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OSTOMY TELEHEALTH FOR CANCER SURVIVORS

NCT#02974634

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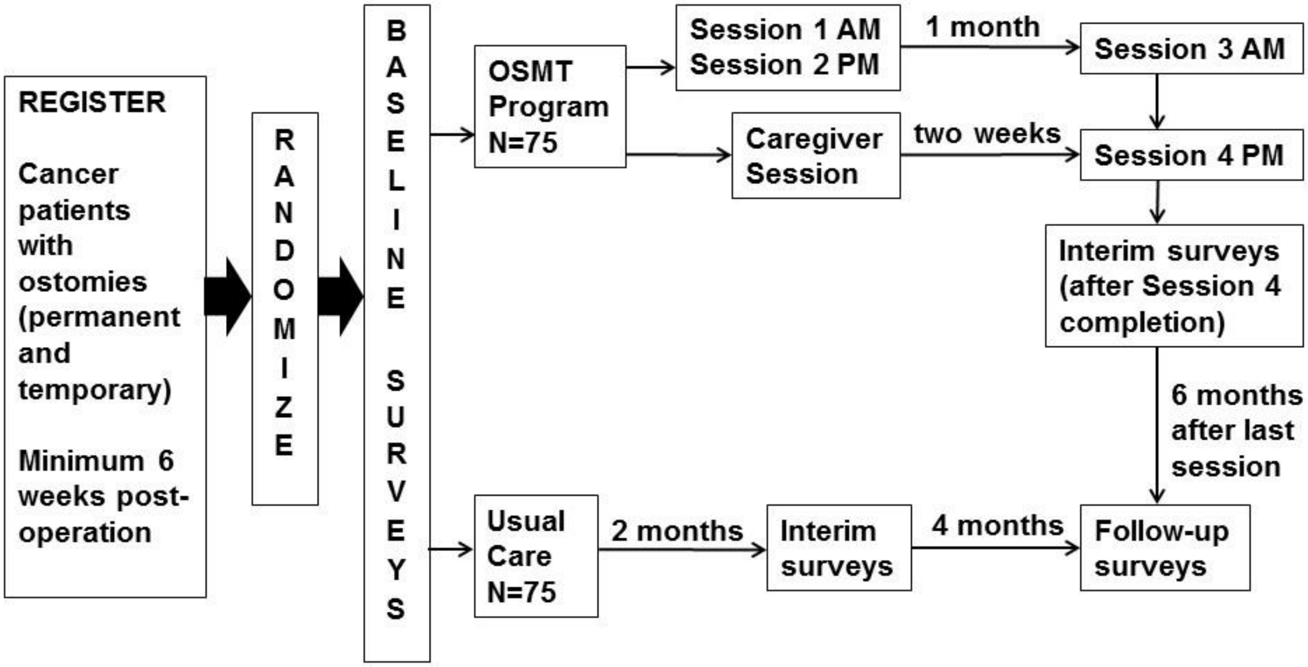
1.0 SCHEMA

Figure 1. Study Design



2.0 OBJECTIVES

2.1 Primary Objectives

Aim 1: Using our enhanced telehealth techniques, determine if **patient activation**, self-efficacy, ostomy-related knowledge, and HRQOL will be improved and sustained over time in the online interactive communication Ostomy Self-Management Telehealth program (OSMT) curriculum compared to a usual care (UC) group.

Hypothesis 1.1: Taking into account time since surgery:

1.1.1 Survivors in the OSMT group will have greater improvement in **patient activation** compared to UC.

1.1.2 Survivors in the OSMT group will have a sustained improvement in **patient activation**.

1.1.3 In survivors in the OSMT group, higher attendance levels will be associated with increased **patient activation**.

Hypothesis 1.2: Taking into account time since surgery:

1.2.1 Survivors in the OSMT group will have greater improvement in **self-efficacy, ostomy-related knowledge, and HRQOL** compared to UC.

1.2.2 Survivors in the OSMT group will have a sustained improvement in **self-efficacy, ostomy-related knowledge, and HRQOL**.

1.2.3 In survivors in the OSMT group, higher attendance levels will be associated with increased **self-efficacy, ostomy-related knowledge, and HRQOL**.

2.2 Secondary Objective(s)

Aim 2: Determine the differences in ostomy-related **medical care utilization** and family **financial burden** imposed on survivors between OSMT and UC groups.

Hypothesis 2.1: OSMT telehealth subjects will use fewer **ostomy-specific family resources** in the 6 months after OSMT compared to UC subjects.

Hypothesis 2.2: OSMT telehealth subjects will use fewer **ostomy-specific health care services** in the 6 months after OSMT compared to UC subjects.

Question 2.1: What is the difference in the overall levels of **ostomy-related family financial burden** between OSMT and UC groups?

Question 2.2: What are types and levels of effort of OSMT intervention personnel and specific equipment, supplies, and informatics support required to implement and operate a successful OSMT program; what are participants' levels of use of ostomy-specific health care services and supplies; and what are the time and in-home requirements for participating in OSMT for survivors and their family caregivers. This information is required for replicating our OSMT intervention in the event that we find it improves the primary and secondary outcomes of OSMT participants.

3.0 BACKGROUND

An ostomy is the externalization of a tubular structure in the body. In the context of this proposal, it relates to intestines externalized to the abdominal wall. It adversely affects health-related quality of life (HRQOL) in a diverse population of cancer survivors. For cancer, ostomies are most commonly placed for rectal cancers, followed by urinary bladder cancer. Ostomies may be needed for other cancers related to bulky or metastatic disease, or in emergencies. In addition, ostomies may be placed on a temporary or a permanent basis. Temporary ostomies may be created in emergencies, such as perforation or obstruction due to tumor, or in planned procedures, as with a low rectal resection for cancer where an ostomy is placed to "protect" a new anastomosis while it heals. Temporary ostomies may become permanent as a result of underlying comorbidities, need for other treatments related to cancer, or poor outcome of anastomosis (leak or stricture). Peri-operative needs are the same regardless of ostomy permanence; survivors should receive clear, systematic, evidence-based ostomy self-management instruction and support.

Cancer survivors with ostomies should have a confirmed level of self-management skills, as well as a commitment to self-management. Cognitive restructuring, problem solving, and self-efficacy/locus of control are essential tools for effective self-management. As in most chronic conditions, this tends to be long-term, complex, and multidimensional. Hit-or-miss ostomy care, nurse counseling, and community referral have been the primary modes of self-management education and support in the peri-operative period. **Clearly, ostomates face many obstacles in coping with their condition, not least of which is medical care that often does not meet their needs for effective information, clinical management, psychological support, and patient activation**.[1-6] Ostomates and their families must engage in ostomy self-management, make behavior changes, and adjust to the consequences of their condition, becoming the principal caretakers and navigators. Preparation of the survivor and unpaid designated caregivers (CGs) (usually family members) is important to assure optimal functioning and HRQOL, as well as to prevent or ameliorate ostomy-related complications and associated health care utilization.[7] Multiple communication issues make it difficult for ostomy survivors to access resources for improving their self-management, and undermine opportunities to improve and sustain HRQOL. These resources include lack of consistent follow-up, travel issues, lack of surgeon focus on ostomy-related problems, and lack of ostomy nurse clinic resources.

Ostomies are associated with multiple HRQOL difficulties.[8-12] Ongoing problems include pouching care, travel out of the home, social interactions, intimacy, and acceptance of/satisfaction with appearance. Studies document persistent challenges including sexuality,[11,13-26] psychological problems,[7,8,10,11,15,26] and interference with work,[17,28,29] and recreation and sporting activities.[17,30-33] However, improved self-efficacy eases psychological and social burden of ostomies.[34] **No reports have been published on the results of a systematic ostomy self-management program to ensure optimal post-operative care, including adaptation, self-management, and ostomy comfort**.

Usual Care. Usual care (UC) in peri-operative and long-term settings is not standardized for ostomy patients. Usual care does not provide any formal, reproducible training for patients or CGs. It typically consists of an Ostomy Care Nurse (OCN) who works with patients and CGs concerning technical issues (fitting, emptying, supplies, surrounding skin care, etc.) while the new ostomate is still an inpatient. Therefore, prior to discharge, most survivors have begun learning to care for their ostomy but will continue learning (primarily on their own) after discharge. For some survivors, training may result in 1 - 2 extra hospital days, although patients are often required to leave hospitals earlier than in the past, leaving less time to adequately train. Additionally, early education is challenging since the bowel or bladder adaptations to surgical changes occur over a matter of weeks and months. Survivors are not typically given specific appointments to a wound care/ostomy clinic. Survivors with ostomies may receive ostomy care or advice in the context of other scheduled clinic appointments, and then only on an "as-needed" basis. Often, there are no recurring support groups or formal peer support systems for survivors with ostomies, and little or no matching of specific products to individual patient needs.

Support Groups. Some communities or health care systems provide contact information of a local ostomy support group chapter, but in our research group's R01 study of Kaiser Permanente (KP) cancer survivors, only 22% of the ostomates reported attending available ostomy support groups. In addition, even where a group is attended, the content is neither systematic, nor based on self-efficacy and skills enhancement, as in our proposed intervention. High levels of consumer satisfaction and outcome evaluations have documented the value of cancer support groups.[35] Research conducted on face-to-face support groups has revealed positive outcomes.[35] However, this research also reveals variations in rates of participation and attendance. Slevin and colleagues provided evidence that physician and nurse-led support groups were preferred by patients, but at least 20% of those invited did not join the group, and another 20% dropped out before the last session.[36] These numbers were approximately the same for Goodwin et al.—66% participated, and 19% dropped[37]—and by Classen et al.—20% declined to participate and 20% dropped.[38] In contrast to the live groups, on-line groups conducted by CancerCare in New York City have had tremendous success recruiting people to virtual telephone groups and having them persist when multiple sessions were conducted.[39] Each of the four 1-hour long sessions on “Living With, Through and Beyond Cancer” had more than 3,000 callers. Clearly, participation through tele-communication can be more successful for cancer survivors than attending face-to-face support groups.

4.0 SIGNIFICANCE

Over one million individuals in the U.S. have ostomies.[40] The American Cancer Society estimates 39,610 rectal cancer cases and 74,000 bladder cancer cases will be diagnosed in 2015.[41] Of these, at least 30,000 will receive ostomies, and an additional unknown number due to gynecologic, other gastrointestinal tumors. The HRQOL impact is tremendous and greater than with many other cancer treatments. An ostomy is often a prolonged or lifelong disabling problem for cancer survivors. The adaptation period is quite variable. In our R01 KP study, 18% of participants took at least one year, or never felt comfortable, in their ostomy care. Importantly, many patients cannot attend self-management programs or patient groups for a myriad of reasons, including distance to travel, monetary outlays, comorbidities making travel difficult, or lack of access to transportation. In addition, a national shortage of OCNs means patients with an ostomy, whether newly placed or a long-term issue, receive little help. It is imperative to study interventions for these cancer survivors aimed to limit family financial burdens, decrease medical care use, and improve well-being.

4.1 Inclusion of Women and Minorities

This study was designed to include women and minorities, but was not designed to measure differences of intervention effects. The anticipated accrual in the ethnicity/race and sex categories is shown in the table below.

Estimated Final Racial/Ethnic and Gender Enrollment Table

Race	Male (N)	Female (N)	Total (N)
American Indian/Alaska Native	0	0	0
Asian	4	6	10
Black/African-American	19	21	40
Hawaiian/Pacific Islander	0	0	0
White	45	47	92
Multi-race	1	3	4
Ethnicity	**Male (N)**	**Female (N)**	**Total (N)**
Hispanic (Latino/Latina)	8	10	18

Non-Hispanic	63	69	132

5.0 ELIGIBILITY CRITERIA

5.1 Eligibility criteria

1. Cancer survivors over 21 years of age having undergone a procedure that needed an intestinal stoma (fecal or urinary). Survivors with temporary ostomies will be included.
2. All participants must have a full understanding of the protocol and be able to sign an informed consent form.
3. Having an identified caregiver is **not** a requirement for eligibility.
4. All participants will attend their first training session at least six weeks after their operation.
5. There is no maximum time since surgery.

6.0 STRATIFICATION FACTORS

Potential stratification factors are gender, medical center site, and fecal vs. urinary ostomy. Gender and site will be stratified in the randomization process, whereas ostomy type will be explored in the analysis.

7.0 REGISTRATION GUIDELINES

7.1 Registration Timing

Patients must be registered by the start time of the first intervention session.

7.2 Investigator/Site Registration

7.2.1 Study Accrual process

7.2.1.1 Patient Identification Patient identification will be variable by site as outlined below. For patients who are asked to participate, a log will be kept without any identifiable information. This log will simply record whether patient accepted or declined. If declined, the reason for declining will get recorded.

7.2.1.2 University of Pennsylvania

UP Research Coordinator will use lists of patients from EPIC records in the Colorectal (under the direction of Dr. Najjia Mahmoud), Urology (under the direction of Dr. Bruce Malkowicz), and Ostomy clinics (under the direction of WOCNs Ave Preston and Matthew Ciabattoni) that have undergone an ostomy procedure. In addition, patients who are seen in these clinics will be asked if they are willing to be contacted regarding this study. These lists include patient names, uncoupled from clinical data.

7.2.1.3 City of Hope

Study CRA will work with site-PI (Dr. Sun) to identify appropriate candidates for the study. The CRA will work closely with the Departments of Medical Oncology and Department of Surgery to identify eligible participants. She will attend key meetings (ambulatory clinics, tumor boards) on a weekly basis and work with attending MDs to identify eligible participants. The attending MD will introduce the study to patients and obtain their permission for the CRA to contact them. With permission, the CRA will contact eligible participants and explain the study purpose, answer questions, and ascertain interest in participation. Study objectives and procedures, and their attendant risks and discomforts, will be carefully explained to the participants.

7.2.1.4 Yale-New Haven

The Yale Research Assistant will work in collaboration with the site-PI (McCorkle) and site-CoI (Ercolano) to identify potential participants for the study. Potential participants must meet eligibility criteria outlined in the study protocol. Potential areas of recruitment include the outpatient setting (ostomy or post-surgical clinics) and inpatient surgical units of the Yale New-Haven Hospital system and Smilow Cancer Center. The appropriate medical and nursing staff involved in the care of these patients will be contacted about the study a priori and a method of communication and referral will be established between the clinical and research staff. We will be in close touch with these referral sources on a daily basis to identify potential patients.
The clinical staff will approach the patient and ask for his or her permission for the RA to contact them. Having this permission, the RA will approach the patient to describe and explain the study purpose, study groups (OSMT training group versus Usual Care Group), randomization procedures, study procedures, and human subjects' protection concerns (right to withdraw, confidentiality, risks and benefits, etc.).

7.2.2 Randomization

Patients who meet eligibility criteria will be approached to enroll in the randomized telehealth intervention versus a usual care comparison group using an approved consent process (see Schema). **Consents will need to be signed and received prior to randomization.**

Subjects will be randomized using stratified permuted block randomization. Once consented, the participant will be randomized to OSMT or UC, using computer-generated random lists blocked by site and gender, and with assigned arm in sealed envelopes blind to investigators and coordinators until assignment. This means that each participating site will have a unique pair of computer-generated randomization lists, one for male and the other for female, ensuring balance by sex between intervention and usual care groups at each site without the need for communication with a data coordinating center core for each randomization. The randomization lists will be comprised of blocks of 4 with permuted patterns so that balance is achieved after multiples of 4 in each sex have been randomized.

7.2.3 Consent

Participant Consent – Potential participants will be afforded sufficient time to consider whether or not to participate in this research study. If the ostomate agrees, informed consent will be obtained. If patients wish to have more time prior to signing the consent, they may mail back the consent. For potential participants contacted over the phone, the same information will be relayed, and they will be asked to mail the consent prior to randomization. Participants will complete the baseline assessment following informed consent.

Caregiver Consent – Participants will designate their caregivers upon registration. It can be anyone they feel they want in that role for this study. As with participants, caregivers will need to have signed a consent prior to participation. Only some basic information will be obtained for caregivers, including age, gender, relationship, and current work status. This will be maintained in a study sheet for every patient. Appendix 11

7.2.4 Study ID

The study ID will be comprised of 4 digits, in which the first digit denotes the medical center site, and the remaining digits number the consented subjects within the site. For the first digit, 1 =

University of Pennsylvania, 2 = Yale, and 3 = City of Hope. Thus, for example, the first subject consented at City of Hope would have study ID 3001.

7.2.5 Subject Reimbursement

Intervention and Usual Care subjects will receive Greenphire ClinCards in the amount of $50 at completion of the initial survey, $50 at completion of surveys at the end of the intervention sessions, and $50 at completion of the follow-up surveys six months after the end of the sessions, for a total of $150. Intervention subject caregivers will receive Greenphire ClinCards in the amount of $25 for each of the two sessions they attend, for a total of up to $50.

8.0 MAILED PACKETS

Mailed packets will include paper materials, described below. All packets will be mailed from and returned to the subjects' respective medical center to ensure that PHI remains at the respective medical center. To mitigate the risk of mixing surveys from multiple participants, each page of paper surveys MUST have the Study ID pre-entered in its field. No PHI will appear on the survey (other than a separate cover letter). After returned paper surveys are processed at the medical center, they will be shipped to the UA Data Core. For RedCap® web-based survey administration (described below), the subject survey ID (separate from the subject ID and specific to each survey time) will be provided by the UA Data Core to the medical centers. Medical Center coordinators will provide their respective subjects survey ID and survey web link at the appropriate time, but the survey responses will transmit directly to the RedCap® server at the University of Arizona.

8.1 Session Information/Preparation

Site coordinators at the three accrual sites will communicate to each other the number of subjects being assigned to a group as they are randomized to the Intervention arm. When the group enrollment gets to six, they will close enrollment to that group and begin enrolling in the next group. Coordinators will slow enrollment if needed so that subjects are not enrolled in a group starting more than 2 months from the enrollment date. If needed, the team will discuss adding additional groups to the schedule on different dates so that subjects will be able to start within the 2-month window from enrollment date.

For intervention session schedules, the protocol will include two different schedules for intervention session administration. This design is to provide flexibility for participants and also to maximize study accrual and participation. The schedules include:

Schedule #1: Two sessions administered on the same day, with a break in between. There will be a 4-week interval between the first set of 2 sessions and second set of 2 sessions. The caregiver session will be held two weeks after the first set of sessions.

Schedule #2: One session administered per day, once a week over a five-week period. There will be a one-week interval between session 2 and session 3 during which the caregiver session will be held.

The two schedules vary throughout the study period based on participants' convenience and preference.

If a subject misses a session, they can make up just the missed session with the next 1 or 2 scheduled groups rather than start over with a new group. If they miss both Session 1 and Session 2, they can be re-assigned to the next group as long as the next group size doesn't exceed 6, or at the ostomy nurses' (Nancy Tallman and Christie Simons) discretion if the group size would exceed 6.

If a subject misses Session 3 or Session 4 or both, they can make up the missed session(s) with the next 1 or 2 scheduled groups. If they miss both chances to make up the sessions, they will be asked to do the surveys and will be analyzed as a separate group using an intent-to-treat contrast.

To account for making up sessions or delays in completing interim surveys, for both intervention and usual care groups, the 6-month followup surveys will be requested from subjects 6 months after the date the interim surveys are completed.

Caregivers who miss the Caregiver session in the subject's assigned group will not be required to make up the session.

At the start of Session 1, the ostomy nurses will review Appendix 9, Group Rules, and remind participants that they can contact their local site Peer Ostomates or ostomy nurses for help.

In any session, if a participant becomes disruptive, it will be noted and if necessary, they will be asked to leave the session. The team will discuss the nature of the disruption and how to handle the participant for future sessions.

8.1.1 Telehealth Connection Information (Appendix 8)
8.1.2 Group Rules (Appendix 9)
8.1.3 Goal Setting (Appendix 10)

Participants will receive the four-page goal setting form (Appendix 10) as part of the patient packet mailed to them before the first session, and will be asked to list goals for helping improve their daily life prior to Session 1 (page 1 of the form). Their goals will be discussed during Session 1 and will be revisited and possibly revised in Session 2 (page 2 of the form) and again in Session 3 (page 3 of the form). Participants should be instructed to keep a copy of the first page of the form and return the completed first page with the baseline surveys. Participants should be instructed to return page 2 after Session 2, and return page 3 after Session 4 along with the interim surveys. The final page 4 should be returned with the followup surveys six months after the end of the sessions. Site Coordinators will key in goal setting data for data entry.

8.2 Surveys (Appendices 2 to 7)

8.2.1 Baseline surveys to be completed are:

1. COH-QOL-CRC (full survey; Appendix 2a AND Appendix 2b)
2. HADS (Appendix 3)
3. PAM (Appendix 4)
4. Self-Efficacy (Appendix 5)
5. Ostomy Knowledge (Appendix 6)
6. Burden of Care (full survey; Appendix 7a [NOTE: **Do not include** Greatest Challenge portion of Appendix 7a])
7. Goal Setting (page 1 of 4; Appendix 10)

8.2.2 End of Session surveys to be completed are:

1. COH-QOL-CRC (43 scaled items only; Appendix 2b)

2. HADS (Appendix 3)
3. PAM (Appendix 4)
4. Self-Efficacy (Appendix 5)
5. Ostomy Knowledge (Appendix 60
6. Burden of Care (short form; Appendix 7b)
7. Goal Setting (pages 2 and 3 of 4; Appendix 10)

8.2.3 6-month Follow-up surveys to be completed are:
1. COH-QOL-CRC (43 scaled items only; Appendix 2b)
2. HADS (Appendix 3)
3. PAM (Appendix 4)
4. Self-Efficacy (Appendix 5)
5. Ostomy Knowledge (Appendix 6)
6. Burden of Care (full survey; Appendix 7a [NOTE: **Include** Greatest Challenge portion of Appendix 7a])
7. Goal Setting (page 4 of 4; Appendix 10

8.2.4 **RedCap® Surveys.** Surveys will be available to complete electronically via the web in RedCap, which will be preferred administration method unless subjects cannot manage the method or express a strong preference against it. The UA Data Core will provide each medical center with a list of survey ID's linked to subject IDs. The survey ID's allow the subject to log into the RedCap survey and can only be used once. Medical centers will provide each subject with the survey link and his or her survey ID at the appropriate time for each of the three survey periods.

8.2.5 **Survey Tracking**. Survey/Participant status will be tracked using an MS Access tracking database maintained at UA Data Core, with mirror databases at each medical center for their respective samples. However, the medical center tracking database will account for all potentially eligible participants, whereas the UA Data Core tracking database will only contain consented subjects. Since paper surveys are returned to respective sites, whereas RedCap surveys are transmitted to UA Data Core, the disposition of consented subjects in the master tracking database will be synchronized with the medical center tracking databases on a weekly basis.

8.2.6 **Survey Follow up.** Telephone contact with respondents will be initiated under four circumstances: 1) for non-respondents (paper survey not returned or RedCap survey not submitted within 2 weeks of mailing or provision of RedCap survey ID); 2) when a returned survey has incomplete or illegible data; 3) when the respondent has questions or requests a call; and 4) if a HADS score is 11 or greater on the depression questions (Appendix 3), the coordinator will inform the participant that this might indicate depression and they should see their physician. This will be documented as a memo in their study file. This will be done within 24 hours of receiving the survey. This will not preclude their participation.

8.2.7 **Returned Survey Processing**. Paper questionnaires returned will be logged in the medical center tracking system. This includes packets returned as "undeliverable, no forwarding address," which would generate a phone call to subject to clarify mailing address. RedCap questionnaires submitted to UA RedCap server will be logged into the Data Core tracking system. Returned paper questionnaires will be stored securely in a locked office or filing cabinet. Each questionnaire will be reviewed for missing responses, improperly marked responses, handwritten comments on the survey forms, and inserted letters and notes from respondents.

8.2.8 **Cleaning PHI**. Any comments that reveal PHI will be masked before photocopying paper questionnaires and destroyed in the case of RedCap surveys.

8.2.9 **Missing Items.** All surveys will be reviewed for completeness based on the criteria outlined below. If the respondent appears to have inadvertently skipped questions, the interviewer will contact the respondent by telephone and attempt to complete the missing items. Unusual situations should be brought to a study project meeting to discuss issues before contacting participant. Use the following guidelines to determine how to handle missing items:

a. Make all decisions of intent based on marginal notes first (i.e., fill in the answers not bubble filled, but indicated by a written note)
b. Appropriately skipped questions based on skip patterns will not be counted as missing.
c. Call backs will be placed when the following criteria are met:
    i. Full page is missing
    ii. >20% questions missing (or more than 1 response to choose best answer questions), not counting open-ended questions, appropriately skipped questions, or sensitive area questions listed below
    iii. The following sensitive questions will not be counted in determining need for callback, nor asked during a call back if missing:
        1. COH-QOL-CRC intimacy item “Has your ostomy interfered with your ability to be intimate?”
        2. COH-QOL-CRC spiritual item “Is support you receive from personal spiritual activities such as prayer or meditation sufficient to meet your needs?”
        3. COH-QOL-CRC religious item “Is support you receive from religious activities such as going to church or synagogue sufficient to meet your needs?”
        4. COH-QOL-CRC Sexual activity items.
        5. COH-QOL-CRC race/ethnicity items
        6. COH-QOL-CRC household income item
        7. Open ended questions will not be counted towards a call back or asked in a callback.
d. If the participant declines to answer a question again during the call back, initials will be placed by the question and the question will be left blank.

8.2.10 **Shipping paper surveys to Data Core.** Hard copy surveys will be reviewed for PHI, which will be masked if present, and scanned to a PDF file within a secure server at each site. These PDF files will be uploaded into RedCap, using a built-in application called Send-It, in which files stay behind the RedCap firewall until retrieved by intended RedCap user recipient from the same RedCap project. Files can only be downloaded by the designated recipient, and that recipient must have log-in capability to RedCap and assignment to the specific project. Within RedCap on the “My Projects” page (one level up from the PCORI project), there is a tab on the right called “Send-it” with an envelope icon. Instructions within the tab are clear to follow. Each PDF file should have only one subject and one event (baseline, interim, followup). Files should be named according to a consistent naming convention for each site based on subject ID number and event (e.g., 1001 baseline.pdf; 2003 followup.pdf, etc.). Data Core staff will download PDF files from Send-it to a secure University of Arizona server and key data responses into the RedCap database. PDF files will be deleted at end of the study.

8.3 Curriculum (Appendix 1)
This will also be sent electronically.

9.0 STUDY PLAN

9.1 Usual Care

The UC control program is designed to compare OSMT to usual care to capture the Hawthorne effect. The final intervention for the UC group includes:

1) Recommending the patient has met at least once with an ostomy nurse (while likely to have happened in the peri-operative period, it may not be universal);
2) Providing the booklet published by The Wound, Ostomy, and Continence Nurses' Society entitled "Basic Ostomy Skin Care: A Guide for Patients and Health Care Providers," with instructions on how to use it;
3) Local support group contact information;
4) Encouraging patients to have seen their surgeons at least once in follow-up after surgery;
5) Contact information for local nutritional and physical therapists; and
6) Ostomy nurse contact information. If patients have specific questions about materials, the research coordinator will clarify the content and encourage the patient to call their physician or ostomy nurse about a continuing problem. These resources will also be given to those in the OSMT program.

9.2 Intervention

9.2.1 Peer Ostomate Screening, and Training. We will employ gender-specific Peer Ostomates at each site. We hope to have them assist with most group sessions, as well as serve as assigned "buddies" for each group of the intervention participants (there will be up to 6 participants for whom each Peer Ostomate is a "buddy" at one time.) Buddies will be available for questions and support during and outside of the training sessions, including exchange of phone numbers if requested. Peer Ostomates have been screened and carefully interviewed to ensure they are well-acclimated to their ostomies and comfortable discussing sensitive issues with participants. Peers will be invited based on relationships with local ostomy nurses or clinicians who feel they would be appropriate for this role. Peer Ostomates who are currently under psychiatric care for serious mental illness or with known psychiatric diagnoses are excluded. At the interview, responsibilities will be clearly described.

Peer Ostomates will only be assigned to those of the same gender. This is to promote discussion of sensitive issues where it might be uncomfortable to talk with someone of the opposite sex. Peer Ostomates will be trained as both co-facilitators and buddies. This will include specific limitations as well as mandates of when to call the research coordinator or site-PI. Examples may be if participants describe medical symptoms (e.g., fevers, abdominal pain, vomiting, bleeding) or psychological problems (e.g., suicidal ideation, extreme depression) that need more urgent medical attention. Peer Ostomates will maintain a log to keep track of how many times they were called by ostomates and the reason for the call. Peers will be trained in the curriculum which will differentiate them from study participants.

9.2.2 Ostomy Care Nurse-Facilitators. We have an experienced OCN-facilitator who will lead sessions from the Tucson site (Nancy Tallman). She participated in the pilot study and is well-versed in the curriculum. Her back-up in Tucson (Christie Simons) has also been instructed on the curriculum, Ostomy Care Nurse facilitators will train participants to become problem solvers, rather than simply giving them a health professional's solution. They will also participate in weekly research team meetings to give updates on issues and events as they transpire. In this way they will give feedback into what components of the program are problematic, as well as what aspects are working well (program evaluation). There will also be OCNs available at the

University of Pennsylvania (UP), City of Hope (COH) and Yale New Haven (YNH) sites as an added resource for participants.

9.2.3 Specific Ostomy Resource Compendium. We have compiled a Tucson-specific resource compendium to distribute to participants. This includes web-based, OCN resource lists, and personal knowledge to identify local ostomy resources, updated for UP, COH and YNH sites. (Appendix 12)

9.2.4 Program Curriculum. OSMT sessions are described in Table 5 below. The OSMT is organized around several concepts that provide the basis for the content and methods. The CCM points to the need for supporting self-efficacy enhancing, evidence based information and peer support. The CG literature points to the need for CGs to be able to step in and provide assistance when participants are unable to do for themselves, but not to take over totally and create dependency in their family member. The teaching content is divided into five 1.5 - 2 hour sessions: three solely for the participants, one for their CG, and one as a conjoined or single visit. Prior to Session 1, participants will list personal goals for participation in OSMT. Participants will be given an assignment at the completion of Session 2, which will be to monitor ostomy output (frequency and consistency of bowel movements and flatus), and problems related to pouching system. As urinary diversion patients also have interruption of their intestine to make their ostomy, with concomitant obstruction/stomal hernia risks, ostomy output issues may also be applicable to them. This exercise will assist the ostomate in becoming familiar with the relationships between input of food and drink, and ostomy output.

9.2.5 Preparation for sessions.

1. Participants will receive reminder calls one day prior to the training sessions, as well as a detailed schedule upon consenting to participate.

2. Participants will review and test the system within one week prior of the first session to ensure they understand how to get on the calls. For technical assistance connecting to Zoom, participants can contact the Arizona Telehealth Program (ATP) Help Desk at 520-626-6978 or atpvcsupport@telemedicine.arizona.edu.

3. Participants who request it will review and test the system within one week prior of the third session to ensure they understand how to get on the calls.

4. Caregivers will receive reminder calls one day prior to their training session. At this time, the coordinator will ask the caregiver’s age, gender, relationship to ostomate, and work status.

5. Caregivers will review and test the system within one week prior of their session to ensure they understand how to get on the calls.

Training Session Descriptions	
1	Content covers self-management, immediate concerns of ostomates (e.g., definitions, associated disease states), daily care, nutritional needs, impact on feelings, skin care and clothing changes. Teaching methods are interactive with hands on practice with equipment, pouches, and belts. Discussion includes potential ostomy complications. Assignment: Monitor ostomy output (frequency and consistency) and problems with pouching system.
2	Discuss completed assignment of personal goals for OSMT. Addresses social well-being, problems of social/interpersonal relationships, public appearances, being prepared for emergencies, intimacy and sexuality, and communication skills within the

Training Session Descriptions	
	cultural framework of the individual participant and their family with home and social environments included in discussions. Fatigue is discussed as a model of long term effects of cancer and other chronic diseases.
CG	A CG will attend a separate session two weeks (one week for alternate schedule) after Session 2, akin to Session 2, covering the same topics specifically tailored to support adjustment of CGs as well as additional content as needed from the other sessions in order to ensure CG also has achieved a comfort level with ostomy care. We recognize that some participants will not have a CG to participate in this session. Focus for the CG will also be within their cultural framework and home environment. Includes HRQOL assessment of CG and evaluation of their participation.
3	Discuss completed assignment. Content promotes a healthy lifestyle via nutritional management, physical activity recommendation and overcoming barriers, psychological health, and improving attitudes. Participants are encouraged to set new priorities, evaluate friends, and work on changing negative attitudes. Tips for traveling are included. Discussion includes potential ostomy complications. Assignment: Review personal goals in regards to ostomy care.
4	Booster Intervention content driven by group demands and needs. The CG will also be invited to this session to help ensure a well-rounded understanding of issues, comfort with ostomy care, and anticipated future dilemmas. Discuss attainment of personal goals for participation in OSMT.

9.3 Telehealth Protocol

9.3.1. Telehealth participation requirements:

a. Applicants to the OSMT study will be placed initially into candidate status. OSMT candidates, or their caregiver, must consult via phone with Arizona Telemedicine Program (ATP) technical staff to review the technical requirements for participation in OSMT sessions via telehealth. Candidates that do not have access to the required technology or internet connectivity, will be offered a temporary loan of compatible technology, based on a first come first served basis, from a pool of tablets and mobile hotspots acquired with OSMT study funding that are designated for loan to study participants. Candidates that do not have access to compatible technology and/or internet connectivity, and that can't be offered an equipment loan due to lack of availability of the required technology from the OSMT device pool, may be offered, at the discretion of the OSMT study leadership, the option to be added to a waiting list for OSMT provided technology to enable them to participate in a later OSMT training group once devices become available again in the OSMT device pool.

   i. OSMT study candidates need the following equipment and capabilities:

      1. Access to a computer, laptop, tablet or smartphone equipped with web cam, microphone and speaker that meets or exceeds the requirements specified by Zoom, Inc. for the Zoom video conferencing service
         - Zoom requirements for computers and laptops are located here: https://support.zoom.us/hc/en-us/articles/201362023-System-Requirements-for-PC-and-Mac
         - Zoom requirements for iOS and Android tablets and smartphones are located here: https://support.zoom.us/hc/en-us/articles/201179966

         a. If the candidate does not have access to a computer, laptop, tablet or smartphone equipped with a webcam, microphone, and speaker that meets the requirements to use the Zoom video conferencing service (see links to requirements above), the candidate will be offered the option of borrowing a compatible tablet, if any are available from the pool of OSMT tablets slated for loan to study participants, configured with WiFi and Verizon cellular data internet access capability. Candidates that opt to borrow a tablet from the OSMT program will need to sign an equipment loan agreement. See agreement in Appendix 13. The tablet along with any required accessories, and a pre-paid return shipping label, will be shipped to the candidate at the address that they specify on the loan agreement.

2. Internet access at the location that candidate will connect to OSMT sessions from that is capable of sustained 1.5 megabits per second download and 1.5 megabits per second upload speeds, and a data plan that has sufficient capacity for data usage associated with OSMT video conferencing sessions. The estimated monthly data usage to fully participate in the OSMT sessions is 5.2 gigabytes. (Data usage per hour of connection to OSMT video conferencing sessions is estimated to be 1.3 gigabytes per hour. Data usage will vary for each video conference participant and may be more or less than the 1.3 gigabyte per hour estimate. OSMT sessions are estimated at 4 hours per month.)
    i. If the candidate has access to a computer, laptop, tablet or smartphone that is WiFi capable, but does not have internet access that meets the requirements for participation in the study, the candidate will be offered the option of borrowing a Verizon 4G mobile hotspot that provides internet connectivity via Verizon's cellular data network, if any are available from the pool of OSMT mobile hotspots slated for loan to study participants. Ostomates that opt to borrow a mobile hotspot from the OSMT program will need to sign an equipment loan agreement. See agreement in Appendix 13 The mobile hotspot along with any required accessories, and a pre-paid return shipping label, will be shipped to the candidate at the address that they specify on the loan agreement.
3. Access to a private and relatively quiet environment such as a room in the candidate's place of residence to connect to the OSMT sessions from. This is important to afford privacy to the OSMT group.

b. OSMT candidates must validate their ability to successfully communicate via the Zoom video conferencing service by successfully completing a test video call with Arizona Telemedicine Program (ATP) helpdesk staff via Zoom.
    1. Zoom test call with ATP will validate that OSMT study candidates:
        i. Have access to and can operate compatible technology
        ii. Have the Zoom video conferencing client application installed
        iii. Are able to successfully join a Zoom online meeting by launching the Zoom application, entering a meeting number and their first name and the name of the state they are calling from (example Mike – Arizona), and then clicking "Join" to connect.

    iv. Can, via Zoom live video conferencing, both see and hear the ATP staff member that is testing with them, and can be seen and heard by the ATP staff member.
    v. Know how to reconnect to a Zoom video conference if they are disconnected unexpectedly for any reason during a live OSMT session.
    vi. Can access Zoom application controls and mute and unmute their microphone, and can disable and enable their live video camera image.
    vii. Know how to leave a Zoom meeting and exit the Zoom application.
    viii. Know how to view the active speaker and how to view other video conference attendees via the gallery view(s).
    ix. Has been advised of the importance of keeping their microphone muted when they are not speaking.
    x. Know how to monitor the image that their camera is capturing and have been advised on the basics of optimizing their image on camera.
    xi. Have the ATP technical support phone number in case of future need of technical support.
    xii. Have been advised to connect their PC/MAC/Tablet/Smartphone to an external power source for the duration of the OSMT Zoom video conferencing sessions as video conferencing is an intensive use of the PC/MAC/Tablet/Smartphone that will quickly drain its battery, if it is a battery powered device.
    xiii. Confirms that they have received printed version of the OSMT technology documentation for reference.

2. OSMT candidates that successfully complete the validation steps listed above will be transitioned to study participant status. Study participants will be contacted by their respective study accrual center for scheduling into an OSMT group.

9.3.2. Upon return of loaned devices from study participants, and before loaning to a different OSMT candidate or participant, tablets and/or mobile hotspots will be wiped down with a manufacturer approved cleaning process, and will have their content and settings erased and reconfigured with settings needed for use with the OSMT study.

9.3.3. As part of the informed consent

a. OSMT study participants are advised that OSMT sessions will not be recorded and that if they miss any part of an OSMT session for any reason, such as, but not limited to, technology or communications failure, that they should contact their OCN to address any concerns that they may have about their ostomy care.
b. OSMT study participants agree that they will not, by any means or technology, photograph, video record, or audio record any portion of the OSMT Zoom video conferencing sessions. This is to protect the privacy of everyone in the OSMT group.
c. OSMT study participant consents to allowing other study personnel and participants to see and hear them as well as allowing the OSMT session group they participate in

to potentially see anything in their camera's field of view and hear any sounds within their microphone's range.

9.3.4. For each scheduled OSMT session, OSMT session group members will join their assigned Zoom video conference by launching the Zoom application on their ATP validated PC/MAC/Tablet/Smartphone device and clicking Join Meeting. They will then enter the meeting ID number and their first name and click "Join". In case of technical difficulties, they will call ATP technical support for assistance connecting to the OSMT Zoom video conference session.

9.3.5. All OSMT video conferencing sessions will use a HIPAA compliant Zoom account acquired and managed by the University of Arizona, Arizona Telemedicine Program. OSMT study participants will receive instructions in the mail detailing how to connect to the OSMT education session calls.

9.3.6. ATP will receive study participant contact information and participant's status in the study, for purposes of providing technical support and shipping and receiving loaner equipment, if required, via verbal communications over telephone directly from study participant's, their caregivers, or study accrual site personnel. ATP will not receive or store study participant information electronically, except temporarily if participant information is left as a voicemail message. ATP will record study participant information in handwriting on paper. ATP will shred paper records of study participant information once both of the following conditions are met: 1. ATP has been informed by a study accrual site that a participant has completed their OSMT sessions or has withdrawn from participation in the study; and 2. Equipment loaned by the study to the participant, if any, has been returned to ATP per the participant loan agreement terms.

9.4 Sessions

Site coordinators will provide the ostomy nurse educator with the name of subjects who will be attending the sessions (use first names only). Attendance lists will be reviewed at the weekly research meetings. Introductions and attendance will be taken at each session and recorded by the group leaders in Tucson. They will also ask what type of device people are using. At the end of the session they will ask to rate 1-4 their ability to connect and how well the technology worked. Any individual issues reported by participants with respect to their ostomy care (e.g., equipment problems, difficulty obtaining supplies, etc.) either during the sessions or in communications with the site coordinators, will be referred to the local site ostomy nurse(s).

If all participants in a session are of the same gender, they will be asked if they are comfortable with the Peer Ostomate of the other gender staying on the session.

9.5 Survey Plan

We will survey HRQOL to measure short term (at the end of Session 4) and long term (6 months) sustainability for all participants.

Baseline – see 8.1

End of Sessions – Surveys will be mailed if requested one day following the last session or instructed on RedCap

6 month follow-up – Surveys will be mailed if requested one day following the last session or instructed on RedCap

9.6 Data Management

A 10% data quality check will be performed every 3 months, after which all data entered to the working database will be archived in the master database.

10.0 STUDY CALENDAR

	SESSIONS (X) AND FOLLOWUP (F)																														
	2016		2017												2018												2019				
Grp	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M
1	X	X							F																						
2		X	X							F																					
3			X	X							F																				
4				X	X							F																			
5					X	X							F																		
6						X	X							F																	
7							X	X							F																
8								X	X							F															
9									X	X							F														
10										X	X							F													
11											X	X							F												
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18																		X	X							F					
19																			X	X							F				
20																				X	X							F			
21																					X	X							F		
22																						X	X							F	
23																							X	X							F

11.0 CRITERIA FOR EVALUATION AND ENDPOINT DEFINITIONS

Study instruments and endpoints	Endpoints
Patient Activation Measure (PAM). The PAM uses a uni-dimensional, probabilistic Guttman-like scale that reflects a developmental model of activation that involves four stages: (1) believing the patient role is important, (2) having the confidence and knowledge necessary to take action, (3) actually taking action to maintain and improve one's health, and (4) staying the course even under stress. High internal consistency (alpha .87) and construct validity have been reported.	PAM (continuous 0 to 100, where 100 is most activated) Level 1: May not yet believe that the patient role is important (PAM ≤ 47.0) Level 2: Lacks confidence and knowledge to take action (PAM 47.1 to 55.1) Level 3: Beginning to take action (PAM 55.2 to 67.0) Level 4: Has difficulty maintaining behaviors over time (PAM ≥ 67.1)
Self-Efficacy to Perform Ostomy Self-Management Behaviors. Modified from Lorig	SE Ostomy Self-Management (1 to 10, where 10 is most confident)

Study instruments and endpoints	Endpoints
and colleagues' Self-Efficacy to Perform Self-management Behaviors Scale, an outcome measure for Chronic Disease Management Interventions, this scale represents 8 domains with reported Cronbach's alpha for original scales: physical activity (.83), information seeking (NA), support (.77), communication with HC providers (.90), ostomy management (.87), social and recreational (.82), symptom management (.91), and depression (.92).	
COH-QOL-CRC Scale. T0he City of Hope QOL-Ostomy questionnaire (developed by Consultant M. Grant) was designed for all adult ostomates, and has a 4-dimensional HRQOL (physical, psychological, social and spiritual well-being) framework gathering demographic, clinical history, personal (e.g., diet, work, and activity) and clinical data. Reported Cronbach's alphas are .94 total scale and .80-.90 subscales. Family version will be used for caregivers.	COH-QOL-CRC Total COH-QOL-CRC Physical COH-QOL-CRC Psychological COH-QOL-CRC Social COH-QOL-CRC Spiritua1 (0 to 10 scores)
Ostomy Knowledge Questionnaire. This brief survey, derived at City of Hope, was modified for the pilot study and further adapted by the study team to ensure major topics were included.	Knowledge score (0 to 11)
Hospital Anxiety and Depression Scale (HADS) The HADS is a self-assessment instrument for detecting anxiety and depression in medical outpatients. Reported Cronbach's alpha .84-.89.	Separate scores for Depression and Anxiety, 0-7 = Normal; 8-10 = Borderline abnormal; 11-21 = Abnormal
Burden of Ostomy Care Based on the model developed by Given, et al., for long-term care, this survey will gather participant self-reports of ostomy-related medical care use, productivity losses, and associated out-of-pocket expenses and time spent for ostomy care in general, and the OSMT intervention, caregivers, and paid housekeeping.	ostomy-specific family resources ostomy-specific health care services ostomy-related family financial burden types and levels of effort of OSMT intervention personnel specific equipment, supplies, and informatics support required

12.0 STATISTICAL CONSIDERATIONS

12.1 General. Aim 1 will be analyzed with linear mixed models for repeated measures. Aim 2 will utilize a variety of sources and methods to enumerate the intervention program and ostomy-related family resources in each study arm.

If a subject misses Session 3 or Session 4 or both, they can make up the missed session(s) with the next 1 or 2 scheduled groups. If they miss both chances to make up the sessions, they will be asked to do the surveys and will be analyzed as a separate group using an intent-to-treat contrast.

12.2 Aim 1: Using our enhanced telehealth techniques, determine if **patient activation**, self-efficacy, ostomy-related knowledge, and HRQOL will be improved and sustained over time in the online interactive communication Ostomy Self-Management Telehealth program (OSMT) curriculum compared to a UC group.

Under an intent-to-treat approach, change in outcomes will be evaluated longitudinally with linear mixed models, testing the effect of study arm adjusted for potential confounders. Such models evaluate both associations and rates of change, accounting for within-subject correlation. The Primary Outcome will be PAM. Secondary Outcomes include SE, COH-QOL-CRC scales, and Ostomy Knowledge. Post hoc contrasts will evaluate effect of training (baseline to post) and whether effect is sustained after training (6 month post to follow-up). Standard multivariable modeling procedures will be used to select or eliminate potential confounding variables, starting with candidate variables that are biologically plausible or found to be associated with endpoint change scores (baseline vs. follow-up) in bivariate analyses with a p-value of less than 0.20. Potential candidate covariates and confounders include (but are not limited to) CG participation in training sessions, depression (HADS), time since surgery, ostomy type, age, sex, stage, anticipated permanence of ostomy, and pre- or post-surgical radiation or chemotherapy. We will explore potential interaction for plausible effect modifiers, such as gender, or having a CG**.**

The COH QOL-CRC assesses ostomy burden and care abilities, including time taken to perform daily ostomy care, comfort with ostomy care, comfort with diet, adjustment of diet for ostomy, appetite, clothing and other problems with ostomy placement. We will also measure clinically related outcomes, including medical attention for problems with bowel, bladder, or ostomy. Changes in these responses will be compared between treatment groups with linear mixed models, chi-square tests or t-tests, as appropriate.

Descriptive statistics will be presented on attendance at training sessions. We will describe and contrast quantity and type of ostomy-care help (professional and lay) sought outside of the training sessions, including calls for support from study Peer Ostomates. Self-reported Peer Ostomate call frequency and duration will be corroborated with a call log maintained by the Peer Ostomate. We will evaluate hypothesized association between OSMT attendance level and outcomes using linear mixed models that have a weighted attendance score as an independent variable**.** Alternative attendance scores will be tested that give weight to ostomy-care help outside of training sessions.

12.3 Aim 2: Determine the differences in ostomy-related **medical care utilization** and family **financial burden** imposed on survivors between OSMT and UC groups.

Hypothesis 2.1: OSMT telehealth subjects will use fewer **ostomy-specific** family resources in the 6 months after OSMT compared to UC subjects.

Hypothesis 2.2: OSMT telehealth subjects will use fewer **ostomy-specific** health care services in the 6 months after OSMT compared to UC subjects.

Question 2.1: What is the difference in the overall levels of **ostomy-related** family financial burden between OSMT and UC groups?

Question 2.2: What are types and levels of effort of OSMT intervention personnel and specific equipment, supplies, and informatics support required to implement and operate a successful OSMT program; what are participants' levels of use of ostomy-specific health care services and supplies; and what are the time and in-home requirements for participating in OSMT for survivors and their family caregivers. This information is required for replicating our OSMT intervention in the event that we find it improves the primary and secondary outcomes of OSMT participants.

The focus of Aim 2 is to compare medical care utilization, patient burden, and impact on patient time and activities for individuals participating in OSMT with those receiving UC. Assessment of these measures is critical for patient-centered care, in order to minimize the financial burdens and non-financial impacts (e.g., time commitment) of new interventions. To address hypotheses 2.1 and 2.2, we will collect detailed information on use of medical care services and supplies related to ostomy care, patient burden for these services and supplies, required patient and caregiver time for ostomy care, interference with employment and volunteer activities, and perceived financial burden. Details regarding the four types of information to be collected for Aim 2 are presented below. We also provide information on assessment on study activities to address replication of the OSMT intervention (Question 2.2).

12.4 Ostomy-Related Medical Care Supplies and Services. We will collect information from study participants on their use of supplies and services related to ostomy care and their out-of-pocket expenses for these supplies/services. Ostomy-related services/supplies will be categorized in two separate groups:

- Medical care encounters and ostomy supplies including: OCN visits; other ostomy-related medical care encounters (including physician and ED visits); surgical revision of stoma; ostomy appliances, wafers, bags; bowel medications; and skin medications.
- Other equipment, household modifications related to ostomy and ostomy care, including: waterproof covers on for mattresses and furniture; bathroom remodels to accommodate ostomy care; special clothing to cover ostomy bag; alteration of clothing to cover ostomy bag, and transportation to and parking for ostomy-related medical care.

12.5 Ostomy-Related Time Requirements. We will also collect ostomy-related time requirements, that is, patient time required to obtain ostomy care, perform ostomy bag and wafer management, and clean ostomy bag spills. We will also ask study participants about use of both formal and informal CGs, time for caregiving activities related to ostomy care, and types of assistance (e.g., with housekeeping and shopping) required due to ostomy and ostomy care.

12.6 Employment/Volunteering Effects. All participants will be asked about their current employment status and volunteer activities (including usual hours per week devoted to work and volunteering). All subjects will be asked if their ostomy-related management and health problems led to work-loss days, sick leave days, leave without pay, changes in amount of hours worked and/or volunteered, loss of employment or volunteer opportunity, job-related corrective actions, and impaired job search and/or volunteer activities.

12.7 Perceived financial burden. The financial impact of ostomy and ostomy care will likely reflect patient burden for ostomy services and supplies as well as patient and caregiver time and interference with employment. Patients will be requested to provide information on perceived financial burden associated with ostomy-related care and on deferral of doctor visits and medication pick-up/refills because of financial pressures.

Information for Aim 2 will be collected using a self-administered patient questionnaire. (Appendix D)

12.8 OSMT Intervention Replication Model. Disseminating/replicating our OSMT intervention program requires: 1) an intervention operations manual; 2) official versions of all intervention materials for interventionists and participants; and, 3) a fully-annotated staffing/budget model. One cannot expect to realize the same outcomes observed from our research implementation of OSMT if subsequent replications are under-budgeted and/or "trimmed" relative to our research and demonstration implementation. Another replication challenge is that the original research proposal may not be an appropriate replication guide because proposal budgets are typically cut by the funding agencies, and research teams revise their interventions in accordance with their lower budgets and implementation obstacles encountered. Consequently, research implementations often differ substantially from the intervention program initially proposed and peer-reviewed. The observed outcomes of an intervention reported in the major outcomes publications were achieved by the program elements that were actually delivered, not by the protocol and resources described in the funded research proposal. We will implement a project resource tracking system and start it as quickly as possible after notice of grant award (so we can document intervention fixed resources and start-up activities and resources, such as interventionist training) and planning efforts prior to the intervention launch. This will allow us to provide actual rather than projected costs associated with the OSMT intervention.

Our OSMT program replication model will include the incremental physical resources required to implement the OSMT program, excluding research-specific inputs. We will follow the methodology outlined in Ritzwoller and colleagues[42] to collect intervention-related inputs in real time (vs. retrospectively). Interventionist and research staff will complete templates weekly to capture the following data: 1) time spent hiring and training interventionists and Peer Ostomate mentors; 2) time incurred preparing training syllabi, Webinar presentations and handouts, participant homework exercises, Webinar attendance records, e-mail and telephone call logs, participant chart folders, etc.; 3) marketing and advertising activities for participant recruitment; 4) Webinar preparation and set-up time, direct Webinar contact time, post-Webinar wrap-up and charting; 5) Peer Ostomate mentoring time; 6) e-mail and telephone contact time between participants and interventionists/peer mentors during and between intervention sessions (number of contacts, duration of each contact, and time required to chart each contact); 7) intervention IT and web conferencing equipment; 8) staff time spent helping participants obtain web appliances and internet service providers, if needed; 9) study-provided web appliances; and, 10) for participants/mentors who are informal caregivers, substitute caregivers to enable participation in OSMT webinars, if necessary. We will collect data on patient-related inputs via survey.

In assessing the resources used by the OSMT intervention, we will pull out research inputs (i.e., resources used only because this is a comparative study rather than a "real-world" clinical program).[42,43] These include project research meetings, surveys to collect research measures (excluding intervention fidelity measures), IRB/HIPAA compliance, and consenting participants. For those items that can be attributed to research and the intervention (OSMT management by PI, project manager time, joint research/intervention project meetings, etc.), we will estimate on a monthly basis the percentage of project intervention labor effort attributable to research and subtract from total project effort.

12.9 Webinar Intervention Staffing. The financial accounting systems of our participating research institutions track proportion of staff time charged to this research project. We will obtain numbers of hours employed for all research staff whose salaries are paid by the project budget. These generic classes of labor resources are producing both research and clinical intervention outputs. We will require all staff to maintain time logs of their project-related activities, with an emphasis on identifying research-specific tasks, intervention-specific tasks, and joint research/intervention tasks. For example, data analysts working on research data and statistical analysis tasks represent a research input. Programmers working on an intervention tracking/scheduling system represent an intervention resource. The most intensive class of labor—investigators—have responsibility for both intervention implementation and fidelity, as well as for designing data collection instruments and performing statistical analyses. Hence, we will require each investigator to apportion their project-specific effort across classes of research and implementation tasks. We will review and revise the time-task data collection instruments so that all staff understands the definitions of the respective tasks and have places to report all their relevant direct effort activities.

12.10 Non-Labor. We will also track all classes of non-labor intervention inputs, including study-furnished web appliances, intervention office supplies, reference materials for interventionists, auto mileage, office space rental, communications (telephone/internet/Web), mailings (for sending intervention materials to interventionists and participants), etc. For purposes of clinical replication, specificity in tracking **quantities of specific inputs** is an essential need. **Note:** We are not proposing to collect or analyze incurred expenses for this study as these will vary substantially over time and place.

12.11 Avoidance of Bias. Randomized trials tend not to be vulnerable to confounding, observation, and information bias. We will further control confounding in multiple regression analysis. Selection bias will be avoided by blinding the assessment team to randomized arm prior to assignment. We will also collect demographic and clinical data, as permitted, on non-participating eligible patients for comparison. We do not expect substantial loss to follow up, given the duration of follow up, our reminder systems, and ability for make-up webinars. If we find there is participation bias by limited times, we will vary times offered for the sessions.

12.12 Qualitative Data. We have an open-ended question at the end of the questionnaire in Appendix D – Survivor/Family Use of Ostomy Care: "… Please share with us the **greatest challenge** you have encountered in having an ostomy." As indicated in the proposal, qualitative content will be placed into an Excel file. Using a qualitative, grounded theory approach[44] and content analysis[45], all survey responses will be reviewed by at least two of the investigators working independently to create a list of unique topics from the data. Codes for these topics will be assigned and grouped into relational categories. The resulting code book with categories and topics will be reviewed separately by two coders in an attempt to resolve any discrepancies in coding. The codebook will then be shared among the entire Research Team, discussed, and any data discordantly coded will be discussed for refinement and consensus. The resulting content will be used to provide data for manuscripts in the same way it was used in the Research Team's past publications with similar text data.[46-50]

12.13 Sample Size and Power. Total potential sample size 240 (up to 120 per arm), to ensure at least 75 per arm completing the study with complete baseline COH-QOL-CRC scaled items, assuming a 15% dropout rate. This will maintain sufficient power for the COH-QOL-CRC scaled items. The larger sample size for the primary endpoints Patient Activation Measure (PAM) and ostomy management self-efficacy (SE) will provide 80% power to detect a 2.75 change in PAM and a 0.50 change in SE, which is not considered excessively powered. Detectable differences based on variances observed from our R21 for PAM and SE, as well as from our R01 for COH-QOL-CRC subscales. We changed two items slightly on the self-efficacy questions to make them ostomy-relevant. Our observed variation for ostomy management SE is consistent with the original form of symptom management SE across different patient samples reported by Lorig's group (SD range 2.1 to 2.4).[51-57] We will examine the reliability of these items and expect them to have a Cronbach's alpha of $\geq$ 0.75. Calculated detectable differences were based on the following assumptions 1) alpha of 0.05, 2) within-subject correlation on repeated measures of 0.60. Estimates are based on repeated measures multivariable modeling, adjusted for baseline, with two follow-up measurements. Also shown for comparison are two rough indices of clinically important differences. Sufficient research has not been performed on these scales to determine with certainty a minimal clinically-important difference that is anchored on participant self-assessment of health status. An alternative suggested by Sloan[58] is the empirical rule effect size (ERES) method to judge minimally important differences (MID) in outcome measures. We also present 50% of the observed sample SD, a common rule-of-thumb for clinically meaningful differences.[59] The table shows that even with substantial shortfall in sample size (down to 65 per group) we still can detect differences below the estimated MID.

Detectable Outcome Differences with 80% Power						
Measure	**SD**	**N= 75**	**N=70**	**N=65**	**ERES[58]**	**.5 SD[59]**
Patient Activation Measure	13	3.4	3.5	3.6	8.0	6.5
Ostomy self-management self-efficacy	2.3	0.60	0.62	0.64	0.80	1.2
COH-QOL-CRC Total	1.6	0.42	0.43	0.45	0.88	0.8
COH-QOL-CRC Physical	1.8	0.47	0.49	0.51	0.88	0.9
COH-QOL-CRC Psychological	1.8	0.47	0.49	0.51	0.88	0.9
COH-QOL-CRC Social	2.1	0.55	0.57	0.59	0.88	1.1
COH-QOL-CRC Spiritual	2.2	0.57	0.59	0.62	0.88	1.1

13.0 STAKEHOLDER OVERSIGHT

13.1 STAKEHOLDER ROLES

13.1.1 Ostomy Nurses: Ostomy Nurses (WOCNs) will have dual roles in this study: 1) Session leaders, and 2) Research Team participants. Ostomy nurses have actively participated in analysis of the results of the pilot study (Ref 6), as well as the design of the current proposal. In particular, WOCNs have assisted with: 1) identification of cancer survivor and caregiver needs related to ostomy care; 2) addressing nursing deficiencies for ostomates; 3) the curriculum design and plan of delivery; and 4) features of the comparator arm. They will co-lead the sessions and ensure participant and research goals are met. They will participate in weekly calls to report on sessions, help troubleshoot as needed, and ultimately prepare and present findings. The non-Tucson Ostomy Nurses will also be asked to participate in sessions and calls. They may impart suggestions as needed during the calls, and may be asked to lead in future calls. For Usual Care participants, if they have never interacted with an Ostomy Nurse, they will be offered at minimum a telephone consultation.

13.1.2 Peer (buddy) Ostomates: Peer Ostomates are patients who live with ostomies and are well-versed with the curriculum and study objectives. They will have dual roles in the study: 1) Session co-leaders, and 2) Research Team participants. Peers who participated in the pilot will also participate in this study, although peers at other sites, who have been screened and agree to participate, will also be trained in the program and develop rapport with the ostomy nurses who will co-lead sessions. They will also be expected to participate in weekly research calls and impart their thoughts on the sessions and issues that need to be addressed. They will participate in presentation of findings, including at local ostomy group meetings and with major publications.

Peers will be trained over the phone by the PI. The curriculum and the protocol will be reviewed, as well as their roles, and to recommend the participant see their physician for any clinically related issues.

Peers will keep a log of any phone calls they receive, including date, time, length of call, and subject discussed. This will be relayed to site coordinators on a weekly basis.

13.2 OVERSIGHT COMMITTEE

13.2.1. Stakeholder Advisory Committee. The SAC is designed to ensure integrity and focus of the study, as well as be a resource for accrual issues, unforeseen problems, and interpretation of results. A well-known role of Patient Advocacy groups in cooperative groups is to troubleshoot accrual issues and assist in finding practical solutions. In addition, unforeseen participant concerns are bound to appear, and an expert panel that meets regularly, as well as on an emergency basis, is an advantageous resource to have in a multi-site study. Finally, while the Research Team is experienced, ostomy nurses and peers will be on the Research Team, and we anticipate members of the SAC will play a role in data interpretation.

13.2.2 SAC Qualifications: The SAC will be composed of ostomy nurses, peer ostomates, patients, and caregivers who have participated in our program to date in Tucson or those recommended by clinicians at City of Hope or Yale. In addition, we will add additional members (peer ostomates and patients) who have completed the telehealth intervention and are interested in continuing to participate with the research as needed. We will have a maximum of six non-Research Team members of the SAC, with an equitable distribution of patients and caregivers. The group will determine its chairperson, who will be expected to report to the Research Team. Members of the SAC (except the Research Team participants) will be compensated for their time with $100 per meeting.

13.2.3 Recruitment to the SAC: Development of our recruitment plan for the SAC will occur during the first meeting of the Research Team at the initiation of the study. Potential SAC members will be reviewed by the Research Team from the first group of participants. They will be invited by a Stakeholder member of the Research Team.

13.2.4 Meetings of the SAC: A telephone conference line will be established for the quarterly meetings of the SAC. The PI will participate in the first meeting providing an overview of the study and outlining the responsibilities of the SAC. One leader will be designated. High priority items for the agenda will be related to recruitment activities. The SAC minutes will be circulated to the Research Team, and the SAC leader will present them at the next Research Team meeting. Subsequent agendas for the quarterly meetings will include a discussion of recruitment to date, and any problems/challenges in study implementation. Feedback to the Research Team will occur via minutes from the SAC. The Research Team will provide a report of the study to date at each meeting. Activities of the SAC will be included in the annual project reports.

13.3 WEEKLY MEETINGS

Weekly meetings will be held via teleconference and include the PI, site PIs, co-investigators, consultants, and Peer Ostomates. Calls will be led by the PI. If he is not able, they will be led by Co-Investigator Dr. Sun or Co-Investigator Dr. McCorkle. There will be no call in proximity to major holidays.

13.3.1 Call Schedule

Calls will be held every Wednesday at 11:00am Pacific (2:00pm Eastern).
Call number: 1-888-450-5996

Access code: 561908# (Leader code: 5619081#)

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15.0 APPENDICES

15.1 Appendix 1 Curriculum

Session 1 - Introduction (5 min., Session 1, Ostomate folder)

You are here to participate in an intervention to help in caring for and coping with your ostomy. We want to remind everyone that participation is completely voluntary and you may withdraw at any time. The sessions are confidential; only first names will be used. Please respect the privacy of others. Please do not, by any means or technology, photograph, video record, or audio record any portion of the OSMT Zoom video conferencing sessions. If you are disruptive to others, we will ask you to no longer participate. In your packet, there is a participant's agreement on conduct. Please only one person speak at a time and allow others to talk; everyone will have a chance to share with the group. If you are disruptive during the session, you may be asked to leave that session. Remember, you can contact your local Peer Ostomate outside the sessions if you need additional assistance. In the interest of safety, we must remind everyone not to join the video conferencing sessions while driving.

We also would like to do a quick roll call. Again, we will be using only first names. Please also tell us what kind of device you are using (e.g. iPad, Apple PC, iPhone, etc.).

Before we begin, did everyone fill out the surveys either electronically or mailed? If the surveys were mailed to you, were they mailed back?

Next, please refer to the page in your packet related to instructions for the telehealth connection. If you are using a smartphone or iPad, please make sure they are charged or plugged in, as these sessions use a lot of energy. Please mute your phone, and remember to unmute if you want to speak. To mute/unmute on a PC/laptop, move the cursor to the lower left corner of your screen until the controls appear in a bar at the bottom, then click on the microphone icon to toggle on/off; on a smartphone or iPad, touch the screen to make the controls appear and touch the microphone to toggle on/off. We encourage participation from everyone. If you are on a phone, you can use your finger to scroll over to see different participants; on a PC/laptop you can see all participants at once by clicking on the Gallery View icon in the upper right corner of the screen. Feel free to ask questions during the session, but we hope not to spend too much time with technical issues. If you have connection, video, or audio problems, disconnect and contact the Arizona Telehealth Program helpdesk at 520-626-6978, then try to reconnect. If you have continued problems, we will get you technical support prior to the next session or before you do a makeup session.

We would like to introduce ourselves as the leaders of this program (Introduction of Ostomy Nurse/Peer Ostomate buddies).

Before we get started, we will provide an overview of the five training sessions. Session 1 will give you the background of an ostomy and the effects it may have on your life (particularly, clothing and diet). Session 2 will provide information on your social well-being. For example, we will help train you in how to maintain and increase social and interpersonal relationships. Caregiver Session is for your spouse/significant other/friend. This session will provide your spouse/significant other/friend with knowledge about your ostomy and ways of coping with differences in the relationships since the ostomy was placed. Session 3 will provide information on healthy lifestyles, psychological (finances/cancer) health, and nutritional intake specific for your new ostomy diet. Session 4 will be a review session in which your spouses/significant others/friends are also invited to review any items that were missed and possible resources for help in the future.

We are reimbursing each of you $50 at completion of the initial surveys, $50 at completion of surveys at the end of the intervention sessions, and $50 at completion of the follow-up surveys six months after the end of the sessions, for a total of $150. We are reimbursing your spouse/significant other/friend $25 for each of the two sessions they attend, for a total of up to $50.

If no questions, we will begin.

Session 1 Teaching Points (30 min)

A. Teaching Points

1. What is an Ostomy?
    a. An ostomy is a surgical opening onto the abdomen. There are three common types of ostomies which will be discussed.
        i. Colostomy—created by bringing a portion of the large intestine through an opening on the abdomen.
        ii. Ileostomy—created by bringing a portion of the ileum (small intestine) through an opening on the abdomen.
        iii. Urostomy (typically known as an Ileal Conduit)—created when bladder has been removed. A small piece of small intestine (ileum) is surgically removed and used as a conduit. Occasionally large bowel is used. The two ureters from the kidneys are attached to this piece of ileum creating the conduit. The one end of bowel is sutured closed and the other end of the conduit is brought out through the abdominal wall creating the stoma.

2. Characteristics of a healthy stoma.
    a. Stoma is not painful. It has no nerve endings.
    b. Always red and moist.
    c. May bleed easily.

3. Associated diseases that can lead to an intestinal ostomy
    a. Cancer – the focus of this program
        i. Rectal Cancer
        ii. Colon Cancer
        iii. Other cancers
            a) Inflammatory Bowel Disease
            b) Diverticulitis
            c) Injury

4. Associated diseases that can lead to a urinary ostomy
    a. Bladder Cancer - the focus of this program
    b. Injury

5. What type of ostomy do you have?
    a. What is your understanding of your ostomy?
    b. What are your goals as an ostomate (person with an ostomy)?
    c. An ostomy may be temporary or permanent. Which do you have?
    d. How do you feel about your ostomy?

6. Be familiar with how you react to different appliances/pouches and certain foods

7. If your ostomy supplies make you feel uncomfortable, try another pouching system

8. Clothing
    a. Immediate changes after surgery, but once healed the optimal goal is to be in pre-operative clothing
    b. Must be recognized that you may not feel comfortable with old clothing
    c. New clothing options
        i. Suspenders
        ii. Loose fitting clothes
        iii. Overalls
        vi. Specialized clothing http://www.securicaremedical.co.uk/clothing-for-ostomates.asp

9. Effects of Nutritional Intake
    a. Foods or types of foods affect everyone differently, so it is important to determine certain foods to avoid or not eat before certain occasions
        i. Examples: Spicy foods, nuts, and seeds
        ii. Food or types of foods that are helpful
        iii. Plenty of fluids (water or juices), particularly in ileostomate and urostomate

Session 1 Equipment Skills Lab (30 min.)

B. Skills Lab

We recognize many people are not comfortable with ostomy supplies yet. This part of the session is to review current and other possible options available in the future.

1. Checking out the equipment: Appliances, Pouches, Belts

2. Skin Preps: Helps lengthen wear time of wafer and pouch, and prevents skin irritation

3. Skin Adhesive Removers
    a. Used to remove adhesive after applying the wafer and pouch (Not recommended for routine use)
    b. Some ostomates find it easier to reapply wafer if some adhesive is left on the skin

4. Deodorizers
    a. Used to reduce odor
    b. Tablet form you eat or drop into pouch
    c. Vents are also available to apply to pouch to release gas and deodorize it as it passes through the vent

5. Stoma Patches and Caps
    a. Used to prevent leakage when colostomy is irrigated and stool is controlled
        i. Pouch Covers: A cover that goes around your pouch to absorb sweat and to cover the contents of the pouch

ii. Convexity
a) Skin irritation can occur from leakage on the skin
b) Use of convex wafer makes the stoma protrude from skin and redirects flow of urine or feces into pouch

6. Pouches
    a. One Piece System
        i. The wafer and pouch are attached as one unit
        ii. Advantages
            a) Quick and easy to use
            b) Less Bulky (One vs. Two Parts)
    b. Two-Piece System
        i. The wafer and pouch are two separate pieces and are attached by attaching the wafer connecter to the pouch connector
        ii. Advantages
            a) Can change bag size for different moments
            b) Easier to relieve gas
        iii) Disadvantage
            a) Since attached wafer to bag, error may occur causing leakage
            b) May be difficult to attach wafer to pouch and abdomen if ostomate is visually impaired

7. Belts
    a. Some ostomates prefer to wear a belt
        i. Attach to wafers using a special tag

8. Daily Care
    a. Colostomy bag should be emptied when reaches 1/3 gas or stool
        i. Achieve pouch adherence up to 5 days
    b. If you use the reusable pouches, make sure they are thoroughly cleaned with mild soap and water

9. Disposal of ostomy bag

10. Reviewing Routines

11. Emergency Kits

Session 1 Assignments (5 min)
C. Assignments
1. Goal Development for Session 2

When you completed the first survey packet, it contained a goal development sheet. We are now going to ask you to please describe the goals you have in regards to your ostomy care.

2. Monitoring timed daily outputs/Nutrition Log by Time

Please monitor your daily bowel movements and how they are affected by different situations or foods. These will be discussed at upcoming sessions and will be useful if issues were written down.

Session 1 Resources (5 min)

D. Resources

Please refer to the section in your packet for resources outside of this training session. If you wish to contact one of the Peer Ostomates outside of this session, their phone numbers are: [read off name and phone number of Peers]

Connectivity

E. Prior to disconnection, we want to ask on a scale of 1-4 your ability to connect to the session and your impression of the technology.

Session 2 - Introduction (5 min., Session 2, Ostomate folder)

We want to remind everyone that participation is completely voluntary and you may withdraw at any time. The sessions are confidential only first names will be used. Please respect the privacy of others. Are there any questions from last session?

We are now going to do a quick roll call, using first names only. Please also tell us what kind of device you are using (e.g. iPad, Apple PC, iPhone, etc.).

Session 2 Scenarios (40 min)
A. How to maintain and increase social/interpersonal relationships

Some ostomates who have an ostomy have problems in social/interpersonal relations. The major goal of this session is to maintain and increase your social and interpersonal skills. Please use the following scenarios to guide our conversations.

1. Scenarios-Paired discussion
    a. How to describe to others
        i. Dating
            a) You are out on a new date
            b) You are intimate for the first time with new partner
        ii. Spouse/Significant Other
            a) You are talking with your spouse about your ostomy
            b) Initiating intimacy with spouse for first time since surgery
        iii. Social Activities
            a) Explaining why you are leaving the room to change your bag
            b) Explaining why you may need help changing your pouch
        iv. Other Family Members; e.g. Children/Grand Children
        v. Practice Talking about ostomy
        vi. What to do about Gas/Odor
            a) During job interview your ostomy makes noise
            b) You are at church and someone notices a bulge on the side of your clothing and asks about the bulge
        vii. Other
            a) Are there any scenarios you would like to discuss

2. Scenarios-Group Discussion
    a. Out into public everyday

    Please describe any ways that you may cope with your ostomy out in public every day. For example, how do you deal with public restrooms?

b. Timing of Intestinal activity in relation to social interactions
Please describe any types of foods you avoid or ostomy care techniques before you go out for social occasions.

c. Sexuality and Intimacy
Please describe any issues you may have with sexuality and intimacy. For example, is your sexual activity the same as before your ostomy?

d. Finding an Ostomate Buddy
Please describe any issues you may have or have already encountered related to finding a person that you can talk to about issues related to your ostomy.

e. Psychological Impact
Please describe any psychological impact you may have had from your ostomy. For example, you don't feel like going out sociably since your ostomy.

f. Managing Morbidities
Please describe any preexisting conditions that may influence the daily care of your ostomy and how you have dealt with the limitations as a result of the condition.

g. Managing other symptoms (fatigue, etc.)
Please describe how you have managed any other symptoms you may have related to your ostomy. For example, you are too tired to go out to the store to go shopping.

h. Other
Please describe any other issues you would like to discuss as a group.

Session 2 Problem-Solving Training (20 min)
B. Being Prepared: Creating an Emergency Ostomy Care Kit
It is very important to be prepared to care for your ostomy when away from home. Many ostomy supply companies have an emergency kit that works well when issues arise when away from the comforts of your home. These kits can be purchased or created by yourself geared towards your needs. Here are some examples.

1. Review Products and equipment
    i. Being Prepared when away from home
        a. A kit for extra supplies, extra pouches, and cleaning packet
        b. Extra Clothes/undergarments
        c. Water Bottles
        d. Other?
            i) What to do if pouch leaks?

Session 2 Assignments (10 min)

C. Assignment

1. Goal Development and review

Using the Goal Development sheet please review the goals you have in regards to your ostomy care.

2. Practice talking with one new person

In the period before your next session please take the time and talk with a new person about your ostomy. For example talk with your neighbor or family member who is not your caregiver. Please fill out worksheet and let us know how the interaction went.

Session 2 Resources (5 min)

D. Resources

Please refer to the section in your folder for possible resources outside of this training session. We are now going to review the resources. If you wish to contact one of the Peer Ostomates outside of this session, their phone numbers are: [read off name and phone number of Peers]

Connectivity

E. Prior to disconnection, we want to ask on a scale of 1-4 your ability to connect to the session and your impression of the technology.

We also want to remind you that the Caregiver session is for your support persons only and both you and your support person will have the opportunity to attend Session 4 together. If you need to assist your support person in setting up the videoconference connection for the session, we ask that you please do that and then leave the room.

Caregiver Session - Introduction (10 min., Caregiver Session, Spouse/significant other/friend folder)
We want to remind everyone that participation is completely voluntary and you may withdraw at any time. The sessions are confidential only first names will be used. Please respect the privacy of others.

We also want to remind you that this session is for support persons only and both ostomates and support persons will have the opportunity to attend Session 4 together. If ostomates need to assist their support person in setting up the videoconference connection for the session, we ask that you please do that and then leave the room.

Before we begin, we will do a quick roll call using first names only. Please also tell us what kind of device you are using (e.g. iPad, Apple PC, iPhone, etc.).

This is a study examining training sessions geared at enhancing ostomy self-management for cancer survivors. You are here because you are a Spouse/Significant Other/ Friend of someone that has an ostomy.

The purpose of this session is to address the support and adjustment of you as caregivers/family support group members to a person with an ostomy. This session will provide the opportunity for you to ask questions about ostomies and ostomy care. This session, lasting about an hour to an hour and a half, will include a 10 min class evaluation form. The things that will be discussed during the session may create a risk of embarrassment in talking about and learning to care for an ostomy. You will not be forced in any way to speak in front of others if you feel embarrassed. Although we have tried to avoid risks, you may feel that some questions [or tasks] we ask you to do may be stressful or upsetting. If this occurs you can stop participating immediately.

By providing the same training session to you that the ostomate receives, it may improve your ability to support them as they learn ostomy self-care skills and adjust to having an ostomy. You will be paid up to $50 dollars for participating ($25 for each of two sessions attended).

Caregiver Session Teaching Points (10 min)
A. Teaching points
1. What is an ostomy?
    a. Colostomy—created by bringing a portion of the large intestine through an opening on the abdomen.
    b. Ileostomy—created by bringing a portion of the ileum (small intestine) through an opening on the abdomen
    c. Urostomy (typically known as an ileal conduit)—created when bladder has been removed. A small piece of small intestine (ileum) is surgically removed and used as a conduit. Occasionally large bowel is used. The two ureters from the kidneys are attached to this piece of ileum

creating the conduit. The one end of conduit if sutured closed and the other end of conduit is brought out through the abdominal wall creating a stoma.

2. Characteristics of a healthy stoma
    a. Stoma is not painful. It has no nerve endings
    b. Always red and moist if healthy stoma
    c. May bleed easily

3. Associated diseases that can lead to an intestinal ostomy
    a. Cancer
        i. Rectal cancer
        ii. Colon cancer
        iii. Other cancers
    b. Inflammatory Bowel Disease
    c. Diverticulitis
    d. Injury

4. Associated diseases that can lead to a urinary ostomy
    a. Bladder cancer
    b. Injury

5. What type of ostomy does your ostomate have?
    a. What is your understanding of an ostomy
    b. What are your goals as a caregiver of an ostomate
    c. An ostomy may be temporary or permanent. What type does your ostomate have?
    d. How do you feel about his/her ostomy?

6. Are you familiar with the different pouching systems?

7. Clothing
    a. Does your ostomate have any problems with clothing?

8. Effects of Nutritional intake
    a. Foods or types of foods affect everyone differently, so it is important to determine certain foods to avoid or not eat before certain occasions
        i. Examples: Spicy foods, nuts and seeds
        ii. Food or types of foods can be healthful
        iii. Important to drink plenty of fluids, particularly an ileostomate or urostomate

Caregiver Session Major Issues (30 min)

A. Major issues of experience and ostomy care

We are going to discuss major issues or experiences of ostomy care with spouses/significant other/friends of ostomates with ostomies. In particular we want to know what you already know about ostomy care, issues you feel you need to know, possible caregiving goals, and how to deal with ostomy care issues.

1. What do they know?

What does everyone know about ostomy care?

2. What do they need to know?

What are some issues you would like to know related to ostomy care?

3. What are your caregiving goals?
    a. Are you the primary care taker? Are other family/friends involved in caregiving?
        i. QOL is better if they are their own caretaker
        ii. How independent is the patient with ostomy and what is your role with the ostomy?
        iii. Any other medical problems that prevents the patient from being their own caregiver?

4. How to deal with ostomy care issues
    a. Odor and leakage
    b. Place to do care
    c. Set up bathroom
    d. Procedure to get rid of full bags
    e. Do you have an emergency kit?
    f. Disposal of ostomy bag

5. Review Equipment

Session 3 Nutritional Dietary Issues (5 min)

B. Nutrition/Dietary issues

We are going to discuss possible Nutritional/Dietary issues related to their ostomy. In particular are there any foods that cause increased intestinal activity?

1. Who does the grocery shopping and cooking?

2. If spouse/significant other/Friend does the grocery shopping do you buy specific items for the ostomate?

3. Review Nutritional log

Please refer to the folder for your spouse/significant other/Friend’s nutritional logs.

    a. Is there any food in particular that affects your spouse/significant other/Friend?

Caregiver Session Clothing Issues (5 min)

C. Clothing issues

1. Immediate changes after surgery

2. Once healed optimal goal is to be in pre-operative clothing

3. Must be recognized that you may not feel comfortable with old clothing

4. New Clothing options
    - a. Suspenders
    - b. Loose Fitting Clothes
    - c. Overalls
    - d. Specialized Clothing
        - i. http://www.securicaremedical.co.uk/clothing-for-ostomates.asp

Caregiver Session Sexual Intimacy (10 min)

D. Sexuality/Intimacy

We are going to discuss sexuality and intimacy with an ostomate. This topic is sometimes difficult to talk about so please remember to respect others in the session. We would like to open up a conversation on how you can help support intimacy and sexuality in your relationships with an ostomate.

1. Ostomy can create sexuality/Intimacy problems for ostomates and caregivers

An ostomate is influenced in many ways by their ostomy. Your partner may not want to be intimate because of the ostomy. It is important for you to encourage dialogue with your spouse/Significant other/Friend concerning intimacy and the other issues discussed in this training session.

2. Preoperative information from surgeon and if enough time to adjust to the idea of sexual impairment
    - a. What did you understand about the process from surgeon?
    - b. Did radiation therapy cause sexual problems before the ostomy?

Caregiver Session Resources (10 min.)

E. Resources

Do you have the resource list given to the ostomate? If not, would you like one either emailed or paper mailed to you? *If you wish to contact one of the Peer Ostomates outside of this session, their phone numbers are: [read off name and phone number of Peers]*

Connectivity

F. Prior to disconnection, we want to ask on a scale of 1-4 your ability to connect to the session and your impression of the technology.

Session 3 - Introduction (5 min., Session 3, Ostomate folder)

We want to remind everyone that participation is completely voluntary and you may withdraw at any time. The sessions are confidential only first names will be used. Please respect the privacy of others. This session focuses on nutrition, healthy lifestyles, and finances.

We will now do a quick roll call using first names only. Please also tell us what kind of device you are using (e.g. iPad, Apple PC, iPhone, etc.).

Are there any questions from the last session?

Session 3 Nutrition and Education Timing (15 min)

A. Nutrition and education timing, specific foods **(Group Discussion)**

1. Review of nutritional logs as a group
    a. What foods give you gas?
    b. What foods increase the number of daily bowel movements?
    c. What foods are helpful

Session 3 Healthy Lifestyles (10 min)

B. Implementing a healthy living style

There are many ways of implementing healthy lifestyles. Below are a few items related to healthy lifestyles:

1. Daily activities

The goal is to do everything you did before your surgery. What daily activities did you do before your surgery? Some examples are:

a. Lawn Mowing
b. Motorcycle Riding
c. Leisure Swimming

Are you able to still do these activities?

2. Exercise

It is important to continue the exercise regimen you had before your surgery. What types of exercises did you do before your surgery? If you did little to no exercise this would be a great opportunity to start. Some examples are:

a. Running
b. Swimming laps
c. Daily Walking

3. Nutrition

This would be a great opportunity to improve your diet and here are some basic suggestions:

a. Daily Caloric intake is recommended to be 2,000 but depends on body features
b. Moderate portions
c. Eat fruits and vegetables – for bowel function and healthy living
d. Plenty of fluids—10-12 glasses of water or juice daily. (Coffee, tea, carbonated beverages do not count!)

4. Smoking Cessation

Do we have any smokers in the group? If so this would be a great opportunity to quit. We have listed some resources in your packet.

Session 3 Psychological Health (10 min)

C. Psychological Health

We have focused on issues related to your ostomy but we also recognize that you recently have been diagnosed with cancer. Review these selected issues below and determine how these issues have affected you. We would like to discuss some of these issues now.

1. Revaluate Life
    a. Have you revaluated your priorities in life?

2. Set New Priorities
    a. Based on treatments are there new priorities in life?

3. Second Chance to live
    a. Do you view your ostomy as a chance to live?

4. Life altering, not life threatening
    a. Do you view your ostomy as an impediment on life?

5. Changing attitudes
    a. May need to change negative friends

6. Review Psychological impact
    a. Do you still feel like going out for social occasions?

7. Talk about cancer and perceived needs

Please use this opportunity to discuss any Issues with cancer survivorship

a. Have you ever had any other form of cancer other than colorectal cancer?
b. Other issues?

8. Possible sexual/intimacy issues after cancer treatment
    a. Impotency
    b. Scarred tissue

9. Moods

Please describe any moods that you have experienced since your cancer diagnosis

Session 3 Problem-Solving Training (15 min)

D. Being Prepared for Traveling

We are going to review equipment and tips for traveling with your ostomy. It is important to always be prepared. If traveling out of the country or to a remote area your particular items may not be available.

1. Review Products, equipment, and tips for traveling
    - i. You can obtain a Travel Certificate
    - ii. Availability of WOCN in the area

Session 3 Finances (10 min)

E. Finances

Finances can affect an individual's Quality of Life. These can come from bad/lack of insurance or loss of employment due to your ostomy.

1. Possible problems with ostomy supplies cost

2. Employment issues
    - a. Loss of jobs
    - b. Not able to perform same duties at work
        - i. Switch jobs
        - ii. Unemployment

Session 3 Assignments (10 min)

F. Assignment

1. Goal Development and Review

Using the Goal Development sheet please review the goals you have in regards to your social and interpersonal well-being.

Session 3 Resources (5 min)

G. Resources

Please refer to the section in your folder for possible resources outside of this training session. Each week resources will be provided with a different list of resources relating to the topics discussed that session. If you wish to contact one of the Peer Ostomates outside of this session, their phone numbers are: [read off name and phone number of Peers]

Connectivity

H. Prior to disconnection, we want to ask on a scale of 1-4 your ability to connect to the session and your impression of the technology.

Session 4 – Review Session Introduction (5 min., Session 4, Ostomate folder)

We want to remind everyone that participation is completely voluntary and you may withdraw at any time. The sessions are confidential only first names will be used. Please respect the privacy of others. This session focuses on different techniques for ostomy care and will cover any items not reviewed because of time constraints of the previous sessions. The new faces on the call are your spouses, significant others, and friends.

At this time we will do a quick roll call please using only first names. For those who are new on the call, please introduce yourself to the group. Please also tell us what kind of device you are using (e.g. iPad, Apple PC, iPhone, etc.).

Are there any questions from last session?

Session 4 Daily Care (15 min)
A. Review Daily care, new products, etc.
Please use this time to discuss any new products or techniques that have worked well for you. Note: Please review elements for section E. If there is relevance discuss in this section.

1. Different techniques for management
    a. Irrigation
        i. Though not widely used anymore different people are comfortable with different things.
        ii. Irrigation is the process that the stoma is irrigated with water
        iii. This method must be used for a while
    b. What are some other techniques?

Session 4 Psychological Impact (15 min)
B. Discuss Psychological Impact
Please use this time to discuss any psychological effects your ostomy may have had on you. These may include social phobias or depression. NOTE: Please review elements for section E. If there is relevance discuss in this section.

Session 4 Specific Issues (15 min)
C. Talk about problems
Please use this time to take specific problem you may have and we will discuss as a group possible solutions. NOTE: Please review elements for section E. If there is relevance discuss in this section

Session 4 Nutritional Timing (15 min)
D. Nutrition/Exercise timing
Please use this time to discuss any issues related to food timing or any possible solutions you have developed to alleviate these problems. NOTE: Please review elements for section E. If there is relevance discuss in this section.

Session 4 Program Review (15 min)

E. Review Content from sessions 1-4

NOTE: This section will change by cohort. Information missed during each session will be discussed in the weekly teleconferences and will determine if it is important enough to review given the time constraints.

Session 4 Survey reminders

Please take this time to fill out the surveys electronically or what has been mailed to you as soon as possible after this session. We hope you enjoyed and benefitted from these sessions. In addition, you will be getting reminders and mailings if you prefer for follow-up surveys in six months. Are there any questions? If not, thank you and goodbye.

Connectivity

F. Prior to disconnection, we want to ask on a scale of 1-4 your ability to connect to the session and your impression of the technology.

15.2 Appendix 2a COH-QOL-CRC (full survey)

Survey: City of Hope Quality of Life baseline questions

Subject ID ☐☐☐☐

Today's Date (month/day/year) ☐☐/☐☐/☐☐

Ostomy Location/Care/Pre-Op

1. What kind of ostomy do you have?

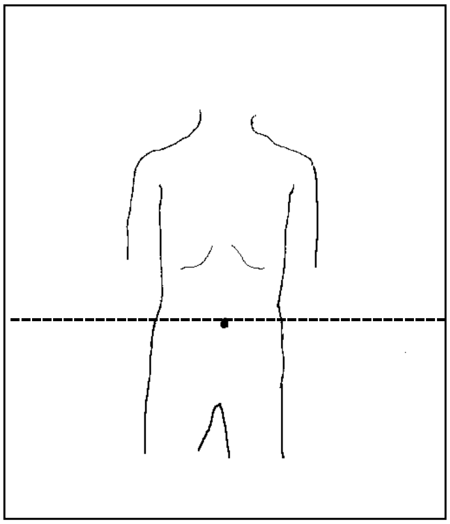
Colostomy ☐
Ileostomy ☐
Urostomy ☐
Don't Know ☐

2. If you have a urinary ostomy, please skip this question. If you have an ileostomy or colostomy, was it supposed to be permanent or temporary?

Permanent ☐
Temporary ☐
Don't Know ☐

3. Please mark with an X on the figure of an abdomen the location of your ostomy?

RIGHT SIDE



LEFT SIDE

3b. Please choose one of the following to describe the location of your ostomy?

☐ Lower Left Side;
☐ Lower Right Side;
☐ Upper Left Side;
☐ Upper Right Side

4. Does the location of your ostomy cause problem with clothing?

☐ Yes; ☐ No

5. Does this location of your ostomy cause you other problems? (if yes, please explain below)

____

____

____

6. Have you changed the style of clothing you wear because of your ostomy?

☐ Yes; ☐ No

7. Was your abdomen marked for the ostomy site before your surgery?

☐ Yes; ☐ No ☐ Don't remember

8. Did a nurse specialist (ostomy nurse) or physician explain your ostomy prior to your surgery?

☐ Yes; ☐ No ☐ Don't remember

9. Did a nurse specialist (ostomy nurse) help you learn to care for your ostomy after your surgery?

☐ Yes; ☐ No ☐ Don't remember

Sexual Activity

10. Were you sexually active before getting your ostomy?

☐ Yes; ☐ No

11. Have you been sexual activity since having your ostomy?

☐ Yes; ☐ No

12. Are you currently sexually active?

☐ Yes; ☐ No

12b. If you ARE NOT currently sexual active, are you fearful of resuming sexual activity?

☐ Yes; ☐ No

12c. If you ARE NOT currently sexual active, is that a problem for you?

☐ Yes; ☐ No

12d. If you ARE currently sexual active, is there fear or anxiety associated with sexual activity?

☐ Yes; ☐ No

12e. If you ARE currently sexual active, is your sexual activity satisfying?

☐ Yes; ☐ No

13. Is undressing in front of your partner after your Ostomy a problem?

☐Not a problem,
☐A little problem,
☐Somewhat a problem,
☐Very much a problem,
☐NA

14.

Females Only

Have you ever had a problem with…

15.

	Prior to Ostomy	After Ostomy	Currently
a. Vaginal Dryness	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
b. Vaginal stricture(narrowing)	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
c. Vaginal Pain	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

Males Only

Have you ever had a problem with…

	Prior to Ostomy	After Ostomy	Currently
a. Getting an Erection	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
b. Maintaining an Erection	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

Diet

16. In a typical day,
    a. how many meals other than snacks do you eat? ____________
    b. How many snacks do you eat? ____________
    c. How many 8 oz cups of liquid do you drink? (Please count all beverages such as water, tea, coffee, soft drinks, and juices. Do not include alcoholic beverages) ____________
    d. How many alcoholic beverages do you drink? (Please count all beer, wine, and liquor. Note: one drink is equal to one shot of liquor, 12 oz can or bottle of beer, or one glass of wine) ____________

17. How would you describe your current diet? (Check all that apply)

☐ High protein, low carb
☐ Fast Foods
☐ Diabetic
☐ Vegetarian
☐ Vegan
☐ Heart Healthy
☐ No Special Diet
☐ Other ________________

18. Because of your ostomy, have you adjusted your diet?

☐ Yes; ☐ No

19. How long after your ostomy surgery did you feel comfortable with what you eat?

☐< 1 month;
☐1-12 months;
☐>12 months;
☐ I am still not comfortable

Physical Activities

20. Considering a typical 7-day period (a week) in the past month, how many times on average did you do any of the following kinds of exercise for more than 15 minutes during your free time and for how long per exercise session (in minutes)?

Please write the number of **times per week** in the first box and the **average amount of time** for each exercise session in the second box. If you did no recreational activity in the past month, please put a zero (0) in the spaces provided. Please do not leave blanks.

.

a. Strenuous Activity (heart beats rapidly, heavy sweating)
____times per week ____average minutes

b. Moderate Activity (not exhausting, light sweating)
____times per week ____average minutes

c. Mild Activity (minimal effort, no sweating)
____times per week ____average minutes

d. How does the past 30 days of activity reflect your normal activities?
☐ More
☐ Less
☐ Same

Smoking

21. Which of the following best describes your smoking history?

☐ I am a current smoker → skip to question 23
☐ I have never smoked → skip to question 24
☐ I once was a smoker → please answer question 22, 24

22. If you used to smoke but have stopped when did you quit? ______ Year

23. If you are currently a smoker or have been a smoker in the past:

a. How many cigarettes per day on average? ________
b. How many total years of smoking: ____________

24. Do you currently use other tobacco products (chewing tobacco, snuff, pipes, cigars, etc.)?

☐ Yes; ☐ No

Demographics

25. What is the level of school you have completed?
    - Did not complete high school ☐
    - Completed high school /GED ☐
    - Vocational/secretarial/business ☐
    - Some college ☐
    - College degree ☐
    - Some graduate school ☐
    - Completed graduate degree ☐

26. What is your height? ________ Feet, _______ Inches

27. What is your current weight? ________ Pounds

28. What was your approximate weight at the time of your surgery? ________ Pounds

29. Is your ethnicity Hispanic, Latino, or Chicano?
    - Yes ☐
    - No ☐

30. What race do you consider yourself?
    - White ☐
    - Black or African American ☐
    - American Indian or Alaska Native ☐
    - Asian ☐
    - Native Hawaiian or Other Pacific Islander ☐
    - Other ☐
    - More than one race (Please specify) ☐

    ____

    ____

31. What is your current annual income of your household?
    - <15,000 ☐
    - 15,000-30,000 ☐
    - 30,001-50,000 ☐
    - 50,001-75,000 ☐
    - 75,001-100,000 ☐
    - greater than 100,000 ☐

32. What was your marital/partner status immediately prior to your ostomy? (please choose one)

☐Single; ☐Married; ☐Divorced; ☐Widowed; ☐Separated; ☐Partnered

33. What is your marital/partner status now?

☐Single; ☐Married; ☐Divorced; ☐Widowed; ☐Separated; ☐Partnered

34. If your marital status has changed, was it a result of your ostomy? Yes ☐ No ☐

15.2 Appendix 2b COH-QOL-CRC (scaled items only)

Survey: City of Hope Quality of Life Colorectal Cancer (COH-QOL-CRC) scaled items

Subject ID ☐☐☐☐

Today's Date (month/day/year) ☐☐/☐☐/☐☐

Directions: We are interested in knowing how the experience of having an ostomy affects your quality of life. Please answer all of the following questions based on your life at this time.

Please **fill in** the bubble 0-10 that best describes your experiences. For example:
How difficult is it for you to **climb stairs**?

Not at all difficult **Extremely Difficult**

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

Filling the bubble "2" would mean you have some but not a lot of difficulty climbing stairs.

Related to your ostomy**, to what extent are the following a problem for you at this time?**

Quality of Life

Related to your ostomy, to what extent are the following a problem for you at this time?

1. **Physical Strength**

no problem severe problem

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

2. **Fatigue**

no problem severe problem

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

3. **Skin Surrounding the Ostomy**

no problem severe problem

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

4. **Sleep Disruptions**

no problem severe problem

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

5. **Aches or Pains**

no problem severe problem

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

6. **Gas**

no problem severe problem

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

7. **Odor**

no problem severe problem

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

8. **Constipation**

no problem severe problem

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

9. **Diarrhea**

no problem severe problem

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

10. **Leaking from pouch (or around appliance)**

no problem severe problem

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

11. **Over-all physical well being**

no problem severe problem

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

12. How difficult has it been for you to **adjust your ostomy**?

not at all a great deal

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

13. How **useful** do you feel?

not at all extremely useful

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

14. How much **satisfaction or enjoyment** in life do you feel?

none at all a great deal

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

15. How much are you **embarrassed** by your ostomy?

not at all extremely embarrassed

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

16. How good is your **overall quality of life**?

extremely poor excellent

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

17. How is your ability to **remember** things?

extremely poor excellent

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

0 1 2 3 4 5 6 7 8 9 10

18. How difficult is it to **look** at your ostomy?
not at all extremely Difficult
☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
0 1 2 3 4 5 6 7 8 9 10

19. How difficult is it for you to **care** for your ostomy?
not at all extremely Difficult
☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
0 1 2 3 4 5 6 7 8 9 10

20. Do you feel like you are **in control** of things in your life?
not at all completely
☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
0 1 2 3 4 5 6 7 8 9 10

21. How satisfied are you with **your appearance**?
not at all extremely satisfied
☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
0 1 2 3 4 5 6 7 8 9 10

22. How much **anxiety** do you have?
none at all severe
☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
0 1 2 3 4 5 6 7 8 9 10

23. How much **depression** do you have?
none at all severe
☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
0 1 2 3 4 5 6 7 8 9 10

24. Are you **fearful that your disease will come back**?
not at all extremely fearful
☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
0 1 2 3 4 5 6 7 8 9 10

25. Do you have **difficulty meeting new people**?
not at all extreme Difficulty
☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
0 1 2 3 4 5 6 7 8 9 10

26. How much **financial burden** resulted from your illness or treatment?
not at all extreme
☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
0 1 2 3 4 5 6 7 8 9 10

27. How distressing has your illness been for your **family**?
not at all extremely distressing
☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
0 1 2 3 4 5 6 7 8 9 10

28. How much does your ostomy interfere with your **ability to travel**?
not at all completely
☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
0 1 2 3 4 5 6 7 8 9 10

29. Has your ostomy interfered with your **personal relationships**?

not at all completely

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

30. How much **isolation** is caused by your ostomy?

none a great deal

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

31. Is **support** from friends and family sufficient to meet your needs?

not at all extremely

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

32. Has your ostomy interfered with your **recreational/sports activities**?

not at all a great deal

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

33. Has your ostomy interfered with your **social activities**?

not at all a great deal

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

34. Has your ostomy interfered with your **ability to be intimate**?

not at all a great deal

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

35. Do you have enough **privacy at home** for doing your ostomy care?

not at all a great deal

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

36. Do you have enough **privacy when traveling** for conducting your ostomy care?

not at all a great deal

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

37. How much **uncertainty** do you feel about your future?

none at all extreme

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

38. Do you sense a **reason** for being alive?

not at all a great deal

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

39. Do you have a sense of **inner peace**?

not at all a great deal

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

40. How **hopeful** do you feel?

not at all extremely

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

41. Is support you receive from **personal spiritual activities** such as prayer or meditation sufficient to meet your needs?

not at all completely

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

42. Is support you receive from **religious activities** such as prayer pr meditation sufficient to meet your needs?

not at all completely

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

43. Has having an ostomy made **positive changes** in your life?

not at all a great deal

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

15.3 Appendix 3 HADS

Hospital Anxiety and Depression Scale (HADS)

(please check box for single best answer for each question)

1. I feel tense or wound up	☐ most of the time	☐ a lot of the time	☐ occasionally	☐ not at all
2. I still enjoy the things I used to enjoy	☐ definitely as much	☐ not quite as much	☐ only a little	☐ hardly at all
3. I get a sort of frightened feeling as if something awful is about to happen	☐ quite badly	☐ not too badly	☐ a little	☐ not at all
4. I can laugh and as see the funny side of things	☐ as much as I always could	☐ not quite so much now	☐ definitely not so much now	☐ not at all
5. Worrying thoughts go through my mind	☐ a great deal of the time	☐ a lot of the time	☐ from time to time	☐ only occasionally
6. I feel cheerful	☐ not at all	☐ not often	☐ sometimes	☐ a lot
7. I can sit at ease and feel relaxed	☐ definitely	☐ usually	☐ not often	☐ not at all
8. I feel as if I am slowed down	☐ nearly all the time	☐ very often	☐ sometimes	☐ not at all
9. I get a sort of frightened feeling like butterflies in the stomach	☐ not at all	☐ occasionally	☐ quite often	☐ very often
10. I have lost interest in my appearance	☐ definitely	☐ I don't take so much care as I should	☐ I may not take quite as much care	☐ I take just as much care as ever
11. I feel restless as if I have to be on the move	☐ very much	☐ quite a lot	☐ not very much	☐ not at all
12. I look forward with enjoyment to things	☐ as much as ever	☐ rather less than I used to	☐ definitely less than before	☐ hardly at all
13. I get sudden feelings of panic	☐ very often	☐ quite often	☐ not often	☐ not at all
14. I can enjoy a good book or program	☐ often	☐ sometimes	☐ not often	☐ very seldom

15.4 Appendix 4 Patient Activation Measure

PATIENT ACTIVATION MEASURE

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. If the statement does not apply to you, circle N/A.
Your answers should be what are true for you and not just what you think the doctor wants you to say.

When all is said and done, I am the person who is responsible for managing my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
Taking an active role in my own health care is the most important factor in determining my health and ability to function	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I know what each of my prescribed medications do	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident that I can tell when I need to go get medical care and when I can handle a health problem myself	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident I can tell my health care provider concerns I have even when he or she does not ask	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident that I can follow through on medical treatments I need to do at home	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I understand the nature and causes of my health conditions(s)	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I know the different medical treatment options available for my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I have been able to maintain the lifestyle changes for my health that I have made	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I know how to prevent further problems with my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident I can figure out solutions when new situations or problems arise with my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident that I can maintain lifestyle changes like diet and exercise even during times of stress	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

15.5 Appendix 5 Self Efficacy Survey

SELF-EFFICACY TO PERFORM SELF-MANAGEMENT BEHAVIORS

We would like to know **how confident** you are in doing certain activities. For each of the following questions, please write the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1) SE Exercise Regularly

Not at all confident	1	2	3	4	5	6	7	8	9	10	Totally confident

How confident are you that you can…

a. Do gentle exercises for muscle strength and flexibility three to four times per week (range of motion, using weights, etc.)? _____
b. Do an aerobic exercise such as walking, swimming, or bicycling three to four times each week? _____
c. Exercise without interfering with your ostomy equipment? _____

2) SE Get Ostomy Information

Not at all confident	1	2	3	4	5	6	7	8	9	10	Totally confident

How confident are you that you can…

a. Get ostomy information from your health care system? _____
b. Get ostomy information from community resources? _____
c. Get ostomy information from resources on the web? _____
d. Get ostomy information from a peer who has an ostomy? _____

3) SE Obtain Help From Community, Family, and Friends

Not at all confident	1	2	3	4	5	6	7	8	9	10	Totally confident

How confident are you that you can…

a. Get family and friends to help you with the things you need help with (such as household chores, transportation) ? _____
b. Get help with the things you need help with (such as household chores, transportation) from resources other than friends or family, if needed? _____
c. Get family and friends to help you with ostomy care? _____
d. Get emotional support from friends and family (such as listening or talking over your problems) ? _____
e. Get emotional support from resources other than friends or family, if needed? _____

4) SE Communicate with Physician

Not at all confident	1	2	3	4	5	6	7	8	9	10	Totally confident

How confident are you that you can…

a. Ask your health care providers things about your ostomy concerns? _____

b. Discuss openly with your health care providers any personal problems that may be related to your ostomy or surgery? _____
c. Work out differences with your health care providers when they arise? _____

5) SE to Manage Disease in General

Not at all											Totally
confident	1	2	3	4	5	6	7	8	9	10	confident

How confident are you that you can…

a. Having an illness often means doing different tasks and activities to manage your ostomy. How confident are you that you can do all the things necessary to manage your ostomy on a regular basis? _____
b. Judge when the changes in your condition mean you should visit a health care provider? _____
c. Do the different tasks and activities needed to manage your ostomy so as to reduce your need to see a health care provider? _____
d. Reduce the emotional distress caused by your ostomy so that it does not affect your everyday life?
e. Manage your ostomy care? _____?

6) SE Social/Recreational Activities

Not at all											Totally
confident	1	2	3	4	5	6	7	8	9	10	confident

How confident are you that you can…

a. Continue to do your hobbies and recreation? _____
b. Continue to do the things you like to do with friends and family (such as social visits and recreation)? _____
c. Travel distances from your home (if you desire)? _____

7) SE Manage Ostomy Symptoms

Not at all											Totally
confident	1	2	3	4	5	6	7	8	9	10	confident

How confident are you that you can…

a. Reduce your physical discomfort or pain? _____
b. Keep the leakage from interfering with the things you want to do? _____
c. Keep the gas from interfering with the things you want to do? _____
d. Keep any odor you have from interfering with the things you want to do? _____
e. Maintain the integrity of your skin (prevent skin breakdown) ? _____
f. Control any other ostomy-related problems you have so that they don’t interfere with the things you want to do? _____

8) SE Control/Manage Depression

Not at all											Totally
confident	1	2	3	4	5	6	7	8	9	10	confident

How confident are you that you can…

a. Keep from getting discouraged when nothing you do seems to make any difference? _____

b. Keep from feeling sad or down in the dumps? _____
c. Keep yourself from feeling lonely? _____
d. Do something to make yourself feel better when you are feeling lonely? _____
e. Do something to make yourself feel better when you are feeling discouraged? _____
f. Do something to make yourself feel better when you feel sad or down in the dumps? _____

15.6 Appendix 6 Ostomy Knowledge Survey

OSTOMATE KNOWLEDGE SURVEY

1. It is important that one knows the specific type of ostomy he/she has because:
   A. Each has its own unique management style.
   B. There are different types of equipment that might be better.
   C. It helps communication with an Ostomy Nurse.
   D. All of the above.

2. When using a solid skin barrier or wafer, it should be cut to fit at the base of the stoma allowing:
   A. Snug with the stoma
   B. 1/8 inch clearance from the stoma.
   C. 1/2 inch clearance from the stoma.
   D. It does not matter the distance from the stoma.

3. If the wafer is not properly fitted
   A. The stoma could be traumatized.
   B. Leakage may be more likely.
   C. The peristomal skin could breakdown.
   D. All of the above.

4. When cleansing the peristomal area, the proper method would be accomplished by using
   A. Wet warm washcloth
   B. Alcohol wipes
   C. Baby wet wipes
   D. Dial soap

5. An ostomy pouching system should typically be changed
   A. Whenever you have time to change.
   B. Every 4-7 days.
   C. Whenever there is stool in the pouch.
   D. Once a week.

6. An ostomy pouch should be emptied when the pouch is
   A. Full
   B. Half full
   C. One third full
   D. Every day

7. Which of the following must the ostomate AVOID?
   A. All sports activities
   B. Sexual intimacy
   C. Small children
   D. All of the above.
   E. None of the above.

8. Which of the following is accurate regarding the urine of a urostomate? (Answer only if you have a urostomy (urinary diversion))
    A. It may contain some mucous shreds.
    B. If persistent bleeding is evident, the urostomate should notify urologist or go to ER.
    C. If no urine is produced in 4 hours, the urostomate should consult urologist or go to ER.
    D. Urine should be transparent.
    E. All of the above.

9. The purpose of colostomy irrigation is (Answer only if you have a colostomy):
    A. To regulate and control bowel function.
    B. To keep the bowel clean.
    C. To eliminates gas.
    D. Decrease time spent caring for my ostomy.

10. Some foods that may cause problems for the ileostomate include:
    A. Corn/popcorn
    B. Nuts
    C. Seeds
    D. All of the above.

11. Regarding pouching systems:
    A. One should never change pouching systems.
    B. One should always change a pouching system if there are frequent leaks.
    C. It is reasonable to look at new products at regular intervals.
    D. Pouching systems have similar costs.
    E. None of the above.

15.7 Appendix 7a Burden of Ostomy Care Survey (full survey, baseline and followup)

BURDEN OF OSTOMY CARE

This study aims to collect data on the burden associated with families' use of ostomy care and supplies, including ostomy-related medications, ostomy-related health care visits, travel costs to obtain ostomy-related care and supplies, and time spent on ostomy management tasks. We ask that you please answer these questions while thinking specifically about the burden of ostomy-related care. This is not a test; please give us your best estimates based on your personal experience.

1. **What kind of Ostomy do you have?** Colostomy ☐ Ileostomy ☐ Urostomy ☐ Other ☐
2. **In-person Visits with Wound and Ostomy Care Nurse in the <u>past 4 weeks</u>:**
   a. Did you visit a Nurse in person in the past 4 weeks (at a medical office, hospital, and/or in your home)? No ☐ (**If NO**, skip to Question 3. below.) Yes ☐
   b. **If YES:** How many times did you visit the Nurse in the past 4 weeks? 1 ☐ 2 ☐ 3-4 ☐ 5-8 ☐ More than 8 ☐

Please answer questions 2c through 2g thinking specifically about your most recent visit to the Nurse.

   c. How much do you typically pay out-of-pocket for each Nurse visit (copayments, deductibles, or other costs for the visit that weren't covered by your insurance)?
      Nothing ☐ $1-$10 ☐ $11-$25 ☐ $26-$50 ☐ $51-$75 ☐ $76-$100 ☐ $101+ ☐
   d. Did you have to travel to see the Nurse for your most recent visit? No ☐ (If NO, skip to Question 3. below.) Yes ☐
   e. How much do you typically pay out-of-pocket to get to and from each Nurse visit (such as the cost for taxi, bus, or parking)? $1-$5 ☐ $6-10 ☐ $11-15 ☐ $16-$25 ☐ $26-$50 ☐ $51-$100 ☐ $101+ ☐
   f. Approximately how far did you have to travel to the Nurse Visit location? 1-4 miles ☐ 5-8 mi. ☐ More than 8 mi. ☐
   g. Approximately how much time did it take you to get from your home to the Nurse Visit location? 1-10 mins ☐
      11-30 mins ☐ More than 30 mins ☐

3. **Telephone and/or email consultations with a Wound and Ostomy Care Nurse in the <u>past 4 weeks</u>:**
   a. Did you have any telephone and/or web consultations with the Nurse in the past 4 weeks? No ☐ (**IF NO,** skip to Question 4 below.) Yes ☐
   b. **If YES:** How many telephone and/or web consultations have you had with a Wound and Ostomy Care Nurse over the past 4 weeks? 1 ☐ 2 ☐ 3-4 ☐ 5-8 ☐ More than 8 ☐

Please answer Question 3c thinking specifically about your most recent telephone or web consultation with the Nurse.

   c. How much did you have to pay out-of-pocket for this Nurse consultation?
      Nothing ☐ $1-$10 ☐ $11-$25 ☐ $26-$50 ☐ $51-$75 ☐ $76-$100 ☐ $101+ ☐

4. **In-person Visits with a Physician for stoma and/or bowel function problems in the <u>past 4 weeks</u>:**
   a. Did you visit a Physician in person for stoma and/or bowel function problems in the past 4 weeks? No ☐ (**IF NO**, skip to Question 5. below.) Yes ☐
   b. **IF YES:** How many times did you visit the Physician in the past 4 weeks?
      1 ☐ 2 ☐ 3-4 ☐ 5-8 ☐ More than 8 ☐

Please answer Questions 4c through 4g thinking specifically about your most recent visit to the Physician.

c. How much do you typically pay out-of-pocket for each Physician visit (copayments, deductibles, or other costs for the visit that weren't covered by your insurance)?
Nothing ☐ $1-$10 ☐ $11-$25 ☐ $26-$50 ☐ $51-$75 ☐ $76-$100 ☐ $101+ ☐

d. Did you have to travel to see the Physician for your most recent visit? No ☐ (If NO, skip to Question 5. below.) Yes ☐

e. How much do you typically pay out-of-pocket to get to and from each Physician visit (such as the cost for
taxi, bus, or parking)? $1-$5 ☐ $6-10 ☐ $11-15 ☐ $16-$25 ☐ $26-$50 ☐ $51-$100 ☐ $101+ ☐

f. Approximately how far did you have to travel to the Physician visit location? 1-4 miles ☐ 5-8 mi. ☐ More than 8 mi. ☐

g. Approximately how much time did it take you to get from your home
to the Physician visit location? 1-10 mins ☐ 11-30 mins ☐ More than 30 mins ☐

5. **What other sources do you use to find more information about your ostomy and daily care?** (Fill in all that apply)
Internet ☐ Magazines ☐ Other people with an ostomy ☐ Support Group ☐
Other (please specify) ☐
____

6. **If you wear a pouch and have encountered any problems with it, please explain below what those problems are/were?**
____
____
____

7. **How long was it before you felt comfortable with your daily ostomy care?**
0 < 1 month ☐ 1-12 months ☐ 12+ months ☐ I am still not comfortable ☐

8. **On average, how long does it take to do your daily ostomy care?**
0-5 min ☐ 5-10 min ☐ 10-15 min ☐ 15-30 min ☐ 30-60min ☐ More than 60min ☐

9. **Do you irrigate (flush) your ostomy?**
Yes ☐ → Please answer 9a. I used to but stopped ☐ → Please answer 9b No ☐ Please skip to 10.

9a. **IF YES, How often do you irrigate your ostomy?** Once a day ☐ Every other day ☐ Every third day ☐ Other ☐ (please specify) ________________________________

9b. **If you used to irrigate but stopped, why did you stop?** Pain ☐ Hernia ☐ Too time consuming ☐
Other ☐ (Please specify) ________________________________

10. **Please describe the reasons you irrigate your ostomy.** (Check all that apply)
To control timing of bowel movements ☐ To avoid blockage ☐ To avoid pain ☐ Convenience ☐
Other ☐ (please specify)

11. **Telephone and/or email consultations with a Physician for stoma and/or bowel function problems in the <u>past 4 weeks</u>:**

a. Did you have any telephone and/or web consultations with a Physician for stoma and/or bowel function problems in the past 4 weeks? No ☐ (**IF NO**, skip to Question 12. below.) Yes ☐

b. **IF YES:** How many telephone and/or web consultations have you had with a Physician over the past 4 weeks? 1 ☐ 2 ☐ 3-4 ☐ 5-8 ☐ More than 8 ☐

Please answer Question 11c thinking specifically about your most recent telephone or web consultation with the Physician.

c. How much did you have to pay out-of-pocket for this consultation?
Nothing ☐ $1-$10 ☐ $11-$25 ☐ $26-$50 ☐ $51-$75 ☐ $76-$100 ☐ $101+ ☐

12. Emergency Room visits for stoma and/or bowel function problems <u>in the past 4 weeks</u>:

a. Did you have any visits to the Emergency Room for stoma and/or bowel function problems in the past 4 weeks? No ☐ (**IF NO,** skip to Question 13. below.) Yes ☐

b. **IF YES:** How many times did you visit the Emergency Room for stoma and/or bowel function problems in the past 4 weeks? 1 ☐ 2 ☐ 3-4 ☐ 5-8 ☐ More than 8 ☐

Please answer Question 12c thinking specifically about your most Emergency Room visit for stoma and/or bowel function problems.

c. How much did you pay out-of-pocket for your most recent ER visit (copayments, deductibles, or other costs for the visit that weren't covered by your insurance))?
$0 ☐ $1-$5 ☐ $6-10 ☐ $11-15 ☐ $16-$25 ☐ $26-$50 ☐ $51-$100 ☐ $101+ ☐

d. How much did you pay out-of-pocket to get to and from this ER visit (such as the cost for taxi, bus, or parking)? $0 ☐ $1-$5 ☐ $6-10 ☐ $11-15 ☐ $16-$25 ☐ $26-$50 ☐ $51-$100 ☐ $101+ ☐

e. Approximately how far did you have to travel to the ER visit location? 1-4 miles ☐ 5-8 mi. ☐ More than 8 mi. ☐

f. Approximately how much time did it take you to get from your home to the ER visit location? 1-4 minutes ☐ 5-8 min. ☐ More than 8 min. ☐

13. Urgent Care visits for stoma and/or bowel function problems <u>in the past 4 weeks</u>:

a. Did you have any visits to an Urgent Care facility for stoma and/or bowel function problems in the past 4 weeks? No ☐ (**IF NO**, skip to Question 14 below.) Yes ☐

b. **IF YES:** How many times did you visit an Urgent Care center for stoma and/or bowel function problems in the past 4 weeks? 1 ☐ 2 ☐ 3-4 ☐ 5-8 ☐ More than 8 ☐

Please answer questions 13c through 13f thinking specifically about your most recent Urgent Care visit for stoma and/or bowel function problems.

c. How much did you pay out-of-pocket for your most recent Urgent Care visit (copayments, deductibles, or other costs for the visit that weren't covered by your insurance)?
$0 ☐ $1-$5 ☐ $6-10 ☐ $11-15 ☐ $16-$25 ☐ $26-$50 ☐ $51-$100 ☐ $101+ ☐

d. How much did you pay out-of-pocket to get to and from the Urgent Care visit (such as the cost for taxi, bus, or parking)? $0 ☐ $1-$5 ☐ $6-10 ☐ $11-15 ☐ $16-$25 ☐ $26-$50 ☐ $51-$100 ☐ $101+ ☐

e. Approximately how far did you have to travel to the Urgent Care visit location? 1-4 miles ☐ 5-8 mi. ☐ More than 8 mi. ☐

f. Approximately how much time did it take you to get from your home to the Urgent Care visit location? 1-4 minutes ☐ 5-8 min. ☐ More than 8 min. ☐

14. What type of ostomy bag system are you using? One piece ☐ Two piece ☐

15. How many of each of the following have you used over the past 4 weeks?

a. Wafers: 10 or less ☐ 11-20 ☐ 21-30 ☐ 31-50 ☐ More than 50 ☐

b. Bags: 10 or less ☐ 11-20 ☐ 21-30 ☐ 31-50 ☐ More than 50 ☐

16. Medications to manage your bowel function in the past 4 weeks

a. Have you used any medications to manage your bowel function in the past 4 weeks? (e.g., Imodium©, Metamucil©, Miralax©, Loperamide) No ☐ (**IF NO**, skip to Question 16. below.) Yes ☐

b. **IF YES:** how many different medications have you used to manage your bowel function in the past 4 weeks? ___

c. Please list up to three medications you used most frequently to manage your bowel function and the number of days you took these medications in a typical week:

i. Medication ____________________________ Number of days used (0 to 7) ____________________

ii. Medication ____________________________ Number of days used (0 to 7) ____________________

iii. Medication ____________________________ Number of days used (0 to 7) ____________________

17. **Do you use the Eakin seal (moldable donut or ring**)? No ☐ Yes ☐

18. **Medications to manage – treat or prevent – skin problems around your stoma in the past 4 weeks**

a. Have you used any prescription medications to manage skin problems around your stoma in the past 4 weeks? (e.g., Nystatin powder). No ☐ (**IF NO,** skip to Question 18. below.) Yes ☐

b. **IF YES:** how many different medications have you used to manage skin problems around your stoma in the past 4 weeks? None ☐ 1-2 ☐ 3-4 ☐ 5 or more ☐

c. Please list up to three medications you used most frequently to manage skin problems around your stoma and the number of days you took these medications in a typical week:

i. Medication ____________________________ Number of days used (0 to 7) ________________

ii. Medication ____________________________ Number of days used (0 to 7) ________________

iii. Medication ____________________________ Number of days used (0 to 7) ________________

19. **How much have you spent on purchases of ostomy appliances (including wafers and bags in total <u>over the past 4 weeks</u>?** $0 ☐ $1-$25 ☐ $26-50 ☐ $51-100 ☐ $100-$150 ☐ $150-$200 ☐ $200-$250 ☐ over $250 ☐

20. **About how many times a day do you empty your drainable ostomy bag (or discard your closed/disposable bag)?**
None ☐ 1-4 ☐ 5-8 ☐ More than 8 ☐

21. **<u>Over the past 4 weeks</u>, what was the highest number of bag emptyings in a 24-hour period?**
None ☐ 1-4 ☐ 5-8 ☐ More than 8 ☐

22. **<u>Over the past 4 weeks</u>, what was the lowest number of bag emptyings in a 24-hour period?**
None ☐ 1-4 ☐ 5-8 ☐ More than 8 ☐

23. **How often do you typically discard a used bag and use a new bag?**
At every emptying ☐ Once a day ☐ Once every 2-3 days ☐ Less often ☐

24. **How much time does it usually take you to empty/dispose your bag?**
1-5 minutes ☐ 5-10 minutes ☐ 10-15 minutes ☐ More than 15 minutes ☐

25. **How often do you typically change your wafer on a typical week?** 1 ☐ 2 ☐ 3 ☐ 4-7 ☐ More than 7 ☐

26. **How much time does it usually take you to change your wafer and bag?**
1-15 minutes ☐ 16-30 minutes ☐ 30–45 minutes ☐ 45–60 minutes ☐ More than 60 minutes ☐

27. **Do you usually receive help caring for your stoma and changing your ostomy appliance?**

a. No ☐ (skip to Question 27 below)

b. Yes ☐ IF Yes, please check who your helper(s) is(are):

Spouse/Significant Other ☐ Other family member ☐ Friend ☐ Home care nurse ☐ Other Paid Caregiver ☐ Other ☐ (please specify) ____
____

28. Has your bag leaked at any time <u>over the past 4 weeks</u>?

a. No ☐ (skip to Question 28 below)

b. Yes ☐ **IF YES,** how many times? 1-4 ☐ 5-8 ☐ More than 8 ☐

c. How many of these times involved a full spillage of your bag contents? 1-4 ☐ 5-8 ☐ More than 8 ☐

d. How much time does it require to clean up after a bag leak or spill? 1-30 minutes ☐ 31-60 mins. ☐ More than 60 mins ☐

29. Do you have waterproof covers on your mattress and primary chair(s)?

a. No ☐ → Skip to Question 29 below.

b. Yes ☐ **IF YES**, how much did you spend to purchase them?
$0 ☐ $1-$10 ☐ $11-$25 ☐ $26-$50 ☐ $51-$75 ☐ $76-$100 ☐ $101-$150 ☐ $151+ ☐

30. Do you have to make alterations to your clothing to accommodate your ostomy appliance?

a. No ☐ **IF NO**, skip to Question 30 below.

b. Yes ☐ **IF YES,** do you make these modifications yourself?

   i. No ☐

   ii. Yes ☐ → **IF YES,** How much do you spend for these modifications?
   $0 ☐ $1-$5 ☐ $6-$10 ☐ $11-$15 ☐ $16-$25 ☐ $26-$50 ☐ $51-$100 ☐ $101+ ☐

31. Do you make some or all your own clothes because you have an ostomy and nothing in the clothing stores will fit you appropriately?

a. No ☐ → **IF NO,** skip to Question 32 below.

b. Yes ☐ → **IF YES,** how much do you spend to make your own clothes in a year?
$0 ☐ $1-$5 ☐ $6-$10 ☐ $11-$15 ☐ $16-$25 ☐ $26-$50 ☐ $51-$100 ☐ $101+ ☐

32. Did you purchase any fashion accessories specifically made for someone with an Ostomy (for example, fashion wraps, special underwear, Stealth belt)?

a. No ☐ → **IF NO,** skip to Question 33 below.

b. Yes ☐ → **IF YES,** how much did you spend to purchase your special underwear/girdle/body wrap?
$0 ☐ $1-$5 ☐ $6-$10 ☐ $11-$15 ☐ $16-$25 ☐ $26-$50 ☐ $51-$100 ☐ $101+ ☐

33. Do you wear a hernia belt?

a. No ☐ → **IF NO,** skip to Question 34 below.

b. Yes ☐ → **IF YES,** how much did you spend to purchase your hernia belt(s)?
$0 ☐ $1-$5 ☐ $6-$10 ☐ $11-$15 ☐ $16-$25 ☐ $26-$50 ☐ $51-$100 ☐ $101+ ☐

34. How would you describe your current employment?
(Please select only one)

Full time ☐
Part time ☐
Retired and not working another job ☐
Home maker ☐
Temporarily laid off ☐
Unemployed and looking for work ☐
Unemployed and **not** looking for work ☐
On disability ☐

Other: ☐ (please explain) ____

____

---

35. **Do you volunteer on a regular basis?** No ☐ Yes ☐ **IF YES,** about how many **hours per week** did you spend on volunteer activities in the past four weeks? 1-4 hrs. ☐ 5-8 hrs. ☐ 9-24 hrs. ☐ 25-40 hrs. ☐ More than 40 hrs. ☐

FOR INTERVENTION PARTICIPANTS ONLY:

a. Number of on-line intervention sessions participated in: Number:____________

b. Duration of on-line sessions: Minutes:____________

c. How long did it take to set up the video streaming for these sessions? Minutes:____________

d. If you already had Internet Service available to access the sessions, what is your monthly expense?
$0 ☐ $1-$5 ☐ $6-10 ☐ $11-15 ☐ $16-$25 ☐ $26-$50 ☐ $51-$100 ☐ $101+ ☐

Thank you very much for taking time to share your health care experiences!

FOR FINAL SURVEY

36. Many people have shared stories about their lives with an ostomy. Please share with us the **greatest challenge** you have encountered in having an ostomy.

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15.7 Appendix 7b Burden of Ostomy Care Survey (short survey, after session completion)

BURDEN OF OSTOMY CARE: CHECK-IN REPORT

This study aims to collect information on families' use of ostomy care and supplies, including ostomy-related medications, and ostomy-related health care visits. We ask that you please answer these questions while thinking specifically about your ***ostomy-related care***. This is not a test. Please give us your best estimates based on your personal experience.

1. **In-person Visits with Wound and Ostomy Care Nurse in the <u>past 4 weeks</u>:**
   a. Did you visit a Nurse in person in the past 4 weeks (at a medical office, hospital, and/or in your home)? No ☐ (**If NO**, skip to Question 3. below.) Yes ☐
   b. **If YES:** How many times did you visit the Nurse in the past 4 weeks? 1 ☐ 2 ☐ 3-4 ☐ 5-8 ☐ More than 8 ☐

2. **Telephone and/or email consultations with a Wound and Ostomy Care Nurse in the <u>past 4 weeks</u>:**
   a. Did you have any telephone and/or web consultations with the Nurse in the past 4 weeks? No ☐ (**IF NO,** skip to Question 4. below.) Yes ☐
   b. **If YES:** How many telephone and/or web consultations have you had with a Wound and Ostomy Care Nurse over the past 4 weeks? 1 ☐ 2 ☐ 3-4 ☐ 5-8 ☐ More than 8 ☐

3. **In-person Visits with a Physician for stoma and/or bowel function problems in the <u>past 4 weeks</u>:**
   a. Did you visit a Physician in person for stoma and/or bowel function problems in the past 4 weeks? No ☐ (**IF NO**, skip to Question 5. below.) Yes ☐
   b. **IF YES:** How many times did you visit the Physician in the past 4 weeks?
      1 ☐ 2 ☐ 3-4 ☐ 5-8 ☐ More than 8 ☐

4. **What other sources do you use to find more information about your ostomy and daily care?** (Fill in all that apply)
   Internet ☐ Magazines ☐ Other people with an ostomy ☐ Support Group ☐
   Other (please specify) ☐
   ____
   ____

5. **If you wear a pouch and have encountered any problems with it, please explain below what those problems are/were?**
   ____
   ____
   ____

6. **Do you feel comfortable with your daily ostomy care?** Yes ☐ No ☐
7. **On average, how long does it take to do your daily ostomy care?**
   0-5 min ☐ 5-10 min ☐ 10-15 min ☐ 15-30 min ☐ 30-60min ☐ More than 60 min ☐
8. **How often do you typically discard a used bag and use a new bag?**
   At every emptying ☐ Once a day ☐ Once every 2-3 days ☐ Less often ☐
9. **How often do you typically change your wafer on a typical week?**
   1 ☐ 2 ☐ 3 ☐ 4-7 ☐ More than 7 ☐
10. **How much time does it usually take you to change your wafer and bag?**
    1-15 minutes ☐ 16-30 minutes ☐ 30–45 minutes ☐ 45–60 minutes ☐
    More than 60 minutes ☐
11. **Do you usually receive help caring for your stoma and changing your ostomy appliance?**
    a. No ☐ (skip to Question 12 below)
    b. Yes ☐ IF Yes, please check who your helper(s) is(are):
       Spouse/Significant Other ☐ Other Family Member ☐ Friend ☐ Home Care Nurse ☐
       Other Paid Caregiver ☐ Other ☐ (please specify:) ________________________________
       ____
12. **Has your bag leaked at any time <u>over the past 4 weeks</u>?**
    a. No ☐
    b. Yes ☐ **IF YES,** how many times? 1-4 ☐ 5-8 ☐ More than 8 ☐
       i. How many of these times involved a full spillage of your bag contents?
          1-4 ☐ 5-8 ☐ More than 8 ☐
       ii. How much time does it usually require to clean up after a bag leak or spill?
           1-30 minutes ☐ 31-60 mins. ☐ More than 60 mins ☐

15.8 Appendix 8 Connection to Telehealth Sessions

Please familiarize yourself with the Zoom video conferencing application before your first scheduled conference using Zoom.

Please download and install the Zoom client before attempting to join the meeting. For PC/MAC download the Zoom Client for Meetings from https://zoom.us/download#client_4meeting . For iOS (iPhone/iPad/iPod) https://itunes.apple.com/us/app/id546505307 and for Android devices: https://play.google.com/store/apps/details?id=us.zoom.videomeetings

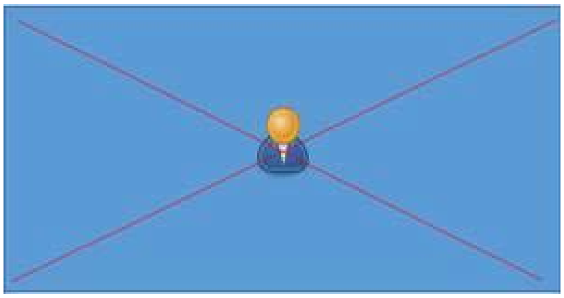
You do not need to create a Zoom account to join a Zoom meeting. Only the meeting host that sends the invitation needs to have a Zoom account. You can create a Zoom account if you wish, but it is not required.

To test your ability to connect to Zoom at any time visit http://zoom.us/test

For technical assistance connecting to Zoom, please contact the Arizona Telehealth Program (ATP) Help Desk at 520-626-6978 or atpvcsupport@telemedicine.arizona.edu

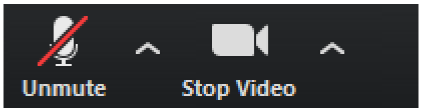
Video conferencing participants should review the following information and instructions:

- Join the video call on MM/DD and MM/DD from a quiet location with minimal background/ambient noise with good lighting (avoid backlighting such as with your back to a brightly lit window). Keep in mind that others on the video call will be able to see everything that is in your camera's field of view. Ideally, position your camera to minimize any potential visual distractions, and as close to eye level as possible.
- Join the video call at 15-30 minutes prior to the start of the video conference session to allow time for troubleshooting in case of connection difficulty.
- Position yourself relative to your device's camera so the camera is capturing a relatively close-up image of your face. Examples:



- Please fill in **your first name only** when joining the call. This can also be done while you are on the video call by viewing the participant list and editing your name. Your entry in the participant list will have (me) next to it.
- Look into the camera when you are speaking to give others on the call the best view of you while you are communicating to them.
- Please practice good video conference etiquette. Mute your microphone and/or camera if you need to do something that would be an audible or visible distraction to others. Video conferencing is similar to being in the same physical room meeting with people, except that sounds, such as rustling paper or bags for example, are much more distracting than they would be if you were meeting in person.

- Keep your microphone muted by clicking / tapping on the microphone icon that appears in the lower left of the screen. For PC/Mac move the mouse pointer within the Zoom video window and look for the controls that appear along the bottom of the window. For tablet or smartphone, touch the screen to display the Zoom controls and then touch the mic icon to mute. Repeat these actions to unmute the microphone. Please unmute before speaking so that others can hear you, but mute the mic as soon as possible following your comments.



- Only 1 device per physical room should be connected to the Zoom video conference. 2 or more participants using different devices in the same physical room should not connect to the same Zoom meeting ID. Having more than one device on the same call in the same physical room will inevitably lead to high pitched audio feedback in the room and on the video call.
- If you lose connection or you see no change in the video image on your screen for an extended time period, you can leave the call by clicking “Leave Meeting” in the Zoom video window and reconnect by clicking on the hyperlink in the meeting invitation again.
- On PC/Mac, clicking on the ^ symbol along the lower left next to the microphone or camera will show a list of available microphones and cameras connected to your system. Generally you won’t need to do anything here, but if others can’t hear you when your mic is not muted, or if you can’t hear even though you have your volume turned up, or others can’t see you when your video should be on, you can check here to make sure that the correct microphone, speakers and camera are selected for your computer.
- On smartphones and tablets, you will want to use the front facing camera, which should be selected by Zoom as the default camera. If the rear camera is being used by Zoom for some reason, touch the screen and tap the camera icon to switch to the front camera.
- For PC/Mac/Smartphone/Tablet, you may also use a headset if you prefer instead of your device’s speakers and/or microphone.
- <u>You need a reliable high-speed Internet connection to video conference</u>. Your connection should be able to support 1.5 megabits per second (Mbps) sustained download and upload speeds for best performance. Connectivity at lower speeds is possible down to about 600 kilobits per second (.6Mbps). At lower speeds motion of video images may become jerky or frozen temporarily. WiFi or Wired Internet connectivity is best.
- It is possible to connect to Zoom via a cellular data connection through carriers such as Verizon, ATT and others. VIDEO CONFERENCING USES A LOT OF DATA. This can quickly exhaust a limited data plan from a wireless carrier. 1.3 gigabytes per hour is a good estimate. For the four sessions of the OSMT program over two months the data plan requirement would be approximately 6 gigabytes per month plus normal monthly data usage. If using WiFi or wireless cellular network to connect, check your device’s signal strength indicator. More bars generally means faster and more reliable connectivity. Aim for full or near full signal strength when video conferencing with your device. Sometimes moving closer to a window, changing device orientation, or moving to another room closer to the exterior of a building can significantly impact signal strength. You can get an estimate of your Internet download and upload speeds by visiting speedtest.net or using the Speedtest.net app and running the speedtest.

15.9 Appendix 9 Group Rules

Rules and Guidelines for Group Participation

1. Openness and respect are essential for group participation.

Use first names only; raise your hand and wait to be acknowledged by the nurse leader, if you want to contribute to the discussion. Every effort will be made to allow all group members to share feelings and experiences openly and respectfully.

2. If you will not be able to attend a session or if you make the decision to no longer attend and participate, notify [local Study Coordinator name], at [local contact phone #]

3. The group meeting times have been pre-established, and the nurse leader will ensure that times for beginning and ending the session will be followed. The nurse leader will guide the discussion in a positive direction and encourage participation that includes everyone.

4. Demonstration of respect for ourselves and others will be essential. This is promoted through sharing feelings and experiences openly and allowing ourselves to talk about them. We respect everyone’s right to discuss his/her own feelings when ready to do so.

5. Group sessions are confidential. We are bound ethically and legally not to disclose contents of the sessions outside of this group. An environment of trust and safety is essential. Do not, by any means or technology, photograph, video record, or audio record any portion of the OSMT Zoom video conferencing sessions. This is to protect the privacy of everyone in the OSMT group

6. Disrespectful comments or disruptive behavior in the group is not acceptable. For persistent disruptions or unacceptable behavior, the nurse leader will ask you to leave the group.

I agree to these rules and guidelines and will attempt at all times to be a contributing and supportive member of the group.

15.10 Appendix 10 Goal Setting

PATIENT GOAL SETTING FORM

(Keep a copy for discussion in Session 1 and complete online or return this first page with initial surveys)

Participant ID: ________________________________ **Date:** _________________

Intervention Nurse: ______________________

Goals for Ostomy Care and Daily Living

What are three goals to help improve your daily life in the next month in the context of your ostomy, either related to the ostomy and ostomy care, or daily living in general, or both? Examples of potential goals might be: *To apply an ostomy bag so no leakage occurs; To explore dietary changes that will not lead to ostomy-related problems; To travel with more confidence in ostomy care; To participate in (special and/or routine) family activities/celebrations; To participate more in social activities (dining out, attending parties, meeting new people, enjoying music/theater/sports/hobbies/other entertainment).*

1. ____

2. ____

3.____

PATIENT GOAL SETTING FORM

(Complete online or return this after Session 2 is completed)

Participant ID: ________________________________ **Date:** _________________

Intervention Nurse: ______________________

Session 1/Session 2 - Please evaluate the progress in achieving each goal from last session. Use only one circle for each goal.

	Goal Achieved	Goal Ongoing	Goal No Longer Necessary
Goal 1	Yes No	Yes No	Yes No
Goal 2	Yes No	Yes No	Yes No
Goal 3	Yes No	Yes No	Yes No

List three goals for the next month. You may include the same goals or add new goals.

1. ____

2. ____

3. ____

PATIENT GOAL SETTING FORM

(Complete online or return this page with other surveys after Session 4)

Participant ID: ________________________________ **Date:** _________________

Intervention Nurse: ______________________

Session 3/Session 4 - Please evaluate the progress in achieving each goal from last sessions.

	Goal Achieved	**Goal Ongoing**	**Goal No Longer Necessary**
Goal 1	Yes No	Yes No	Yes No
Goal 2	Yes No	Yes No	Yes No
Goal 3	Yes No	Yes No	Yes No

List three goals for the next 6 months. You may include the same goals from the previous sessions, or add new goals.

1. ____

2. ____

3.____

PATIENT GOAL SETTING FORM

(Complete online or return this page with 6-month follow-up surveys)

Participant ID: ________________________________ **Date: _________________**

Intervention Nurse: ______________________

Follow-up - Please evaluate the progress in achieving each goal since last sessions.

	Goal Achieved	Goal Ongoing	Goal No Longer Necessary
Goal 1	Yes No	Yes No	Yes No
Goal 2	Yes No	Yes No	Yes No
Goal 3	Yes No	Yes No	Yes No

Thank you for participating in this program.

Comments and Suggestions - Please list any comments or suggestions on favorable or unfavorable experiences with the program.

____

____

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15.11 Appendix 11 Study Form

Study Form

Participant Study ID _______

How did you learn about this study?

Ostomy Support Group ______
Surgeon ______
Other physician ______
Ostomy Nurse (in hospital) ______
Ostomy clinic (outpatient) ______

Participant Age: ______

Participant Gender: M F

Caregiver Age: ______

Caregiver Gender: M F

Caregiver Relationship to ostomate:

Spouse ______
Partner ______
Friend ______
Other Family ______
Paid Caregiver ______

Participant Current Work Status:

Working ______
Retired ______
Homemaker ______
Volunteer Work ______

Caregiver Current Work Status:

Working ______
Retired ______
Homemaker ______
Volunteer Work ______

Participant Living Situation:
(Describe if assisted living facility)

Live with caregiver ______
Live with others (besides caregiver) ______
Live alone ______

Caregiver Living Situation:
(Describe if assisted living facility)

Live with ostomate ______
Live with others (besides caregiver) ______
Live alone ______

Participant Health Problems other than your cancer (check all that apply):

Diabetes ______

Caregiver Health Issues (check all that apply):

Diabetes ______

Heart Disease	______	Heart Disease	______
Vision problems	______	Vision problems	______
Arthritis	______	Arthritis	______
Mobility problems	______	Mobility problems	______
Other	____________	Other	____________

15.12 Appendix 12 Ostomy Resource Compendium

Ostomy Resource Sheet

City of Hope

Ostomy Equipment Resources

Coloplast	1-888-726-7872	Marlen	1-216-292-7060
Convatec	1-800-422-8811	Nu-Hope	1-800-899-5017
Hollister	1-888-740-8999	Securi-T USA	1-877-726-4400
Cymed	1-800-582-0707		

Partial list of Ostomy Supply Distributors

Byram HealthCare	1-877-902-9726	www.byramhealthcare.com
CCS Medical	1-800-722-2604	https://ccsmed.com
Edgepark Medical	1-888-394-5375	www.edgepark.com
Liberator Medical	1-866-643-0956	www.liberatormedical.com
Liberty Medical	1-800-723-9558	www.libertymedical.com
McKesson	1-855-404-6727	https://mpcs.mckesson.com
Parthenon	1-800-453-8898	www.parthenoninc.com
Sterling Medical	1-888-907-8875	www.sterlingmedical.com

Online Ostomy Resources

Ostomy Association of Los Angeles: The Ostomy Association of Los Angeles (OALA) is a non-profit, volunteer-based support association dedicated to improving the quality of life of anyone who has or will have an intestinal or urinary diversion.

- http://www.oa-la.com/
- 818-337-8476
- Need a membership; $25 annual fee

United Ostomy Associates of America, Inc.: United Ostomy Associations of America is the place for ostomy resources, advocacy, and support. UOAA is over 300 Affiliated Support Groups strong, and is here to help you get the answers you need as you begin your “new normal” life. We invite you to explore our website to find information about ostomies. You’ll find answers about nutrition and intimacy, and useful knowledge about living with an ostomy or continent diversion.

- http://www.ostomy.org/Home.html

- 1-800-826-0826

Inspire-Together we're better: Inspire was created with the belief that patients and caregivers need a safe and secure place to support and connect with one another. Inspire was created because: We all need a safe place to discuss health. We can help each other. Together, we are better.

- https://www.inspire.com/about/
    - Create an account for free
- 1-800-945-0381

Ostomy Land: An online ostomy support group; offering ostomy and stoma management and a community of people just like you.

- http://www.ostomyland.com/ostomyland/
    - Create an account for free

COH Contact List and Resources

Ostomy RN: Leddy Hoffman 626-218-0860 lhoffman@coh.org

Sheri & Les Biller Patient and Family Resource Center: The Biller Patient and Family Resource Center integrates all support services at City of Hope. Here you can explore the many resources we offer to strengthen and empower patients and caregivers before, during, and after treatment.

- http://www.cityofhope.org/patients/for-patients-and-visitors/biller-resource-center
- 626-218-CARE (2273)

Nutritionist and Physical Therapy: These resources are available at City of Hope, please contact your physician or nurse so that a referral can be made for you.

Outpatient Ostomy Clinics

- Huntington Hospital- Pasadena, CA
    - http://www.huntingtonhospital.com/Main/OstomyClinic.aspx
    - 626-397-5711
- Memorial Care Health System-Long Beach, CA
    - http://www.memorialcare.org/long-beach-memorial/locations/wound-ostomy-continence-nursing-service-outpatient-long-beach-2888
    - 562-933-3136
- Enloe Medical Center: Wound/Ostomy & Hyperbaric Center-Chico, CA
    - Referral needed-form online
    - http://www.enloe.org/services-and-treatments/woundostomy-hyperbaric-center/woundostomy-services
    - 530-332-7144

Ostomy Class

- UC Irvine Health-Irvine, CA
    - Free class-informative, interactive
    - Offered monthly for patients and families
    - http://www.ucirvinehealth.org/events/health-classes/ostomy/

Smoking Cessation

- California Smoker Helpline
    - http://www.nobutts.org/
    - 1-800-NO-BUTTS (1-800-662-8887)
- City of Hope
    - Free Smoking Cessation Support Group
        - City of Hope- Sheri & Les Biller Patient and Family Resource Center
        - Every Monday at 3pm
    - Nicotine Anonymous Meeting
        - City of Hope-Needleman Bldg., Rm 101 (Next to Fountain)
        - Every Tuesday at 6:30pm
    - Contact: Sophia Yeung
        - 626-218-9114
        - 626-253-3983
        - syeung@coh.org

Ostomy Resource Sheet

Penn Medicine - Philadelphia

Hospital of the University of PA (HUP) Ostomy Nurse Specialist Contact Info

HUP Ostomy Nurse Office	215-662-6163
HUP Ostomy Clinic	215-662-2078

Ostomy Manufacturer Information

Hollister	1-888-740-8999	www.hollister.com
Coloplast	1-888-726-7872	www.coloplast.us
Convatec	1-800-422-8811	www.convatec.com
Cymed	1-800-582-0707	www.cymed.us
Nu-Hope Labs	1-800-899-5017	www.nu-hopelabs.com
Securi-T USA	1-877-726-4400	www.securitusa.com

Ostomy Supply Distributors (Partial list; Most commonly used distributors listed first)

McKesson	1-855-404-6727	https://mpcs.mckesson.com
Edgepark Medical	1-888-394-5375	www.edgepark.com
Byram HealthCare	1-877-902-9726	www.byramhealthcare.com
CCS Medical	1-800-722-2604	https://ccsmed.com
Flagship Medical	1-800-344-6472	www.flagshipmedical.com
Liberty Medical	1-800-379-9617	www.libertymedical.com
Parthenon	1-800-453-8898	www.parthenoninc.com

United Ostomy Association Support (UOA) Groups

http://www.ostomy.org/Find_a_Support_Group.html

Local Ostomy Support Groups

Philadelphia, PA	Stanley Cooper	215-487-2584
Riddle Hosp. Media, PA	Dee Foster, CWOCN	484-227-4273
Lower Bucks County, PA	Dennis Hickey	215-638-3297
Woodbury, NJ	Kathy Pfleger	856-845-0100 X 6420

Ostomy Accessory Websites

Ostomy Secrets	1-877-613-6246	www.ostomysecrets.com
Stealth belt	1-800-237-4491	www.stealthbelt.com

General Cancer Support Services at Penn Medicine's Perelman Center

Type https://www.pennmedicine.org/cancer into you internet browser. Click on "Navigating cancer care" and then click on "Support services." The services at Penn Medicine are listed below.

- Counseling for patients and families (Psychosocial Counseling Program)
- Faith and Hope Boutique
- Home Care Services (infusion therapy)
- Hospice
- Nutrition Counseling- 215-615-0534
- Palliative Care and Pain Management
- Patient Education
- Patient Navigators
- Stress Management
- Support Groups Penn Program for Mindfulness

Ostomy Resource Sheet

Yale University

Ostomy Equipment Resources

Coloplast	1-888-726-7872	Marlen	1-216-292-7060
Convatec	1-800-422-8811	Nu-Hope	1-800-899-5017
Hollister	1-888-740-8999	Securi-T USA	1-877-726-4400
Cymed	1-800-582-0707		

Partial list of Ostomy Supply Distributors

Byram HealthCare	1-877-902-9726	www.byramhealthcare.com
CCS Medical	1-800-722-2604	https://ccsmed.com
Edgepark Medical	1-888-394-5375	www.edgepark.com
Liberator Medical	1-866-643-0956	www.liberatormedical.com
Liberty Medical	1-800-723-9558	www.libertymedical.com
McKesson	1-855-404-6727	https://mpcs.mckesson.com
Parthenon	1-800-453-8898	www.parthenoninc.com
Sterling Medical	1-888-907-8875	www.sterlingmedical.com

United Ostomy Associates of America, Inc.: United Ostomy Associations of America is the place for ostomy resources, advocacy, and support. UOAA is over 300 Affiliated Support Groups strong, and is here to help you get the answers you need as you begin your “new normal” life. We invite you to explore our website to find information about ostomies. You’ll find answers about nutrition and intimacy, and useful knowledge about living with an ostomy or continent diversion.

- http://www.ostomy.org/Home.html
- 1-800-826-0826

Online Ostomy Resources cont.

Inspire-Together we're better: Inspire was created with the belief that patients and caregivers need a safe and secure place to support and connect with one another. Inspire was created because: We all need a safe place to discuss health. We can help each other. Together, we are better.

- https://www.inspire.com/about/
    - Create an account for free
- 1-800-945-0381

Ostomy Land: An online ostomy support group; offering ostomy and stoma management and a community of people just like you.

- http://www.ostomyland.com/ostomyland/
    - Create an account for free

Ostomy Secrets 1-877-613-6246 www.ostomysecrets.com

Osto Group LLC

www.ostogroup.org 877 678 6690

Ostomy products for the uninsured

Connecticut Ostomy Clinics

Yale New Haven Hospital out-patient Ostomy Clinic

www.yalecancercenter.org

Smilow Cancer Center

35 Park Street, 8th floor

New Haven CT, 06520

203 200 4422 for appointments

203 737 2634 Lucinda Pinchot, WOCN Ostomy Nurse

Lawrence and Memorial Hospital

Waterford, CT

860 271 4949 for appointments

Bridget Mejza WOCN

http://www.lmhospital.org/services/wound-and-hyperbaric.aspx

15.13 Appendix 13 Telehealth Equipment Loan Agreement

USE AGREEMENT

For the Use of Telehealth Connection Equipment for Study Purposes

This Agreement is entered into between the [Name of Site] and

____

Whereas User wishes to obtain the temporary use of the Equipment for the following purpose(s): Connection to Telehealth Ostomy Care sessions ____

at the following address:

____

____

User has permission for the temporary use of Equipment (Make, Model, Serial #) ______________________

____

from ___________________________to __________________________________ under the following conditions:

1. User shall be responsible for the security and care of Equipment.
2. The User agrees to exercise due care in the use of said Equipment and at the termination of the Agreement to return the Equipment in as good condition as at the commencement of the Agreement and to be responsible for said equipment while it is in their possession.
3. User is responsible for their use of network communications during the time the tablet or mobile hotspot is in their possession.

User shall not sublet or lend or dispose of the Equipment, or permit it to be used by anyone other than User.

[Name of Site]	USER:
_____________________________________	By:__________________________________
	Print Name:___________________________
Date:_________________________________	Date:_________________________________

Equipment returned Date:_____________________