 505–517, 1984, doi: 10.1037//0278-6133.3.6.505.

[10] K. Malterud, V. D. Siersma, and A. D. Guassora, 'Sample Size in Qualitative Interview Studies: Guided by Information Power', *Qual Health Res*, vol. 26, no. 13, pp. 1753–1760, 2016, doi: 10.1177/1049732315617444.

[11] M. Lewis, K. Bromley, C. J. Sutton, G. McCray, H. L. Myers, and G. A. Lancaster, 'Determining sample size for progression criteria for pragmatic pilot RCTs: the hypothesis test strikes back!', *Pilot Feasibility Stud*, vol. 7, no. 1, p. 40, 2021, doi: 10.1186/s40814-021-00770-x.

[12] J. C. Holland, T. L. Deshields, and B. Andersen, 'NCCN Clinical Practice Guidelines in Oncology: Distress Management. Version 2.2018'.

[13] S. Kripalani, R. Bengtzen, L. E. Henderson, and T. A. Jacobson, 'Clinical research in low-literacy populations: using teach-back to assess comprehension of informed consent and privacy information.', *IRB*, vol. 30, no. 2, pp. 13–19, 2008.

[14] J. Fereday and E. Muir-Cochrane, 'Demonstrating Rigor Using Thematic Analysis: A Hybrid Approach of Inductive and Deductive Coding and Theme Development', *Int J Qual Methods*, vol. 5, no. 1, pp. 80–92, 2006, doi: 10.1177/160940690600500107.

[15] N. K. Gale, G. Heath, E. Cameron, S. Rashid, and S. Redwood, 'Using the framework method for the analysis of qualitative data in multi-disciplinary health research.', *BMC Med Res Methodol*, vol. 13, p. 117, Sep. 2013, doi: 10.1186/1471-2288-13-117.

[16] A. Srivastava and S. Thomson, 'Framework Analysis: A Qualitative Methodology for Applied Policy Research', *JOAAG*, vol. 4, Nov. 2008.

[17] N. Collaço, R. Wagland, O. Alexis, A. Gavin, A. Glaser, and E. K. Watson, 'Using the Framework Method for the Analysis of Qualitative Dyadic Data in Health Research', *Qual Health Res*, vol. 31, no. 8, pp. 1555–1564, 2021, doi: 10.1177/10497323211011599.

[18] M. M. Archibald *et al.*, ‘Perspectives of Frailty and Frailty Screening: Protocol for a Collaborative Knowledge Translation Approach and Qualitative Study of Stakeholder Understandings and Experiences’, *BMC Geriatr*, vol. 17, no. 1, Apr. 2017, doi: 10.1186/s12877-017-0483-7.

[19] P. A. Harris, R. Taylor, R. Thielke, J. Payne, N. Gonzalez, and J. G. Conde, ‘Research electronic data capture (REDCap)-A metadata-driven methodology and workflow process for providing translational research informatics support’, *J Biomed Inform*, vol. 42, no. 2, pp. 377–381, Apr. 2009, doi: 10.1016/j.jbi.2008.08.010.

[20] WHO, ‘World Health Organization Harvard National Model United Nations’, vol. 61, no. July, pp. 1194–1198, 2004.

[21] A. S. Zigmond and R. P. Snaith, ‘The hospital anxiety and depression scale.’, *Acta Psychiatr Scand*, vol. 67, no. 6, pp. 361–370, Jun. 1983, doi: 10.1111/j.1600-0447.1983.tb09716.x.

[22] D. L. Larsen, C. C. Attkisson, W. A. Hargreaves, and T. D. Nguyen, ‘Assessment of client/patient satisfaction: development of a general scale.’, *Eval Program Plann*, vol. 2, no. 3, pp. 197–207, 1979, doi: 10.1016/0149-7189(79)90094-6.

[23] J. Fereday and E. Muir-Cochrane, ‘Demonstrating Rigor Using Thematic Analysis: A Hybrid Approach of Inductive and Deductive Coding and Theme Development’, *Int J Qual Methods*, vol. 5, no. 1, pp. 80–92, 2006, doi: 10.1177/160940690600500107.

[24] A. Srivastava and S. Thomson, ‘Framework Analysis: A Qualitative Methodology for Applied Policy Research’, *JOAAG*, vol. 4, Nov. 2008.

[25] N. Collaço, R. Wagland, O. Alexis, A. Gavin, A. Glaser, and E. K. Watson, ‘Using the Framework Method for the Analysis of Qualitative Dyadic Data in Health Research’, *Qual Health Res*, vol. 31, no. 8, pp. 1555–1564, 2021, doi: 10.1177/10497323211011599.

[26] N. K. Gale, G. Heath, E. Cameron, S. Rashid, and S. Redwood, ‘Using the framework method for the analysis of qualitative data in multi-disciplinary health research.’, *BMC Med Res Methodol*, vol. 13, p. 117, Sep. 2013, doi: 10.1186/1471-2288-13-117.

[27] A. L. Nevedal *et al.*, ‘Rapid versus traditional qualitative analysis using the Consolidated Framework for Implementation Research (CFIR)’, *Implementation Science*, vol. 16, no. 1, Dec. 2021, doi: 10.1186/s13012-021-01111-5.

[28] B. Taylor, C. Henshall, S. Kenyon, I. Litchfield, and S. Greenfield, ‘Can rapid approaches to qualitative analysis deliver timely, valid findings to clinical leaders? A mixed methods study comparing rapid and thematic analysis’, *BMJ Open*, vol. 8, no. 10, Oct. 2018, doi: 10.1136/bmjopen-2017-019993.

[29] G. Guest, A. Bunce, and L. Johnson, ‘How Many Interviews Are Enough?: An Experiment with Data Saturation and Variability’, *Field methods*, vol. 18, no. 1, pp. 59–82, Feb. 2006, doi: 10.1177/1525822X05279903.

[30] S. Hendren *et al.*, ‘Clinical practice guidelines for ostomy surgery.’, *Dis Colon Rectum*, vol. 58, no. 4, pp. 375–387, Apr. 2015, doi: 10.1097/DCR.0000000000000347.

[31] D. Rades, A. Al-Salool, N. Y. Yu, and T. Bartscht, ‘Emotional Distress Prior to Chemoradiation for Rectal or Anal Cancer.’, *In Vivo*, vol. 37, no. 3, pp. 1205–1210, 2023, doi: 10.21873/invivo.13197.

[32] C. Acquati *et al.*, ‘Psychological and sexual distress in rectal cancer patients and partners.’, *Psychooncology*, vol. 31, no. 6, pp. 920–928, Jun. 2022, doi: 10.1002/pon.5880.

[33] S. Weiner, ‘A Growing Psychiatrist Shortage and an Enormous Demand for Mental Health Services’, *AAMC News*, no. Cim. 2022.

[34] M. J. Follick, T. W. Smith, and D. C. Turk, ‘Psychosocial adjustment following ostomy.’, *Health Psychol*, vol. 3, no. 6, pp. 505–517, 1984, doi: 10.1037//0278-6133.3.6.505.

[35] P. B. Jacobsen, ‘Screening for psychological distress in cancer patients: challenges and opportunities’, *J Clin Oncol*, vol. 25, pp. 4526–4527, 2007.

[36] R. S. Krouse *et al.*, ‘Coping and acceptance: The greatest challenge for veterans with intestinal stomas’, *J Psychosom Res*, vol. 66, no. 3, pp. 227–233, Mar. 2009, doi: 10.1016/j.jpsychores.2008.09.009.

[37] R. S. Krouse *et al.*, ‘Coping and acceptance: the greatest challenge for veterans with intestinal stomas.’, *J Psychosom Res*, vol. 66, no. 3, pp. 227–233, Mar. 2009, doi: 10.1016/j.jpsychores.2008.09.009.

[38] W. R. Burnham, J. E. Lennard-Jones, and B. N. Brooke, ‘Sexual problems among married ileostomists. Survey conducted by The Ileostomy Association of Great Britain and Ireland.’, *Gut*, vol. 18, no. 8, pp. 673–677, Aug. 1977, doi: 10.1136/gut.18.8.673.

[39] J. Pachler and P. Wille-Jørgensen, ‘Quality of life after rectal resection for cancer, with or without permanent colostomy.’, *Cochrane Database Syst Rev*, vol. 12, no. 12, p. CD004323, Dec. 2012, doi: 10.1002/14651858.CD004323.pub4.

[40] T. R. Nichols, ‘Social connectivity in those 24 months or less postsurgery.’, *J Wound Ostomy Continence Nurs*, vol. 38, no. 1, pp. 63–68, 2011, doi: 10.1097/won.0b013e318202a804.

[41] T. L. Bosshardt, ‘Outcomes of Ostomy Procedures in Patients Aged 70 Years and Older’, *Archives of Surgery*, vol. 138, no. 10, pp. 1077–1082, Oct. 2003, doi: 10.1001/archsurg.138.10.1077.

[42] U.S. Department of Health & Human Services, ‘Average length of stay for discharges from short-stay hospitals, by age and first-listed diagnosis: United States, 2010 [Discharges of inpatients from nonfederal hospitals. Excludes newborn infants. Diagnostic groupings and code numbers are based on the’, pp. 26–27, 2010, [Online]. Available: http://www.cdc.gov/nchs/data/nhds/2average/2010ave2_dischargesage.pdf

[43] L. M. Thompson, A. Diaz-Artiga, J. R. Weinstein, and M. A. Handley, ‘Designing a behavioral intervention using the COM-B model and the theoretical domains framework to promote gas stove use in rural Guatemala: A formative research study’, *BMC Public Health*, vol. 18, no. 1, pp. 1–17, 2018, doi: 10.1186/s12889-018-5138-x.

[44] M. A. Handley *et al.*, ‘Applying the COM-B model to creation of an IT-enabled health coaching and resource linkage program for low-income Latina moms with recent gestational diabetes: The STAR MAMA program’, *Implementation Science*, vol. 11, no. 1, pp. 1–15, 2016, doi: 10.1186/s13012-016-0426-2.

Figure and Table Legend:
Figure 1: Concept Model for Improving Communication after Surgery
Figure 2: Overview of the Communication Intervention for fecal ostomy Surgery (CI-oSurg) Prototype

Figure 1: Concept Model for Improving Communication after Surgery

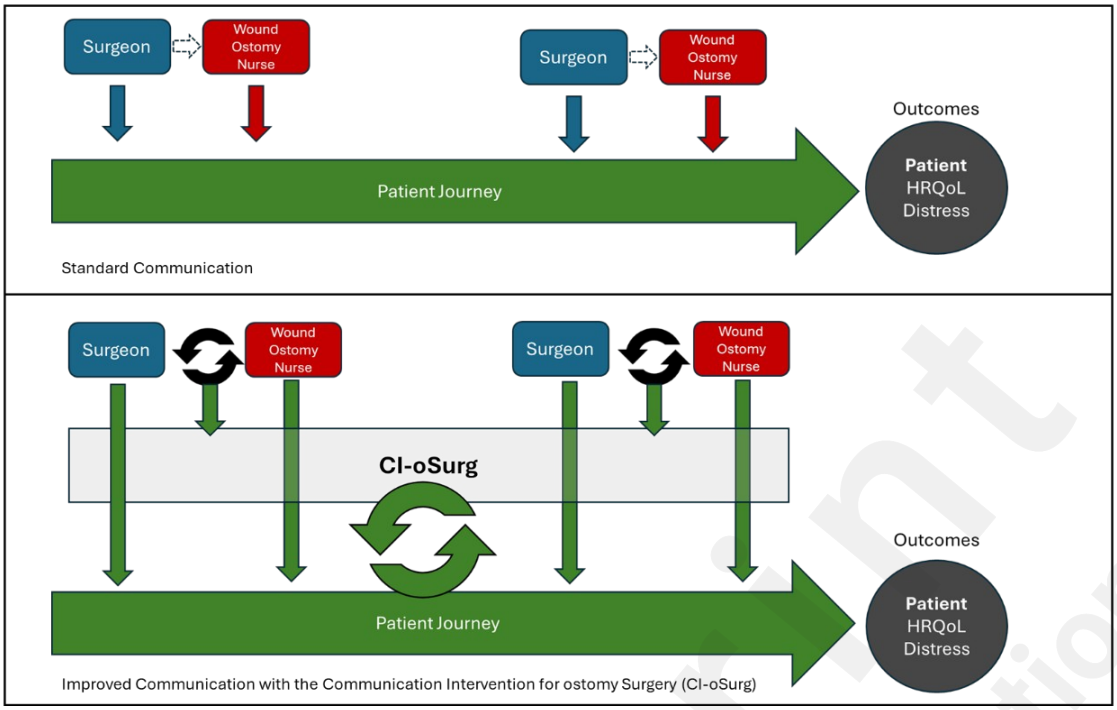
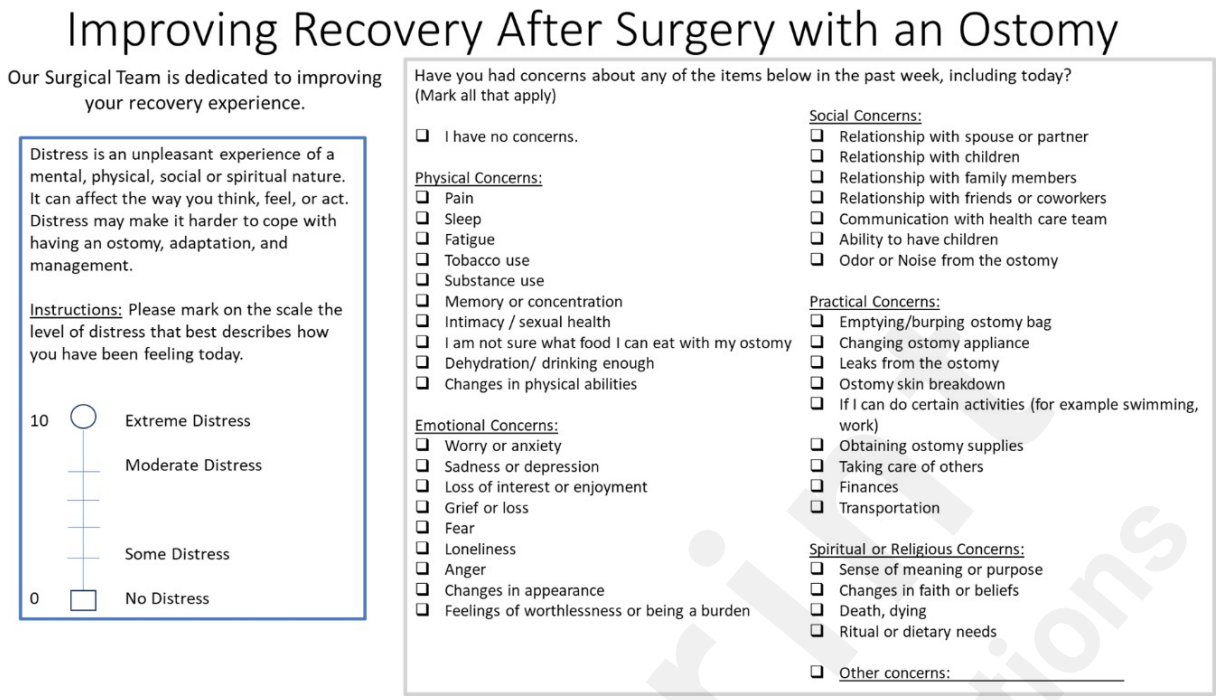
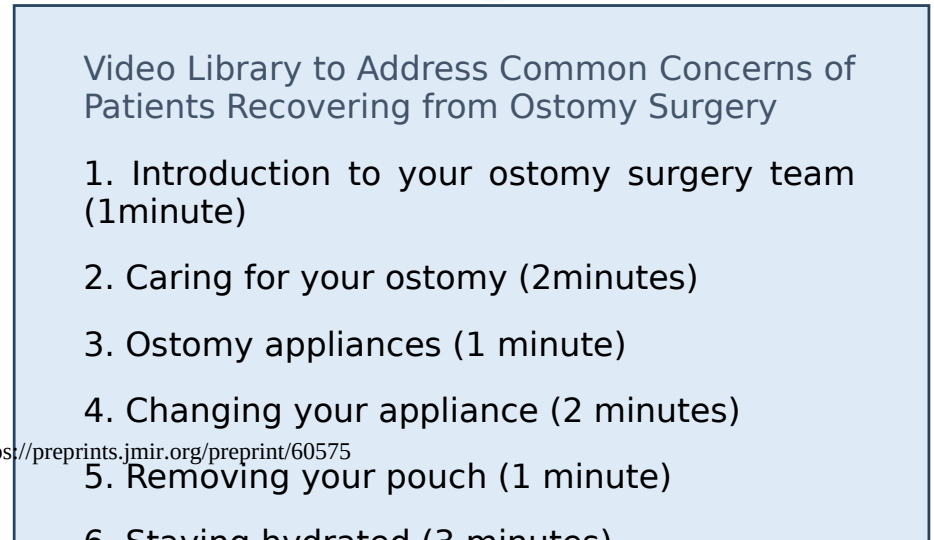


Figure 2: Overview of the Communication Intervention for fecal ostomy Surgery (CI-oSurg) Prototype





participate in an intervention

bout problems that caused

nage your ostomy and adapt

to life at home after surgery (show the distress one-page survey).

I. Recruitment procedures:
    1. What do you think are motivators for patients like you to participate in this type of intervention?
    2. What was your general impression of being recruited for this study?
    3. In your opinion, are there any ostomy patients that would NOT be suitable for this intervention?
II. Intervention acceptability:
    1. Consider the one-page survey with problem list (share screen).
        1. What did you think of this part of the intervention overall?
        2. What did you find helpful with this part of the intervention?
        3. Were there things that you did not like about this part of the intervention?
        4. Were there things that you wish were included in this part of the intervention (for example different problems for the list)?
    2. Consider the videos (show list of videos)
        1. What did you think of this part of the intervention overall?
        2. What did you find helpful with this part of the intervention?
        3. Were there things that you did not like about this part of the intervention?
        4. Were there things that you wish were included in this part of the intervention (for example different videos)?
III. Intervention feasibility
    1. Did you have any difficulty accessing the survey or viewing the videos?
    2. Did you use the videos after you were discharged from the hospital?
        1. What did you think about the length of time for the videos?
        2. What did you think about the number of videos and surveys?
    3. What did you think about the timing of this interview and completing the quality of life survey?
    4. Were there barriers to completing any portion of the study?
IV. Intervention useability
    1. Would you prefer to use a hospital provided tablet to view the videos or a personal device?
    2. Would you prefer having the videos available to view at your convenience or to have a staff member present to help you open the videos
    3. How would sharing the video content or survey findings with a care-partner or family member affect your recovery?
V. Retention procedures:
    1. Did you have any difficulty accessing the survey to complete at the end of the study?
    2. How can we improve completion of surveys or interviews with patients several

weeks after surgery for future studies?

VI. Wrap up

Is there anything else that we did not ask that you would like to share?

Thank you for participating. [*Instruct to press the red hang-up button.*]

Clinician guide: As part of patients' hospital stay they will be asked to participate in an intervention to improve ostomy patient care, which includes a survey about problems that may cause distress during surgical recovery and videos to help better manage their ostomy and adapt to life at home after surgery (show the distress one-page survey).

VII. Recruitment procedures:
1. What do you think are motivators for patients like the ones you care for to participate in this type of intervention?
2. What was your general impression of patients being recruited for this study?
3. In your opinion, are there any ostomy patients that would NOT be suitable for this intervention?

VIII. Intervention acceptability:
1. Consider the one-page survey with problem list (share screen).
    1. What did you think of this part of the intervention overall?
    2. What did you find helpful with this part of the intervention?
    3. Were there things that you did not like about this part of the intervention?
    4. Were there things that you wish were included in this part of the intervention (for example different problems for the list)?
2. Consider the videos (show list of videos)
    1. What did you think of this part of the intervention overall?
    2. What did you find helpful with this part of the intervention?
    3. Were there things that you did not like about this part of the intervention?
    4. Were there things that you wish were included in this part of the intervention (for example different videos)?

IX. Intervention feasibility
1. Do you think patients will have difficulty viewing the videos?
    1. What do you think about the length of time for the videos?
    2. What do you think about the number of videos and surveys?
2. What do you think about the timing of this interview and completing the quality of life survey?
3. Were there barriers to completing any portion of the study?

X. Intervention useability
1. Would it be best to use a hospital provided tablet to view the videos or a personal device for inpatients?
2. Do you think patients would prefer having the videos available to view at their

convenience or to have a research member/staff present to help patients open the videos

3. How would sharing the video content or survey findings with a care-partner or family member affect patient recovery?

XI. Retention procedures:

1. Did you have any difficulty accessing the survey to complete for this study?
2. How can we improve completion of surveys or interviews with patients several weeks after surgery for future studies?

XII. Wrap up

Is there anything else that we did not ask that you would like to share?

Thank you for participating. [*Instruct to press the red hang-up button.*]

Appendix 2: Rapid analysis template

Date:

Prepared by:

Interviewer:

Stakeholder Information:

Occupation:

Years of Experience Working with surgery patients (if clinician):

Other relevant characteristics*:*

Domain 1: Usual Surgical Care after fecal ostomy surgery

CI-oSurg Intervention Recommendations and Procedures

General Impressions

Video Content

CI-oSurg Procedures

Screening Procedures

Recruitment Procedures

Maximizing Feasibility and Acceptability Outcomes

Important observations and reflections

Broad themes and topics of interest in the interview *(e.g., things not covered in rapid data analysis domains*)**:**

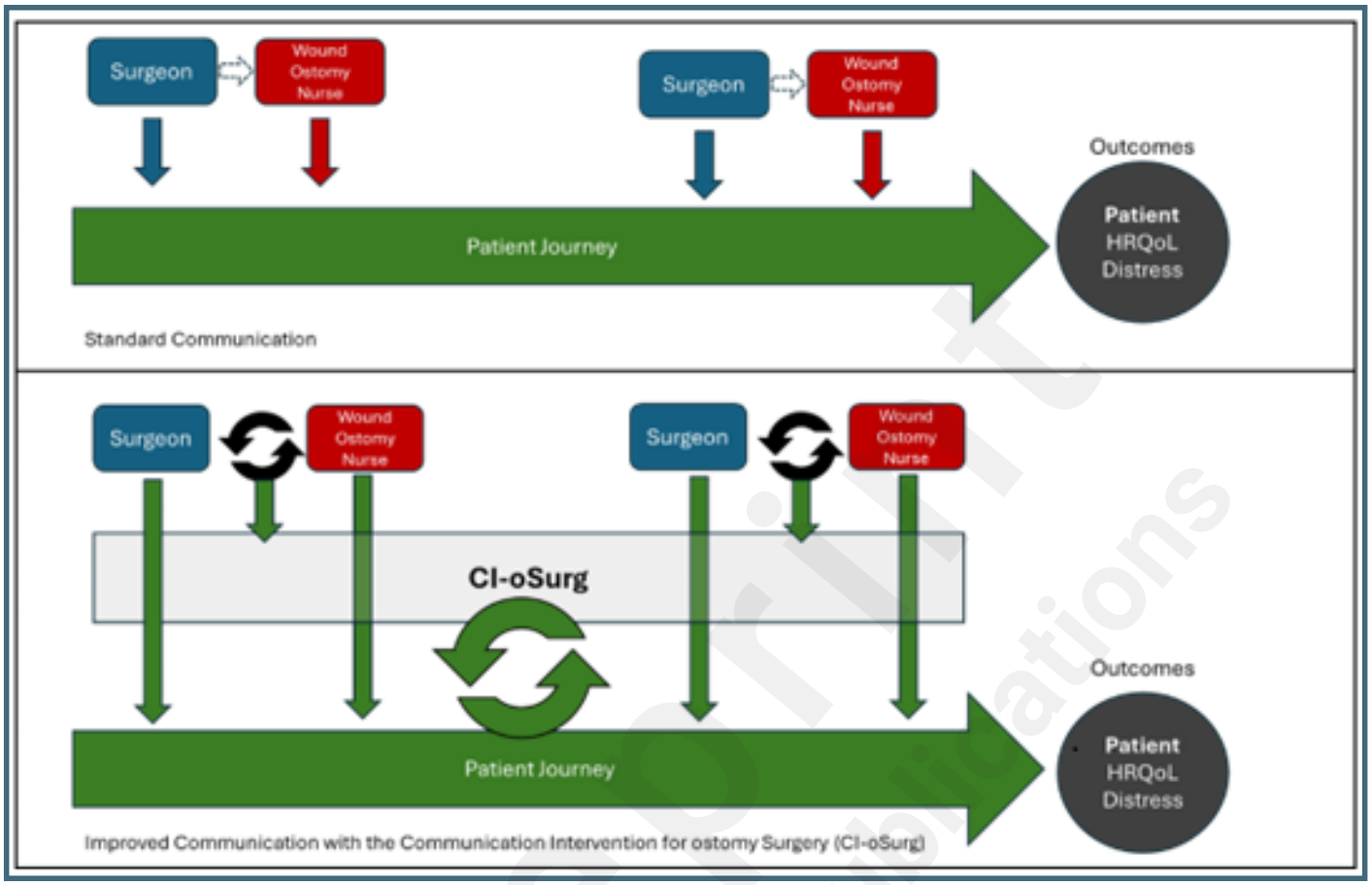
Important quotations

Interviewee analytic notes + reflexivity (e.g., any aspects of researchers' identity, beliefs, social positioning and how they might influence the interview content and observations—consider how your field notes are your own *interpretations* of the interactions that took place)**:**
Behind-the-scenes information (nonverbal information; etc.):

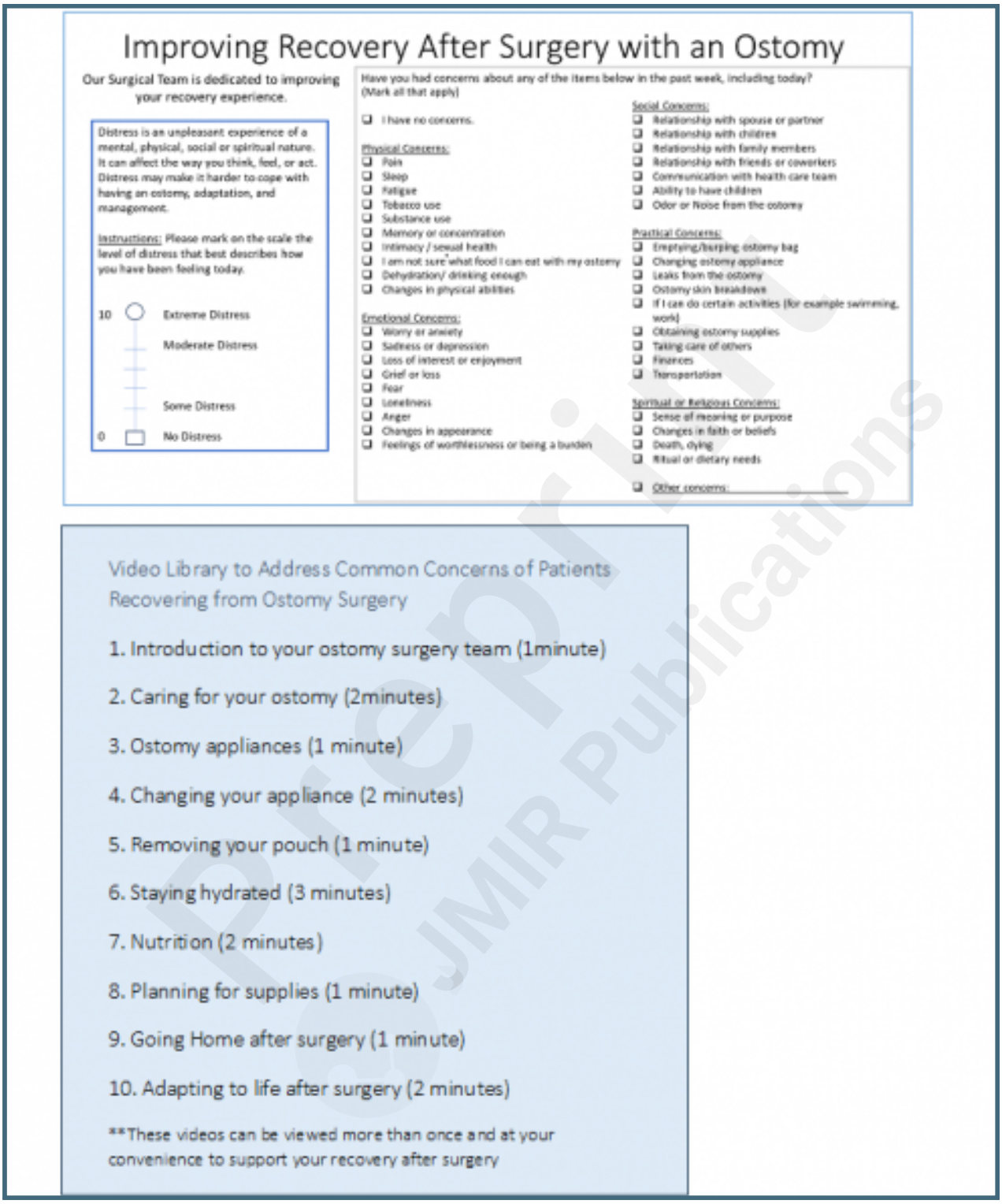
Supplementary Files

Figures

Concept model for improving communication after surgery.



Overview of the Communication Intervention for fecal ostomy Surgery (CI-oSurg) prototype.



Existing Peer-Review Reports from Funding Agencies (for protocols/proposals only)s

Protocol funding statement (Harvard Catalyst KL2/CMERIT). I also include NIH comments (of the same proposal) from my K23 application (summary statement) after peer review of grant proposal.
URL: http://asset.jmir.pub/assets/e733a4d47117722f136de36bed85bf15.pdf