



PROTOCOL TITLE:

POW-R Health: Power to Redefine your Health (Internal Title: A Pragmatic Dietary Intervention to Improve Bladder Cancer Survivorship)

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1. OBJECTIVES

We hypothesize that a behavioral dietary intervention designed to modestly increase cruciferous vegetable intake in patients with Non-Muscle Invasive Bladder Cancer (NMIBC) will significantly reduce recurrence and progression. Findings from our *in vitro*, *in vivo*, and epidemiologic studies¹⁻¹⁰ have shown that dietary isothiocyanates (ITCs) exert potent anti-cancer activities against bladder cancer. ITCs are a group of phytochemicals primarily derived from cruciferous vegetables and oral consumption of dietary ITCs can be rapidly metabolized, delivered to the bladder, and concentrated in the urine—rendering the abnormal bladder epithelium the best target. In our retrospective study¹, higher consumption of raw cruciferous vegetables was associated with reduced bladder cancer-specific and overall mortality.

We will use the ORBIT Model¹¹ to translate our strong preclinical findings into a novel, dietary behavioral intervention to reduce bladder cancer recurrence and progression in diverse patients with NMIBC. We will partner with the New York State Cancer Registry (NYSCR) to recruit and enroll eligible patients and their clinical care providers in our catchment area, which is characterized by a disproportionately high risk of and mortality rate for bladder cancer. The dietary intervention will be based on Social Cognitive Theory¹² and developed in collaboration with our Community Advisory Board consisting of bladder cancer care providers and patients to ensure optimal uptake by survivors. To facilitate the rapid translation of research into evidence-based practice, implementation support strategies will be identified at the clinic level as an incremental step towards integrating the dietary behavioral intervention into current healthcare systems serving patients with bladder cancer. The study's specific aims are:

Specific Aim 1: Develop an evidence-based behavioral intervention to increase cruciferous vegetable intake, with the goal of attaining desirable urinary ITC levels effective for anti-cancer activities. We will work with our Community Advisory Board to adapt materials and methods from current evidence-based fruit and vegetable interventions and leverage our findings on ITC yield from cruciferous vegetables to develop our dietary intervention, using a systematic process consisting of information gathering, discussion groups, and mock intervention delivery.

Specific Aim 2: Conduct a feasibility pilot of our dietary behavioral intervention through a hybrid I implementation randomized controlled design in 80 NMIBC survivors, where the treatment group (n=40) will receive an evidence-based telephone intervention to increase cruciferous vegetable intake and the control group (n=40) will receive a general fruit and vegetable intake intervention based on NCI guidelines. The primary outcomes will be cruciferous vegetable intake and urinary ITC levels, and the secondary outcome will be gene expression changes in urinary exfoliated epithelial cells as a surrogate for intermediate efficacy.

Exploratory Aim: Engage the clinical care providers of patients enrolled in our intervention to ascertain the barriers and facilitators of intervention implementation within clinical practice through conducting 20 semi-structured interviews. The goal is to gain feedback and refine the intervention for “real-world” implementation.

Primary Objective(s)

- Develop an evidence-based behavioral intervention to increase cruciferous vegetable intake, with the goal of attaining desirable urinary ITC levels effective for anti-cancer activities. We will work with our Community Advisory Board to adapt materials and methods from current evidence-based fruit and vegetable interventions and leverage

our findings on ITC yield from cruciferous vegetables to develop our dietary intervention, using a systematic process consisting of information gathering, discussion groups, and mock intervention delivery.

- Conduct a feasibility pilot of our dietary behavioral intervention through a hybrid I implementation randomized controlled design in 80 NMIBC survivors, where the treatment group (n=40) will receive an evidence-based telephone intervention to increase cruciferous vegetable intake and the control group (n=40) will receive a general fruit and vegetable intake intervention based on NCI guidelines. The primary outcomes will be cruciferous vegetable intake and urinary ITC levels.

Secondary Objective(s)

- The secondary outcome will be to ascertain the level of gene expression changes in urinary exfoliated epithelial cells (due to the intervention) as a surrogate for intermediate efficacy.

Exploratory Objective(s)

- Engage the clinical care providers of patients enrolled in our intervention to ascertain the barriers and facilitators of intervention implementation within clinical practice through conducting 20 semi-structured interviews. The goal is to gain feedback and refine the intervention for “real-world” implementation.

2. BACKGROUND

The problem of bladder cancer. Bladder cancer is the sixth most common cancer in the US, contributing to over 80,000 new cases and 17,000 deaths annually². The majority of bladder cancer (70-80%) is diagnosed at an early stage with cancer confined to the epithelial and lamina propria layer of the bladder—also known as non-muscle invasive bladder cancer (NMIBC)⁴. The standard treatment for NMIBC is transurethral resection of bladder tumor, which is a routine clinic procedure without hospitalization. However, NMIBC typically recurs (50-80%) with some patients experiencing multiple recurrences at similar stages and others (20-30%) progressing to muscle-invasive disease, which is associated with cystectomy and poor survival³⁻⁵. Depending on pathological characteristics, approximately 15% of tumors are defined as high-risk and receive one or more doses of intravesical therapeutic agents⁶, of which Bacillus Calmette–Guerin (BCG) has been the gold standard for four decades⁷. Yet approximately 30% of these patients will be non-responders to BCG, and high incidence of local side effects are concerns⁷. For the majority of NMIBC patients, no other treatment is available, although they are still at risk of recurrence and progression. Current clinical management requires life-long surveillance by cystoscopy for NMIBC patients, amounting to bladder cancer being the most expensive cancer to treat per patient⁸⁻¹⁰. An estimated 696,440 people are living with bladder cancer in the US²³, the majority of which are off treatment and under surveillance. Novel, non-invasive, cost-effective strategies to control NMIBC recurrence and progression are urgently needed.

Dietary isothiocyanates (ITCs) in bladder cancer chemoprevention. Dietary ITCs are a group of phytochemicals primarily derived from cruciferous vegetables (cruciferae) with multi-faceted anti-cancer mechanisms. Our group has published 10 peer-reviewed papers¹¹⁻²⁰ involving *in vitro*, *in vivo*, and epidemiologic studies demonstrating the important role of dietary ITCs and ITC-rich cruciferae in preventing bladder cancer recurrence and progression. The four most common dietary ITCs and their primary urinary metabolites potently inhibited the growth of a panel of human

bladder cancer cells including NMIBC cells with IC₅₀ values around 10µM averagely^{15, 17}, which is realistically achievable in the urine with a single oral dose of ITC at 10 µmol/kg weight in rats²⁴. ITC at 10 µmol/kg (approximately 1 mg/kg) is also readily achievable in humans, with some cruciferae yielding as much as 3.4 mg ITC per gram²⁵. Daily oral administration of ITC at the same dose level for three weeks significantly inhibits orthotopic bladder cancer growth²⁰. Importantly, we demonstrated that dietary ITCs not only inhibit bladder cancer development, but also prevent tumor progression into muscle-invasive disease^{18, 20}. Our group also discovered that orally ingested ITCs are rapidly and almost exclusively delivered to the bladder and concentrated in urine, showing 2-3 orders of magnitude higher concentration of ITCs and metabolites in the urine than in the plasma within 3 hours of dosing^{18, 20}. Storage of the urine in the bladder further enhances exposure of malignant cells to ITCs. Therefore, this unique metabolism and disposition pathway makes the bladder the best target for ITCs or ITC-rich cruciferae. In our retrospective study of 239 bladder cancer patients^{11, 12}, raw cruciferae intake was inversely associated with bladder cancer risk, and importantly, associated with a significantly improved disease-specific survival (hazard ratio = 0.43, 95% confidence interval = 0.25-0.74).

Low cruciferae intake in bladder cancer survivors (BCS). Although the potential beneficial effect of dietary ITCs in bladder cancer is compelling, the consumption of the primary dietary resource of ITCs—cruciferae—is generally low among BCS. An average of 0.45 serving per day was observed in our retrospective study¹², similar to the report of the daily consumption of 0.44 servings in a pilot study of 48 BCS²⁶. Preliminary analysis of food frequency questionnaire (FFQ) data from over 1,400 newly diagnosed NMIBC patients from our Be-Well study (R01CA172855)²⁷ reported that daily intake of cruciferae was about 52.7 gram, or approximately 0.7 servings; while urinary ITC level was around 4.4 µM, which is below the averagely 10 µM of ITCs observed to stop or kill at least 50% of bladder cancer cells in *in vitro* models^{15, 17}. Based on our recent findings on the diverse range of ITC yield from cruciferae and the various impact of cooking methods on the ITC yield^{28, 29}, we believe that at least one serving (~1 cup raw or ½ cup cooked) of cruciferae per day, with guidance on the choice of vegetables and cooking conditions, will increase urinary ITC levels to the desirable doses needed to exert anti-cancer activities in the bladder.

Lack of interventions to increase cruciferae intake. Systematic reviews³⁰⁻³⁴ and meta-analyses³⁵ have documented the effectiveness of behavioral dietary interventions to increase vegetable intake in adults, including older and male participants, who comprise the majority of BCS⁴. Only one study tested an intervention designed to increase vegetable intake in BCS²⁶. Compared to control participants, intervention participants significantly increased their daily vegetable intake (2.4 to 3.9 servings) from baseline to 6-months, but not cruciferae intake. The intervention also failed to deliver the corresponding increase in urinary ITC concentrations, showing comparable ITC levels between intervention and control groups at 6-month follow-up. We will use *our prior work* to maximize ITC exposure in the following ways: 1) ITC yield varies as much as 300-fold from raw cruciferae²⁸, thus we will recommend proper vegetables (e.g. arugula, cabbage) in our intervention; 2) heavily cooking largely reduces ITC yield, while lightly cooking substantially increases ITC yield from cruciferae²⁸. Thus, we will recommend proper cooking conditions (e.g. stir-frying, microwaving) in our intervention; 3) peak urinary concentration is achieved within 3 hours of dosing and more than 50% of the dose is excreted and accumulated in urine within 8 hours of dosing^{20, 36}. Thus, we will recommend consumption at dinner time to avoid ITCs being quickly excreted out of body from frequent urination during the day.

Scientific premise. Bladder cancer will recur in the majority (50-80%) of NMIBC patients, yet current management is close monitoring with additions of intravesical therapies for a small portion of patients (15%) only^{4, 6}. Effective interventions are needed to prevent disease recurrence and progression and improve cancer-specific survival for NMIBC survivors with minimum side effects, participant/provider burden, and cost. Robust preclinical and epidemiological data document the promising anti-cancer effects of cruciferae as a source of ITCs against bladder cancer. Numerous dietary interventions have effectively increased vegetable intake in diverse adults. Yet an effective intervention designed to improve bladder cancer prognosis through increasing cruciferae intake has not been developed. We propose to translate our basic science research findings in dietary ITCs and bladder cancer into an evidence-based behavioral intervention for NMIBC patients with potential for population-level impact. The proposed research will accelerate what we currently know into an intervention that could meaningfully impact cancer survivorship in ***a population at high risk of recurrence and progression that are currently under surveillance.***

Preliminary Studies. Dr. Tang's work has documented the anti-cancer potential of dietary ITCs and ITC-rich cruciferae against bladder cancer¹¹⁻²⁰. Her recent findings on ITC composition data in food commonly consumed in the Western diet and the effects of cooking methods on ITC yield from cruciferae²⁸ informed the proposed intervention. Dr. Tang co-led the Be-Well study (R01CA172855), a prospective cohort of NMIBC survivors²⁷, which provided data to support the need of a behavioral dietary intervention to increase cruciferae intake to boost urinary ITC levels. Dr. Yeary led The WORD study (2P20MD002329-06), a behavioral weight loss trial of 426 adults that included a dietary component to meet intake goals of at least 5-9 servings of fruits and vegetables a day³⁸. The intervention significantly increased vegetable intake by 3.44 (1.51, 5.36) servings from baseline to 6 months. Components of this intervention will be used in our cruciferae intervention for BCS.

3. INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria

Cancer Patient:

To be included in this study, participants must meet the following criteria:

1. Age 18 years old or older (no upper limit).
2. English speaking.
3. Diagnosed with stage Tis, Ta, or T1 bladder cancer.
4. Resides in the Western New York catchment area.
5. Did not receive a partial or radical cystectomy.
6. Does not have a prior cancer diagnosis within 12 months of their bladder cancer diagnosis.
7. Does not have a subsequent more advanced bladder cancer diagnosis.
8. For Roswell Park Cancer Registry only: Bladder cancer diagnosed 2016-2018, 2019-current.
9. Participant must understand the investigational nature of this study and sign an Independent Ethics Committee/Institutional Review Board approved written informed consent form prior to receiving any study related procedure.

Physician:

To be included in this study, physicians must meet the following criteria:

1. English speaking.
2. Physician in a clinic located in the catchment area.
3. Currently treats bladder cancer patients.

Refer to **Appendix A** for the Investigator Study Eligibility Verification Form: Inclusion Criteria.

Exclusion Criteria

Cancer Patient:

Participants Recruitment will be excluded from this study for the following:

1. Participants who have had chemotherapy or radiotherapy within 4 weeks (6 weeks for nitrosoureas or mitomycin C) prior to entering the study or those who have not recovered from adverse events due to agents administered more than 4 weeks earlier.
2. Participants with known brain metastases should be excluded from this clinical trial because of their poor prognosis and because they often develop progressive neurologic dysfunction that would confound the evaluation of neurologic and other adverse events.
3. Adults unable to consent.
4. Adults unable to complete study measures in English.
5. Individuals who are not yet adults (infants, children, teenagers).
6. Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.
7. Unwilling or unable to follow protocol requirements.

Physician:

1. Unable to complete the study measures in English.

Refer to **Appendix B** for the Investigator Study Eligibility Verification Form: Exclusion Criteria.

Inclusion of Women and Minorities

Both men and women and members of all races and ethnic groups are eligible for this study.

Special Populations

The following special populations ae excluded from this study:

- Cognitively impaired adults/adults with impaired decision-making capacity
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners

4. LOCAL AND STUDY-WIDE NUMBER OF SUBJECTS

We will recruit 80 bladder cancer patients \geq 18 years of age. We will recruit up to 20 physicians in the Western New York area. Recruitment for both patients and physicians will take place over the span of two years (study duration).

5. LOCAL AND STUDY-WIDE RECRUITMENT METHODS

Patient Recruitment. Using ICD-O-3 codes provided, Dr. Kuliszewski of the NYSCR will lead her staff to identify qualifying patients from their database based on the study's eligibility requirements. The NYSCR has identified 199 cases that meet the study's eligibility criteria in 2018 and anticipate at least 400 eligible cases in total in 2018 and 2019. A total of 250 eligible patients will be contacted to enable researchers to recruit from a pool of at least 100 patients. In prior studies, 52.4% to 62.5% of patients contacted by the NYSCR agreed to be contacted by researchers for study consent. The NYSCR will send a letter to the physician of record for selected cases notifying that the patient was identified for the study, requesting that the NYSCR be notified if the patient is unable or ineligible to participate in the study, and requesting information about the case's primary care physician if different from the contacted physician. If no contraindication has been received from the physician or if the physician has not responded within 3 weeks, the NYSCR will send an informational packet to the patient. The packet will contain: 1) a letter with study information; 2) a participant information sheet; and 3) a release of information consent form. After two weeks without response, a reminder packet will be sent and followed with up to five phone calls. If the NYSCR can't reach the patient, the patient will be considered a refusal. The NYSCR's materials and procedures will be reviewed by the New York State Department of Health IRB. For patients who agree to be contacted about the study, the NYSCR will securely share the patient's name, contact information, and information about their diagnosis with the Roswell study team through a secure file transfer. We estimate that from the pool of at least 100 patients who consent to be contacted, we will be able to obtain informed consent from at least 80 patients (80%). Research staff will contact patients who have agreed to be contacted by phone, whereby they will provide a general study overview and conduct a screening interview to confirm eligibility. Staff will obtain informed consent to participate in the study by phone; the consent form along with a Participant Welcome Letter (Appendix O) will be mailed to participants for record. To assist with study retention, we will ask participants for contact information to be used in follow-up. Participants will also be given incentives for completing study assessments. The Roswell study team will share information with the NYSCR team on the patients who agree to participate in the study, as well as any information obtained from study participants that does not match the information provided from the NYSCR database (e.g., race, ethnicity).

Roswell Park Cancer Registry. Due to low enrollment from the NYS Cancer Registry, we will also recruit participants from the Roswell Park Cancer Registry that meet the study's eligibility criteria. To avoid overlap with NYS Cancer Registry patients, we will identify potential participants by focusing on patients diagnosed within last five years and exclude patients diagnosed within 2018-2019 (original parameters for the NYS Cancer Registry recruitment list). Study staff will consult with Roswell Park urologist to determine if the patient is unable or ineligible to participate in the study. The patients accessioned from the Roswell Park Cancer Registry will be contacted by letter (See Appendix T) asking them to participate in the study. Study staff will follow-up with potential participants to determine whether they received the letter and if they are interested in participating.

Physician Recruitment. We will ask intervention participants to nominate physicians to participate in a short 15-minute semi-structured interview. Research staff will mail an invitation letter to nominated physicians that will include an information sheet (Appendix J), opt-in/opt-card card, and stamped reply envelope. Within 2-weeks, physicians who do not respond will be contacted by phone, fax, or email with no more than 5 attempts. Participating physicians will

receive \$100. Physicians who verbally consent to participate will be asked to refer other physicians to the study. Community Advisory Board (CAB) members will also utilize their networks to nominate physicians for staff to contact. We will recruit up to 20 physicians to ensure data saturation⁶¹. Among clinicians involved in cancer treatment, enrollment rates between 46.3%-92% have been reported^{60, 62, 63}, with one study reporting an enrollment rate of 48% among clinicians involved in bladder cancer treatment⁶². Out of the 80 participants enrolled in our intervention, we anticipate 40 to nominate their physicians and we expect to receive referrals for 5 additional physicians from enrolled physicians and 5 physicians nominated by our CAB. Given an anticipated enrollment rate of 48%, we anticipate recruitment of 20 physicians.

6. MULTI-SITE RESEARCH

Since this is NIH funded study, Single IRB will be pursued for the NYS DOH (NYS CR) and Roswell Park will be serving as the IRB of Record.

7. STUDY TIMELINES

Figure 1

Study Timeline		Year 1												Year 2												
Specific Aim 1: Develop a novel dietary intervention for bladder cancer survivors																										
Phase 1: Information gathering	X																									
Phase 2: Review intervention components		X	X																							
Phase 3: Mock intervention delivery to CAB				X	X																					
Phase 4: Refine intervention						X	X																			
Train staff to deliver the intervention								X	X																	
Specific Aim 2: Hybrid Type I Feasibility Trial																										
NYSCR and Roswell Park Cancer Registry recruitment (patient agree to contact)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Participant recruitment	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Participant participation*	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Data analysis and dissemination																									X	X
Exploratory Aim: Engage providers to ascertain implementation strategies																										
Recruit providers																				X	X	X	X			
Conduct semi-structured interviews																				X	X	X	X			
Data analysis and dissemination																									X	X

*Participant study participation is only for a total of 6 months after enrollment.

8. STUDY ENDPOINTS

Primary Endpoint(s)

- Urinary ITC levels will be measured using HPLC-based cyclocondensation assay^{14, 51}, which measures ITCs and metabolites as low as a few picomoles and has been routinely performed in Dr. Tang's laboratory. The results will be adjusted by urinary creatinine level using creatinine assay kits (Caymen, Ann Arbor, MI). Cruciferae intake will be assessed using a questionnaire adapted from Thomson et al.⁵² to capture both intake and cooking styles.

Secondary Endpoint(s)

- Gene expression will be evaluated via RNA-seq as a surrogate for intermediate efficacy, conducted at Roswell Park's Genomics Shared Resource using NextSeq500 platform (Illumina Inc.). We have worked with the Genomics core to optimize the extraction of RNA samples from urine. With the addition of TRIzol™ right before the storage of the cell pellet samples, we were able to extract sufficient amounts of RNA and generate high quality RNA-seq data. Dietary intake will be evaluated by three non-consecutive 24-hour dietary recalls (two weekdays, one weekday) conducted by trained staff using the interview-administered Nutrition Data System for Research (NDSR)⁵³.
- Additional urinary metabolites and potential biomarkers will be explored using proteomic and/or metabolomic approaches.

Exploratory Endpoint(s)

- Our exploratory endpoint will be identification of barriers, facilitators, and other process-related measures relevant to informing the implementation of an evidence-based cruciferae intervention within clinical practice.

9. DESIGN

We will use a Hybrid I implementation randomized-controlled design to simultaneously gather outcomes regarding the intervention's feasibility and process data to facilitate wide-spread implementation and dissemination of the intervention into clinical practice if the intervention is effective. A total of 80 patients will be recruited on a rolling basis. Forty will be randomized to intervention and 40 to control.

10. TREATMENT

The planned evidence-based behavioral intervention using techniques associated with effective dietary change in older adults (Table 1): problem solving, plan social support, goal setting, follow-up prompts, and provide feedback. The 6-month intervention will likely consist of the following, although aspects of the intervention may change based on data from the adaptation process: 1) Mailed educational materials about the importance of consuming cruciferae, how to maximize urinary ITC levels, serving size goals, the importance of self-monitoring, and strategies to increase intake, along with booklets to record daily cruciferae intake; 2) One live phone call (~45-60 minutes) delivered two weeks after mailing materials to verify understanding of the educational information and help participants complete a personalized action plan where participants will identify barriers and facilitators (e.g. social support) to meet identified goals (problem solving); 3) 11 Interactive Voice Response (IVR) phone messages that will begin by asking participants to input the servings of cruciferae consumed the previous week (follow-up prompt). Depending on number of servings participants input, they will be routed to one of three paths: a) meeting goals, b) not meeting goals but has some progress, c) no progress. Participants on each path will receive a tailored phone message (provision of feedback) selected from a library of messages to enable participants to meet or maintain their cruciferae goal. A total of 11 IVR calls will be delivered weekly for the first three weeks and then bi-weekly for the remainder of the 6-month intervention.

Table 1. Intervention Components

Intervention component	Intervention content/ behavior technique	SCT Construct	CAB adaptation
Educational Materials	<ul style="list-style-type: none"> Relationships between cruciferae, ITC yield, and bladder cancer Type of vegetable, cooking methods, and timing of intake for maximum ITC exposure Program goal of 1 serving of cruciferae per day/Goal setting Keeping track of servings eaten per day 	<ul style="list-style-type: none"> Knowledge Outcome expectations Behavioral skills Barriers and opportunities Intentions 	<ul style="list-style-type: none"> Barriers and facilitators to meeting goals, examples from BCS day-to-day life, strategies to meet goals, visuals pleasing to BCS
1 Live phone call	<ul style="list-style-type: none"> Review materials Action plan to meet program goal/problem solving 	<ul style="list-style-type: none"> Knowledge Behavioral skills Barriers and opportunities Self-efficacy 	<ul style="list-style-type: none"> Potential problems and subsequent solutions for BCS to meet goals
11 Interactive Voice Response (IVR) phone calls	<ul style="list-style-type: none"> Participants enter by phone servings of cruciferae eaten in prior week/follow-up prompt Automated feedback based on the extent participants met program goal/ feedback 	<ul style="list-style-type: none"> Barriers and opportunities Reinforcement Self-efficacy 	<ul style="list-style-type: none"> How to structure the cruciferae intake form to make it easy for BCS to use Construct library of IVR feedback messages relevant to BCS

11. PROCEDURES INVOLVED

Aim 1: Develop an evidence-based behavioral intervention to increase cruciferous vegetable intake

Adaptation. Working with our Community Advisor Board (CAB) consisting of a urologist, clinic staff, and BCS, we will refine current evidence-based vegetable interventions to develop a novel dietary intervention for BCS. We will use a systematic process consisting of information gathering, discussion groups, and mock intervention delivery. Dr. Yeary, who has extensive experience adapting evidence-based behavioral interventions for diverse groups, will lead the team through a four-stage adaptation process based on the Barrera and Castro framework⁴² and PEN-3 model for cultural adaptation⁴³. We will: 1) identify relevant factors to increase cruciferae intake in BCS; 2)

use the PEN-3 model to review each of the intervention's components (e.g. graphics, terminology, saliency of behavioral messages); 3) administer the revised intervention to the CAB for their feedback; and 4) refine the intervention based on Step 3. We will also present the program to the BCS group meeting at Roswell Park to ensure the intervention is salient to our target population by demographic characteristics. The final product will be a 6-month cruciferae intervention for BCS grounded in Social Cognitive Theory (SCT). CAB members will each be compensated \$100 per meeting (up to three meetings), each meeting lasting about 1.5 hours and will be conducted via phone or computer. CAB members (bladder cancer survivors) may be asked to complete a structured interview over the phone and complete some demographic questions about themselves. Structured interviews will last approximately 60 minutes and CAB members will be paid \$50 for completion of the structured interview. See Appendix K for Study Information Sheet for CAB members and Appendix L for CAB Interview Guide)

Intervention Design. Drawing from the large body of literature on evidence-based behavioral fruit and vegetable interventions, the intervention will likely include components used by Wolf et al.⁴⁴ and Djuric et al.⁴⁵ (i.e. educational materials, phone calls, written plans, self-monitoring), who significantly increased vegetable intake among participants whose demographic characteristics mirror the majority of our target population (i.e. age 65 and older, diverse, male). The following evidence-based behavioral techniques associated with effective dietary change in older adults⁴⁶ will also be incorporated (Table 1): *problem solving, plan social support, goal setting, follow-up prompts, and provide feedback*. The 6-month intervention will likely consist of the following, although aspects of the intervention may change based on data from the adaptation process: 1) Mailed educational materials about the importance of consuming cruciferae, how to maximize urinary ITC levels, serving size goals, the importance of self-monitoring, and strategies to increase intake, along with booklets to record daily cruciferae intake (See Appendix P); 2) One live phone call (~45-60 minutes) delivered two weeks after mailing materials to verify understanding of the educational information and help participants complete a personalized action plan where participants will identify barriers and facilitators (e.g. *social support*) to meet identified goals (*problem solving*) (See Appendix Q); 3) 11 Interactive Voice Response (IVR) phone messages that will begin by asking participants to input the servings of cruciferae consumed the previous week (*follow-up prompt*). Depending on number of servings participants input, they will be routed to one of three paths: a) meeting goals, b) not meeting goals but has some progress, c) no progress. Participants on each path will receive a tailored phone message (*provision of feedback*) selected from a library of messages to enable participants to meet or maintain their cruciferae goal. A total of 11 IVR calls will be delivered weekly for the first three weeks and then bi-weekly for the remainder of the 6-month intervention. The CAB will give specific feedback about visual material that would be the most appealing to BCS, specific barriers survivors may have to meet study goals, examples from survivors' day-to-day lives to incorporate in the materials, specific phrases and language to clearly convey the content, strategies to consume cruciferae with minimum effort, and tailored wording or terms that would optimize the participants' response to IVR feedback. We selected phone and mail modalities of intervention delivery because: 1) Phone-based dietary interventions are effective³⁵; 2) phone-based interventions are more feasible to implement on a wide-scale compared to face-to-face interventions, which take more resources⁴⁷; 3) IVR would be more cost-effective for a clinic to incorporate within its system vs. dedicating staff to provide frequent calls. Further, IVR is more feasible and accessible to the target population because BCS are typically older (average age at diagnosis is 73 years old); use of text messaging is lower among older groups, with less than half reporting email or text messaging for communication⁴⁸.

Control intervention. Participants in the control arm will receive mailed materials about general fruit and vegetable intake intervention based on published NCI guidelines. (<https://cancercontrol.cancer.gov/ocs/>). The control intervention will utilize the same delivery method (i.e. mailed educational materials, live phone call, IVR calls) and follow the same contact schedule as the treatment schedule (See Appendix P and Appendix Q). We intend to compare our tailored cruciferae program with general program on increase of fruit and vegetable intake. We anticipate minimal contamination between intervention and control because BCS will be recruited throughout our catchment area and our intervention will be delivered individually with each BCS.

Personnel Training. Dr. Yeary will utilize her extensive experience in training others in the delivery of behavioral interventions to train project staff to implement the intervention. A training-of-trainers model that incorporates didactic education, trainee practice, and written and verbal feedback will be used. Training will build knowledge about behavior change promotion, with a specific emphasis on delivering the live phone call with fidelity, utilizing participant booklets to program the IVR messages, and communicating effectively with participants about health. The training will conclude with project staff demonstrating mastery of concepts through mock phone sessions and live phone calls, and accurate programming based on booklet data received. Project staff will be asked to complete a checklist of topics to monitor intervention fidelity.

Aim 2: Conduct a feasibility pilot of our evidence-based dietary behavioral intervention

Study Design. We will use a Hybrid I implementation randomized-controlled design to simultaneously gather outcomes regarding the intervention's feasibility and process data to facilitate wide-spread implementation and dissemination of the intervention into clinical practice if the intervention is effective. A total of 80 patients will be recruited on a rolling basis. Forty will be randomized to intervention and 40 to control.

Participant Recruitment. Eligibility criteria include: 1) English speaking; 2) diagnosed with stage Tis, Ta, or T1 bladder cancer; 3) resides in the Western New York (WNY) catchment area (Niagara, Orleans, Genesee, Erie, Wyoming, Chautauqua, Cattaraugus, and Allegany counties); 4) did not receive a partial or radical cystectomy; 5) does not have a prior cancer diagnosis within 12 months of their bladder cancer diagnosis 6) does not have a subsequent more advanced bladder cancer diagnosis; and 7) (for Roswell Park Cancer Registry only) diagnosed 2016-2018, 2019-current. We chose not to include current cruciferae intake as an eligible criterion because prior studies have reported that BCS consumed an average of 0.44-0.45 servings per day^{12, 26}, less than half our recommended amount. Using ICD-O-3 codes provided, Dr. Kuliszewski of the NYSCR will lead her staff to identify qualifying patients from their database based on the study's eligibility requirements. The NYSCR has identified 199 cases that meet the study's eligibility criteria in 2018 and anticipate at least 400 eligible cases in total in 2018 and 2019. A total of 250 eligible patients will be contacted to enable researchers to recruit from a pool of at least 100 patients. In prior studies, 52.4% to 62.5% of patients contacted by the NYSCR agreed to be contacted by researchers for study consent. The NYSCR will send a letter to the physician of record for selected cases notifying that the patient was identified for the study, requesting that the NYSCR be notified if the patient is unable or ineligible to participate in the study, and requesting information about the case's primary care physician if different from the contacted physician. If no contraindication has been received from the physician or if the physician has not responded within 3 weeks, the NYSCR will send an informational packet to the patient. The packet will contain: 1) a letter with study information; 2) a participant information sheet; and 3) a release of information consent form. After two weeks without response, a reminder packet will be sent and followed with up to five phone

calls. If the NYSCR can't reach the patient, the patient will be considered a refusal. The NYSCR's materials and procedures will be reviewed by the New York State Department of Health IRB. For patients who agree to be contacted about the study, the NYSCR will securely share the patient's name, contact information, and information about their diagnosis with the Roswell study team. For the Roswell Park Cancer Registry, study staff will consult with Roswell Park urologist to determine if the patient is unable or ineligible to participate in the study. The patients accessioned from the Roswell Park Cancer Registry will be contacted by letter (See Appendix T) asking them to participate in the study. Study staff will follow-up with potential participants to determine whether they received the letter and if they are interested in participating. We estimate that from the pool of at least 100 patients who consent to be contacted, we will be able to obtain informed consent from at least 80 patients (80%). The Roswell study team will share information with the NYSCR team on the patients who agree to participate in the study, as well as any information obtained from study participants that does not match the information provided from the NYSCR database (e.g., race, ethnicity).

Participant Data and Sample Collection Procedures. Research staff will contact patients who have agreed to be contacted by phone, whereby they will provide a general study overview and conduct a screening interview to confirm eligibility. The consent form will be mailed out to patients prior to the consenting discussion. We will ask the patient to mail back the consent form with the appropriate signatures. We will also provide an additional copy of the consent form for their records. We will include a paid postage pre-addressed envelope for the patient to mail back the signed consent form to study staff. Baseline Data Collection will be conducted within four weeks prior to intervention start. The Data Collector, masked to treatment assignment, will conduct telephone surveys with participants and directly enter participants' responses into pre-programmed data collection forms in REDCap^{49, 50}. Surveys will cover sociodemographic variables, faith and spirituality beliefs, dietary, and cruciferae intake (Appendix F). Additionally, 24-hour dietary recalls will be conducted and instructions (Appendix M) and a reference guide (Appendix N) will be mailed out to participants prior to their scheduled recall interview. Participants will also be mailed out track books to help keep track of their fruit and/or vegetable intake during the intervention (Appendix R). Follow-up Assessment (Appendix G1) will be conducted at 6 months following the same protocol as the baseline assessment (Appendix F). Participants will receive \$100 for completing the baseline and 6-month follow-up assessments. In addition, we will ask participants' feedback on the intervention (Appendix G2) as part of the Follow-Up Assessment (Appendix G1). The feedback questions (Appendix G2) will be given to those in the cruciferous arm only. For cruciferous arm study participants that have completed the 6-month follow-up assessment as of the March 21, 2022 Protocol revision, the study participants will be called back to complete the feedback questions (Appendix G2). These study participants will first be sent an information sheet (Appendix W) regarding the additional feedback questions before being called. When they are called regarding the study feedback questions, they will provide verbal consent before proceeding with answering the feedback questions.

Urine Sample Collection will be conducted at baseline and 6-months. Participants will be instructed to collect first-void urine continuously for three days, which will provide a more reliable measurement than one-spot urine samples. A specially designed urine collection device consisting of a 10-mL container and sponge with a plastic holder will be used, which does not impact urinary ITC measurement and has been used in the Be-Well study with documented ease of collection and minimal shipment burden. Staff will mail urine collection kits and instructions (Appendix C) to participants. Given that recent behaviors may have a large impact on urinary ITC levels,

participants will be asked to complete a brief 2-page specimen collection survey (Appendix D) on medical and lifestyle status in the past two days. They will then return the survey and urine samples to Roswell Park in the provided shipping box with biohazard labels and ice packs via pre-paid overnight shipping service. Once received, the urine will be spun down from the sponge, aliquoted, and stored at -80°C at Dr. Li Tang's lab (x8247) at Roswell Park. The urine aliquots will be assayed at Dr. Tang's Lab for ITC analysis using HPLC-based cyclocondensation assay⁶⁴ This method is able to accurately measure as low as a few picomoles of ITCs and their metabolites. Dr. Tang's lab has experience and expertise in running this assay⁶⁵ and will process the urine samples and perform the measurements. The results will be adjusted by urinary creatinine level, which will also be performed in the laboratory, using a commercially available creatinine assay kit (Caymen, Ann Arbor, MI). The cell pellets from three urine samples per participant will be combined and delivered to Genomics Shared Resources at Roswell Park for RNA-seq analysis in a batch. Additional urinary metabolites and potential biomarkers will be explored using proteomic and/or metabolomic approaches. All assays will be conducted on the stored urine samples. Neither new urine sample collection nor patient contact will occur.

Exploratory Aim: Engage providers to ascertain specific clinic-level implementation factors

We will ask intervention participants to nominate physicians to participate in a short 15-minute semi-structured interview. Research staff will mail an invitation letter to nominated physicians that will include an information sheet (Appendix J), opt-in/opt-card card, and stamped reply envelope. Within 2-weeks, physicians who do not respond will be contacted by phone, fax, or email with no more than 5 attempts. Participating physicians will receive \$100. Physicians who verbally consent to participate will be asked to refer other physicians to the study. CAB members will also utilize their networks to nominate physicians for staff to contact.

We will conduct brief 15-minute semi-structured interviews using an interview guide. The guide will give physicians a brief overview of our cruciferae intervention. Research staff will then ask questions regarding facilitators and barriers of intervention adoption within clinical practice³⁷. Staff will ask physicians the needed implementation strategies to sustain the intervention post research funding, in addition to intervention modifications to maximize sustained clinic adoption³⁷.

12. WITHDRAWAL OF SUBJECTS

Participants can stop their participation at any time. Participants may refuse to answer any question and they may leave the study at any time.

13. RISKS TO SUBJECTS

For the survey portion of the study, involvement in this study does not involve any physical risk. The possible risks might be feeling uncomfortable answering questions.

There are no known risks associated with providing a urine sample other than a potential loss of confidentiality.

14. POTENTIAL BENEFITS TO SUBJECTS

Participants in the intervention and feasibility scale-up pilot may benefit from study participation by improving dietary habits and/or reducing bladder cancer recurrence. The information gained may also help other bladder cancer patients in the future. Participants will receive \$100 for completing each assessment—the study will ask participants to complete baseline (see Appendix

F) and 6-month follow-up assessments (See Appendix G1). Thus, participants will be able to receive up to \$200 total in assessments. Participating physicians will receive \$100 for the interview.

15. DATA AND SPECIMEN BANKING

All questionnaire data will be stored in REDCap or in a locked file cabinet. REDCap is a secure application supported by Partners Research Computing, Enterprise Research Infrastructure & Services (ERIS). ERIS has all the necessary physical and operational securities in place to meet or exceed Federal and State security and privacy regulations for data transmission and storage using REDCap. Data will only be removed when coded, entered, or audited. The urine samples will be processed and stored at Dr. Tang's laboratory and a dataset will be created to track and record the results obtained from laboratory assays on urine samples. The dataset will only contain study IDs without any personal identifiable information. The file that contains the link between study ID and subject identifiable information will be maintained separately and can only be accessed by Drs. Yeary and Tang and will never be released to any laboratory staff.

16. MEASUREMENT OF EFFECT

Solid Tumors

N/A

Hematologic Tumors

N/A

Other Response Parameters

We will assess the treatment intervention's effect on the consumption of cruciferae vegetables and ITC yield, as specified under the heading, "STUDY ENDPOINTS". We will also assess changes in gene expression via RNA-Seq, so as to identify a panel of genes that respond specifically to consumption of cruciferae vegetables as specified in the section of STUDY ENDPOINTS. It is well known that isothiocyanates in cruciferae vegetables alter multiple signaling pathways. Therefore, the identified panel of genes can be used as biological biomarkers to understand how individuals respond to the consumption of cruciferae vegetables, and more importantly, be used as biomarkers to monitor the effect of cruciferae vegetables.

17. SAFETY EVALUATION

Reporting Unanticipated Problems.

Unanticipated problem reporting will begin at the time of participant consent. The Reportable New Information (RNI) Form will be submitted to the Roswell Park Clinical Research Service (CRS) Quality Assurance (QA) Office within 1 business day of becoming aware of the Unanticipated Problem. After review, CRS QA Office will submit the RNI to the IRB.

When becoming aware of new information about an Unanticipated Problem, the updated information will be submitted to the CRS QA Office with an updated RNI Form. The site Investigator or designated research personnel will report all unanticipated problems to the IRB in accordance with their local institutional guidelines.

18. DATA MANAGEMENT AND CONFIDENTIALITY

Individual confidentiality concerning study data and measurements will be ensured through the following ways: Participant data will not be identified by name (using only an identification number for identification), all data and records in locked storage areas accessible only to project staff, and password protected computer data files. Participants will not be personally identified in any scientific reports generated by the study. All results will be presented in aggregate form. All project staff will undergo training and ongoing continuing education about methods to protect confidentiality. All project staff will complete Human Subject Training Requirements.

We have contracted with an outside company Above Ground Development (AGD) to conduct the 11 Interactive Voice Response (IVR) phone messages that participants receive as part of the intervention. The study staff will share the following information with AGD that includes participant's name, date of birth and contact phone number. This PHI information will be entered into the secure web portal (user interface) and ALL data will be stored with AGD on a secure HIPAA Compliant server.

Safety of subjects. Data safety and monitoring will be overseen by Drs. Yeary and Tang. The proposed study is considered extremely low risk. Adverse events will be monitored routinely during questionnaire and data collection and participants will be instructed to contact study personnel for any issues. Monthly meetings with Dr. Yeary, Dr. Tang, and the Project Coordinator (Ms. Harfouche) will also be held to evaluate the status of study subjects. Dr. Qiang Li, a Board Certified Bladder Cancer Surgeon, will provide guidance and supervision regarding all the reported side effects or potential symptoms possibly related to study participation. Adverse events will be labeled as to whether attributed to behavior intervention or not, classified as mild, moderate, severe, life threatening, or causing death, and reported to Roswell Park IRB and NIH under Institute guidelines. We will track reporting of adverse events in the REDCap study database. All clinical trials at Roswell undergo yearly review by an independent Data Safety Monitoring Board.

Collection of Data and Biospecimens. Project staff will collect questionnaire data from research subjects by telephone interview, as dictated by study protocol. Questionnaire data will be directly entered into REDCap, a secure web application for building and managing online surveys and databases. Only study identification number (Study ID) will be entered when the data are collected. All data collected by research assistants are considered part of the subject's confidential record. REDCap is a secure application supported by Partners Research Computing, Enterprise Research Infrastructure & Services (ERIS). ERIS has all the necessary physical and operational securities in place to meet or exceed Federal and State security and privacy regulations for data transmission and storage using REDCap. All data will remain confidential. A file will be separately maintained that associates the subject name with that subject's study ID. This file will remain in a locked file cabinet and will not be stored with the actual study data. The urine samples will be collected by the participants at home and directly shipped to Roswell Park using prepaid and addressed shipping labels. All urine samples will be labeled with assigned study IDs only and no personal information will be provided.

Storage of Collected Data and Biospecimens.

N/A

Data Entry Requirement. All data will be coded prior to entry. Any ambiguity in the response to a question will be brought to the attention of Ms. Harfouche for clarification. If Ms. Harfouche is

unsure how to code the response, the matter will be brought to the attention of Drs. Yeary, Tang, and consulted with the statistician (Dr. Yu). Ms. Harfouche will maintain a log, so that future occurrences of problems will be handled in the same manner.

The data entry system will require a login identification and password in order to gain access to the data. Where appropriate, validation and range rules will be applied to the actual entry fields. Only Dr. Yeary, Dr. Tang, Dr. Yu, and data entry personnel will be able to view the data in its raw state. All other authorized personnel will view data via forms and reports in aggregate form created by Dr. Yeary, Dr. Tang, and Dr. Yu.

Access to Cleaned Computer Data. Only Drs. Yeary, Tang, and Yu can give permission for the release of aggregated study data. No confidential information will be released without permission.

19. STATISTICAL PLAN

Patient. We will use SAS for data analysis and R for RNA-seq data. We will generate descriptive statistics and assess group differences at baseline and examine treatment drop-out and missing data patterns' impact on treatment effects. We will calculate summary statistics and compare study endpoints and patient baseline characteristics by treatment group using independent sample *t*-tests and Fisher's exact tests. We will summarize changes between pre- and post-intervention for both arms and calculate point estimates and their corresponding 95% confidence intervals. We will analyze between-group differences in the change of outcome variables between baseline and post-intervention using analysis of covariance (ANCOVA). The intervention group will be used as factors and the baseline variables used as covariates. Within-group difference between two time-points will be compared by paired sample *t*-tests, while between-group differences at each time-point will be compared by independent sample *t*-tests or Wilcoxon rank sum tests. RNA-seq data will be processed and quality-checked by the Bioinformatics Shared Resource at Roswell Park; sample relationships will be explored using sample clustering and principle component analysis. We will use DESeq258 to identify significantly differentially expressed (SDE) genes and conduct pathway analysis with GSEA59 using rank-based gene list from SDE analysis. All tests will be two-sided at the significance level of 0.05. We will use the Benjamini-Hochberg's method to calculate the false discovery rate for gene expression.

Physician. Interviews will be audio-recorded, transcribed verbatim, checked for accuracy and entered into a software program for the management of text data (e.g. NVivo 12). We will code transcripts using content analysis. Coding decisions and emergent findings will be discussed until an agreement is reached⁵⁷.

Sample Size Determination

Patient: With n=40 for each group, the ANCOVA can achieve 80% power to detect a difference of 0.57 within-group standard deviations (SDs) between groups assuming the correlation of post-intervention and baseline outcome is R²=0.2. Data from the Be-Well study reports a within-group SD of 8.9 μ M for urinary ITCs and 62 g/day for cruciferae intake; thus, we can detect a difference equivalent to 5.1 μ M in urinary ITC and 35.3 g/day of cruciferae intake between groups. The intervention's goal is to increase urinary ITC levels from the baseline of 4.4 μ M to the desirable biological dose of 10 μ M and cruciferae intake from the baseline of 52.7 gram (0.7 serving) to at least 75 gram (a typical serving size) at 6-month follow up. Given the generally lower cruciferae intake observed in other BCS studies (around 0.44-0.45 serving, equivalent to 33-34 gram per day)^{11, 26}, the proposed study will have sufficient power to detect our projected differences.

Physician: We will recruit up to 20 physicians to ensure data saturation⁶¹. Among clinicians involved in cancer treatment, enrollment rates between 46.3%-92% have been reported^{60, 62, 63}, with one study reporting an enrollment rate of 48% among clinicians involved in bladder cancer treatment⁶². Out of the 80 participants enrolled in our intervention, we anticipate 40 to nominate their physicians and expect to receive referrals for 5 additional physicians from enrolled physicians and 5 physicians nominated by our CAB. Given an anticipated enrollment rate of 48%, we anticipate recruitment of 20 physicians.

Randomization

Subjects will be randomized in a 1:1 fashion to the control arm and interventional arm using permuted block randomization. We will employ random block sizes of 4 and 2. Randomization will be carried out by the Department of Biostatistics and Bioinformatics.

Demographics and Baseline Characteristics

Descriptive statistics (as appropriate: n, percent, mean, median, min and max) will be used to summarize demographic and baseline characteristics. The patient characteristics will also be summarized by treatment group. The baseline characteristics between groups will be compared by independent sample t-tests and Fisher's exact tests as appropriate.

Primary Analysis.

For primary analysis, the aim is to investigate the between-group differences in the change of urinary ITC levels and cruciferae intake between baseline and post-intervention. The comparison of change from baseline will be made utilizing analysis of covariance (ANCOVA) and F-tests ($\alpha=0.05$). The intervention group will be used as factors and the baseline variables used as covariates. A coefficient for interventional group that is significantly greater than 0 will indicate that the intervention increases the ITC levels or cruciferae intake. Within-group difference between two time-points will be compared by two-sided paired sample t-tests, while between-group difference at each time-point will be compared by two-sided independent sample t-tests ($\alpha=0.05$). Since this is a pilot feasibility study, no adjustment for multiple comparisons will be planned.

Secondary Analyses.

The aim of secondary analysis is to investigate the difference in gene expression patterns between two groups. Three urine samples per participant will be collected at baseline and month 6, and the cell pellets from three urine samples per participants will be combined and subject to RNA-seq. RNA-seq data will be processed and quality-checked by Bioinformatics Shared Resource at Roswell Park; sample relationships will be explored using sample clustering and principle component analysis. We will use DESeq to identify significantly differentially expressed (SDE) genes and conduct pathway analysis with GSEA using rank-based gene list from SDE analysis. All tests will be two-sided at significance level of 0.05. We will use the Benjamini-Hochberg's method to calculate the false discovery rate (FDR) for gene expression.

The additional metabolites and biomarkers will be analyzed using the same approach as in primary analysis. The univariate distributions of these variables will be examined, and appropriate transformations may be applied before analysis. Benjamini-Hochberg's method to control the FDR.

Exploratory Analysis.

Qualitative methodology using content analysis will be used to ascertain physician barriers and facilitators to the intervention's implementation within clinic settings.

Safety Analysis

N/A

Interim Analysis

None

20. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS

N/A

21. VULNERABLE POPULATIONS

N/A

22. COMMUNITY-BASED PARTICIPATORY RESEARCH

The study does not use a “pure” community-based participatory research approach but does include community engagement, which will include engagement of a Community Advisory Board to develop the cruciferae intervention.

23. SHARING OF RESULTS WITH SUBJECTS

Aggregate study results will be disseminated to the project's Community Advisory Board, the Bladder Cancer Survivorship Group at Roswell Park Comprehensive Cancer Center, the New York State Department of Health Cancer Registry, and to participating patients and health care providers who consented to be part of the research, written informed consent for participating patients and verbal consent for participating health care providers. Study participants will be mailed aggregate study results with no personal identifiers. Study results will also be disseminated to academic and practice audiences through scientific papers and conferences.

24. SETTING

Participant Recruitment. NYSCR will send a letter to the physician of record for selected cases notifying him/her that the patient was identified for the study, requesting that NYSCR be notified if the patient is unable or ineligible to participate in the study, and requesting information about the case's primary care physician if different from the contacted physician. If no contraindication has been received from the physician or if the physician has not responded within 3 weeks, the NYSCR will send an informational packet to the patient. The packet will contain: 1) a letter with study information; 2) a participant information sheet; and 3) a release of information consent form. After two weeks without response, a reminder packet will be sent and followed with up to five phone calls. If NYSCR can't reach the patient, the patient will be considered a refusal. The NYSCR's materials and procedures will be reviewed by the New York State Department of Health IRB. For patients who agree to be contacted about the study, the NYSCR will securely share the patient's name, contact information, and information about their diagnosis with the Roswell study team. For the Roswell Park Cancer Registry: study staff will consult with Roswell Park urologist

to determine if the patient is unable or ineligible to participate in the study. The patients accessioned from the Roswell Park Cancer Registry will be contacted by letter (See Appendix T) asking them to participate in the study. Study staff will follow-up with potential participants to determine whether they received the letter and if they are interested in participating. We estimate that from the pool of at least 100 patients who consent to be contacted, we will be able to obtain informed consent from at least 80 patients (80%). Research staff will contact patients who have agreed to be contacted by phone, whereby they will provide a general study overview and conduct a screening interview to confirm eligibility. The consent form will be mailed out to patients prior to the consenting discussion. We will ask the patient to mail back the consent form with the appropriate signatures. We will also provide an additional copy of the consent form for their records. We will include a paid postage pre-addressed envelope for the patient to mail back the signed consent form to study staff. To assist with study retention, we will ask participants for contact information to be used in follow-up. The Roswell study team will share information with the NYSCR team on the patients who agree to participate in the study, as well as any information obtained from study participants that does not match the information provided from the NYSCR database (e.g., race, ethnicity).

The process for contacting the patient, including the number of contact attempts, the letter text and/or phone script, the consent form, the data to be collected, and information on any incentives for participation will be reviewed by the NYSCR, New York State Department of Health (NYSDOH), and the NYSDOH IRB prior to the initiation of any patient/proxy contact. In addition, the research team will follow all NYSDOH procedures in conducting their study, including the following procedures:

1. All written materials must include contact information for people who can answer questions about the research and participant rights.
2. Patient consent to participate must be obtained.
3. If a patient asks to be removed from current or future research studies, this information must be sent within two weeks to the NYSCR, so that the patient's record can be flagged and the patient added to a "Do Not Contact" list.
4. Researchers must immediately report any complaints about the study or the release of patient information to the Director of the NYSCR and to the Administrator of the NYSDOH IRB.

If changes are made to any recruitment materials or processes after NYSDOH departmental and IRB approval, an IRB amendment must be submitted and approved before the changed materials may be used.

Before receiving case-level Registry data, the Principal Investigator for a research study will be required to read and sign a Research Data Use Agreement. This contract describes limitations on the use of the data, as well as restrictions on the dissemination of findings, use of personal identifiers, and contact with patients identified through data provided by the NYSCR. All staff working with confidential data, or with possible access to confidential information from the data, are required to have current IRB training certification and to sign a Confidentiality Pledge. The Research Data Use Agreement and Confidentiality Pledge documents can be obtained by emailing the NYSCR at nyscr@health.ny.gov.

Researchers must agree to maintain the confidentiality of identifiable data received from the NYSCR. Identifiable data include any information that would permit, directly or indirectly, the identification of any individual. When applying to use the data, researchers should indicate how the data will be stored as well as how and when they will dispose of the data after the study is completed. In addition, researchers must attest that: 1) no data will be published or released in any form where a particular individual or establishment is directly or indirectly identifiable; 2) identifiable data obtained from the NYSCR will be used only for the proposed study; 3) identifiable information obtained from the NYSCR will not be released to anyone or any institution without prior written approval by the NYSDOH; and 4) any publication or report produced using the data will acknowledge the source of the data. In the event of a breach of confidentiality, researchers must notify the Director of the NYSCR as soon as possible but no later than two business days after learning of the breach.

Physician Recruitment. Research staff will mail an invitation letter to nominated physicians that will include an information sheet (Appendix J), opt-in/opt-card card, and stamped reply envelope. Within 2-weeks, physicians who do not respond will be contacted by phone, fax, or email with no more than 5 attempts. Participating physicians will receive \$100. Physicians who verbally consent to participate will be asked to refer other physicians to the study. CAB members will also utilize their networks to nominate physicians for staff to contact.

25. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS

Only de-identified data will be accessed and recorded. Data files will be coded numerically and assigned to each participant. Information gathered from participants will remain anonymous and will be referred to only by general category. There will be no reference by name to any participant in any qualitative or quantitative data capture. No patient identity will be disclosed in the event of publication or sharing of data.

For physicians, the study will not collect any identifiers from the physician. The data collected from physician participation would be qualitative only. Therefore, for the physicians only, we are requesting a waiver of HIPPA Authorization.

The data collected from this study will be organized by a unique identification number assigned to the participant so that their identity will be available only to project staff and will remain completely confidential. The data manager, study staff, Co-Is and PI of the study will have access to the data records.

All study records will be kept electronically in Roswell Park maintained and secured equipment. The electronic data records will be saved and secured on the Roswell Park shared server. Survey data will be filed in a locked cabinet located in 311 Carlton House and will not be taken off Roswell Park premises. The data will be kept in a locked room where it will remain for approximately five years following the completion of the project.

26. RESOURCES AVAILABLE

The project will be co-led by Drs. Yeary and Tang, who will serve as multiple PIs on the project. Drs. Yeary and Tang will make joint decisions regarding the project. They will collaborate with the New York State Department of Health Cancer Registry and the Community Advisory Board in making collaborative decisions regarding the project. Communication between the PIs will be done in person, through video conferencing (e.g. Zoom, Webex), phone, and email.

The project will be coordinated by the Ms. Harfouche (Roswell Park) and all project data will be collected by the data collector (Ms. Dauphin). All data will be entered and managed by the database manager (Ms. Harfouche). All quantitative data analyses will be done by Dr. Yu.

Drs. Yeary and Tang will lead the completion of the study's aims, with Dr. Yeary focused on the intervention aspects of the study, and Dr. Tang focused on the biological aspects of the study. Dr. Yeary and Dr. Tang will oversee collaboration with the Community Advisory Board (including Dr. Qiang Li) in developing the intervention. Dr. Yeary will oversee the intervention's implementation and evaluation. Dr. Yeary will oversee Ms. Harfouche, who will oversee the recruiter (Ms. Dauphin), data collector (Ms. Dauphin), and interventionist (Ms. Clark). Dr. Yeary will train the interventionist to deliver the intervention. Both Drs. Yeary and Tang will work closely with the New York State Department of Health Cancer Registry during the initial stage of recruitment. Dr. Tang will oversee the laboratory work and ensure that the biological specimens are adequately collected, processed, and analyzed. Non-dietary data analysis will be led by Dr. Yeary and Tang, in close collaboration with Dr. Yu. Dietary data analysis will be led by Dr. McCann. Specific Aim 3 will be led by Drs. Yeary and Tang, who will oversee staff to recruit providers and complete provider telephone interviews.

The NYSCR employs a staff of over 50 to collect, process, and analyze reports on about 110,000 diagnosed cases of cancer among New Yorkers each year. The staff includes a 10-member research unit, five of whom hold a doctoral degree. Areas of expertise within this unit include cancer epidemiology, biostatistics, geographic analysis, and information science. The NYSCR has a strong national reputation and provides data to many national and international cancer studies.

The PIs will work with the New York State Department of Health Cancer Registry and the Community Advisory Board to disseminate project results and decide next steps.

27. PRIOR APPROVALS

The NYSCR study team will obtain approval of study materials by the NYSDOH Bureau, Division, Center, and the NYSDOH IRB.

28. COMPENSATION FOR RESEARCH-RELATED INJURY

If the subject believes they have been injured as a direct result of their participation in this research study, they will be advised to notify the Roswell Park Patient Advocate at (716) 845-1365 or the Dr. Karen Yeary at (716) 845-6231 or Dr. Li Tang at (716) 845-8247.

Medical diagnosis and treatment for the injury will be offered, and a determination will be made regarding appropriate billing for the diagnosis and treatment of the injury. A financial counselor (716-845-3161) will be able to provide an explanation of coverage and to answer questions the subject may have regarding study related billing.

The subject is not prevented from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

29. ECONOMIC BURDEN TO SUBJECTS

There are no costs associated with participation in the surveys and/or urine collection.

30. CONSENT PROCESS

Prior to administration of any assessment, participants are informed of the purpose of the study and told that their participation is voluntary. Participants are also informed that their responses to questions will be kept confidential. If the patient consents verbally, NYSCR or Roswell Park Cancer Registry staff will fill out the consent to be contacted form and document that consent to be contacted was obtained via phone (Appendix H). If the Registry is unable to contact the patient via telephone, and no written response has been received, no other contact will be attempted, and the patient will be considered a refusal. At the end of the two registries work, we estimate that there will be a pool of at least 100 patients that have consented to be contacted by research staff based on response rates from previous studies participated in by the NYSCR. Research staff will then contact patients who have agreed to be contacted by phone, whereby they will provide a general study overview and conduct a screening interview to confirm eligibility.

We are requesting a waiver of written consent documentation at the time of initial call, and prior to receipt of the signed written consent, for purposes of starting the baseline survey (Appendix F). The consent script will be a review of the consent document that is being obtained. The consent form will then be mailed out to patients. We will ask the patient to mail back the consent form with the appropriate signatures. We will also provide an additional copy of the consent form for their records. We will include a paid postage pre-addressed envelope for the patient to mail back the signed consent form to study staff. The consent form will indicate that a participant retains the right to withdraw at any time and that their health care will not be affected by their decision to participate or refuse to participate in the study. All investigators and project staff will satisfy the required IRB training and certification requirements. The IRB training will be completed during the early months of the project. For recruitment of health care providers, we will ask intervention participants to nominate physicians to participate in short 15-minute semi-structured interviews. Intervention participants will provide informed consent before providing their health care providers' contact information.

For cruciferous arm study participants that have completed the 6-month follow-up assessment as of the March 21, 2022 Protocol revision, the study participants will be called back to complete the feedback questions (Appendix G2). Therefore, these study participants will first be sent an information sheet (Appendix W) regarding the additional feedback questions before being called. When they are called regarding the study feedback questions, they will provide verbal consent before proceeding with answering the feedback questions.

Our Community Advisory Board members will also utilize their networks to nominate physicians for the research team to contact. Research staff will mail an invitation letter to nominated physicians that will include an information sheet (Appendix K), opt-in/opt-out card (**Appendix U**), and stamped reply envelop. Within 2-weeks, physicians who do not respond will be contacted by phone, fax, or email with at most five attempts. Follow-up contact will use the same invitation letter originally sent out or a phone script mirroring the information sheet (Appendix J). Physicians who decide to participate in the study will provide verbal consent. Physicians who verbally consent to participate will also be asked to refer other physicians to the study. We will recruit up to 20 physicians to ensure data saturation.

The key elements of the informed consent procedure which will be explained to the participants are: 1) the research status of the study- particularly the assessment; 2) the prospect of psychological risk and the provisions for it; 3) the lack of guarantee of benefit from participation in the

assessment, 4) the confidentiality of subjects responses to all study measures; 5) the voluntary nature of the study; 6) the receipt of the money for participating in the assessment, and 7) the freedom to withdraw from the study or to refuse to answer specific questions at any time.

Before the survey is conducted, research study staff members will explain: 1) the nature and purpose of the research endeavor, 2) that participation in the research component is completely voluntary, and 3) that data collected from participants will be confidential and assessed, evaluated and reported as aggregate data, as well as precautions taken in the storage of the data.

The Roswell Park Standard Operating Procedures (SOP): Informed Consent Process for Research (HRP-090) will be followed.

31. PROCESS TO DOCUMENT CONSENT IN WRITING

The Roswell Park “SOP: Written Documentation of Consent (HRP-091)” will be followed:

The Investigator (or IRB specified designee) is responsible for obtaining written consent from each patient participant in accordance with GCP guidelines using the approved informed consent form, before any study specific procedures (including screening procedures) are performed. The informed consent form acknowledges all information that must be given to the participant according to applicable GCP guidelines, including the purpose and nature of the study, the expected efficacy and possible side effects of the treatment(s), and specifying that refusal to participate will not influence further options for therapy. Any additional information that is applicable to the study must also be included. Additional national or institutionally mandated requirements for informed consent must also be adhered to. The participant should also be made aware that by signing the consent form, processing of sensitive clinical trial data and transfer to other countries for further processing is allowed. For physician participants, we are requesting a waiver of written consent. We would not collect any identifiers from the physician. The data from physicians would be qualitative only. Physicians will provide verbal consent.

The Investigator or designee shall provide a copy of the signed consent form to the participant and the signed original shall be maintained in the Investigator File. A copy of the signed consent form must be filed in the participant file. At any stage, the participant may withdraw from the study and such a decision will not affect any further treatment options.

32. DRUGS OR DEVICES

N/A

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34. APPENDICES/ SUPPLEMENTS

- Appendix A Investigator Study Eligibility Verification Form Inclusion Criteria
- Appendix B Investigator Study Eligibility Verification Form Exclusion Criteria
- Appendix C Participant Urine Collection Instructions
- Appendix D Participant Urine Questionnaire
- Appendix E Participant Interview Phone Script
- Appendix F Participant Baseline Bladder Questionnaire
- Appendix G Participant Follow-up
- Appendix H New York State Cancer Registry Contact Materials and Procedures
- Appendix I Physician Interview Guide
- Appendix J Physician Research Study Information Sheet for Structured Interviews
- Appendix K Community Advisory Board (CAB) Research Study Information Sheet
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- Appendix M Participant 24-hour Dietary Recall Instructions
- Appendix N Participant Food Amounts Booklet (FAB)
- Appendix O Participant Welcome Letter
- Appendix P Participant Health Magazines (Intervention and Control)
- Appendix Q Live Call Scripts (Intervention and Control)
- Appendix R Participant Track Books
- Appendix S Participant Thank You Letter
- Appendix T Recruitment Letter for Roswell Park Cancer Registry
- Appendix U. Invitation Letter for Physician Interview and Opt-In/Out Card
- Appendix V POW-R Sympathy Card
- Appendix W Participant Information Sheet for Cruciferous Arm Feedback Questions (For Participants that Completed the 6-Month Follow-up Assessment)

**Appendix A INVESTIGATOR STUDY ELIGIBILITY VERIFICATION FORM
INCLUSION CRITERIA**

Participant Name: _____

Medical Record No: _____

Title: POW-R Health: Power to Redefine your Health (Internal Title: A Pragmatic Dietary Intervention to Improve Bladder Cancer Survivorship)

INCLUSION CRITERIA				
Yes	No	N/A	All answers must be "Yes" or "N/A" for participant enrollment.	Date
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1. Age 18 years old or older (no upper limit)	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2. English speaking	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3. Diagnosed with stage Tis, Ta, or T1 bladder cancer.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. Resides in the Western New York catchment area.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5. Did not receive a partial or radical cystectomy.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6. Does not have a prior cancer diagnosis within 12 months of their bladder cancer diagnosis.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7. Does not have a subsequent more advanced bladder cancer diagnosis.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8. For Roswell Park Cancer Registry only: Bladder cancer diagnosed 2016-2018, 2019-current.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. Participant must understand the investigational nature of this study and sign an Independent Ethics Committee/Institutional Review Board approved written informed consent form prior to receiving any study related procedure.	

Investigator Signature: _____ **Date:** _____

Printed Name of Investigator: _____

Appendix B INVESTIGATOR STUDY ELIGIBILITY VERIFICATION FORM
EXCLUSION CRITERIA

Participant Name: _____

Medical Record No: _____

Title: POW-R Health: Power to Redefine your Health (Internal title: A Pragmatic Dietary Intervention to Improve Bladder Cancer Survivorship)

EXCLUSION CRITERIA				
Yes	No	N/A	All answers must be "No" or "N/A" for participant enrollment.	Date
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1. Participants who have had chemotherapy or radiotherapy within 4 weeks (6 weeks for nitrosoureas or mitomycin C) prior to entering the study or those who have not recovered from adverse events due to agents administered more than 4 weeks earlier.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2. Participants with known brain metastases should be excluded from this clinical trial because of their poor prognosis and because they often develop progressive neurologic dysfunction that would confound the evaluation of neurologic and other adverse events.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3. Adults unable to consent.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. Adults unable to complete study measures in English.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5. Individuals who are not yet adults (infants, children, teenagers).	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6. Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7. Unwilling or unable to follow protocol requirements.	

Participant meets all entry criteria:

Yes **No**

If "NO", do not enroll participant in study.

Investigator Signature: _____ **Date:** _____

Printed Name of Investigator: _____

Appendix C Participant Urine Collection Instructions

POW-R Health: Power to Redefine your Health

Program

INSTRUCTIONS FOR URINE COLLECTION AND SHIPMENT

Thank you for being a part of this study. This sheet provides instructions for urine collection. The first morning urine (the time you typically get up and start daily routine) should be collected over three consecutive days (3 days in a row).

Materials in provided urine collection kit:

1.	Urine collection device (see below picture on the left)	3
2.	Urine collection hat (see below picture on the right)	3
3.	Biohazard bag with 2 absorbent pads	1
4.	Ice packs*	2
5.	Styrofoam shipping box with biohazard label and UN3373 label	1
6.	FedEx shipping priority overnight label	1
7.	Packing tape strips	2
8.	Urine collection questionnaire	1
9.	Plastic bag for urine collection questionnaire	1



* **First**, place the ice packs in your freezer as soon as you get the kit so that they are frozen by the time the samples are ready to be shipped.

URINE COLLECTION INSTRUCTIONS

1. Collect the first void urine in the morning.
2. Urine can be collected in two ways:

Using the urine collection device: take out the sponge with holder from the container, directly urinate onto the sponge, and then insert sponge back into the container.

OR

Using the urine collection hat: place the urine collection hat on the toilet and urinate into it, then submerge the sponge into the urine, and insert the sponge

back into the container. Throw away the urine collection hat into a trash receptacle; do not ship the urine collection hat.

3. Write the date and time of the collection using a pen directly onto the label on the urine collection device.
4. Store the urine sample in its collection device, including both the sponge and container, in your refrigerator. The urine is absorbed into the sponge so it should not leak from the device.
5. Repeat the first morning urine collection for two more days in a row (Steps 1-4), storing the samples in the refrigerator until ready for shipment.

SCHEDULING A FEDEX PICKUP

After collecting the urine samples for three consecutive days, the samples can be shipped to Roswell Park Cancer Institute in Buffalo, NY for processing.

**** NOTE: FedEx pickups should be scheduled for Monday through Thursday only, to ensure prompt delivery to the POW-R Health staff at Roswell Park Cancer Institute. Keep the urine samples and collection devices in the refrigerator until the scheduled shipping day. ****

6. Call FedEx (1-800-GO-FEDEX; 1-800-463-3339) to schedule a pickup to ship the box to Roswell Park Cancer Institute. Do not take the package to a FedEx retail store for shipment or drop in a FedEx drop box.
 - a.) Once you have placed the call to FedEx, say "Schedule a Pickup"
 - b.) After the automated system has registered your request, dial 0, followed by the # sign to be directly transferred to a FedEx representative
 - c.) Let the representative know your samples will be delivered via **FedEx Express service** (priority overnight shipping)
 - d.) Provide the address from where you would like your samples to be retrieved

NOTE: If the FedEx representative asks for the account number, let them know you do not have it. The FedEx charge for your package has been pre-paid, and as long as the provided FedEx shipping priority overnight label is on the outside of your package, it will be picked up.

If you would prefer a FedEx pickup be scheduled on your behalf, please call the POW-R Health Study hotline at 1-716-845-8319.

PREPARING THE PACKAGE FOR SHIPMENT

7. Place all three urine samples and collection devices, including the containers and sponges, in the biohazard bag with absorbent pads. Seal the biohazard bag completely.

8. Remove the styrofoam lid of the shipping box, and place one pre-frozen ice pack on the bottom of the styrofoam shipping box.
9. Place the biohazard bag with the urine samples and collection devices on top of the ice pack in the shipping box.
10. Place the second pre-frozen ice pack on top of the biohazard bag, and replace the styrofoam lid on the shipping box.
11. Complete the urine collection questionnaire. Place the questionnaire in the provided plastic baggie and put it into the shipping box on top of the closed styrofoam container.
12. Seal the shipping box with the provided packing tape strips. As a reminder, the urine collection hats should be thrown away and not shipped back to us.
13. Remove the adhesive on the provided FedEx shipping priority overnight label and place the label on the top of the sealed shipping box.

SHIPPING CHECKLIST

The following items should be included in your shipping box:

- 3 urine samples and collection devices in biohazard bag
- 2 frozen ice packs
- Urine collection questionnaire
- FedEx label on outside of shipping box

If you have any questions about collection or shipping, please contact:

Li Tang, Ph.D.
Roswell Park Comprehensive Cancer Center
Basic Science Building 708
Elm and Carlton Streets
Buffalo, NY 14263
Tel: 716-845-8247

Appendix D Participant Urine Questionnaire

POW-R Health: Power to Redefine your Health Program Urine Collection Questionnaire

Please complete the following table with the date and time of collection for each urine sample:

Urine Sample	Date of Collection	Time of Collection
Sample #1	____ / ____ / ____ Month Day Year	____ : ____ AM / PM <i>Circle one</i>
Sample #2	____ / ____ / ____ Month Day Year	____ : ____ AM / PM <i>Circle one</i>
Sample #3	____ / ____ / ____ Month Day Year	____ : ____ AM / PM <i>Circle one</i>

The following questions are about your diet and lifestyle on the day before your first urine collection

On the day before your first urine collection, did you (Please mark box for Yes or No)

1. Eat Broccoli?

Yes → Please specify the type: Raw Lightly Cooked Thoroughly Cooked

No

2. Eat Broccoli Sprouts?

Yes → **Please specify the type:** Raw Lightly Cooked Thoroughly Cooked

No

3. Eat Cabbage?

Yes → **Please specify the type:** Raw Lightly Cooked Thoroughly Cooked

No

Continue to Next Page

4. Eat Carrots?

Yes → **Please specify the type:** Raw Lightly Cooked Thoroughly Cooked

No

5. Eat Cauliflower?

Yes → **Please specify the type:** Raw Lightly Cooked Thoroughly Cooked

No

6. Eat Brussels Sprouts?

Yes → **Please specify the type:** Raw Lightly Cooked Thoroughly Cooked

No

7. Eat Corn?

Yes → **Please specify the type:** Raw Lightly Cooked Thoroughly Cooked

No

8. Eat Kale, Collard Greens, Mustard Greens, or Turnip Greens?

Yes → **Please specify the type:** Raw Lightly Cooked Thoroughly Cooked

No

9. Eat Peas?

Yes → **Please specify the type:** Raw Lightly Cooked Thoroughly Cooked

No

10. Eat Bok Choy or Chinese cabbage?

Yes → **Please specify the type:** Raw Lightly Cooked Thoroughly Cooked

No

11. Eat Garden or Water Cress?

Yes → **Please specify the type:** Raw Lightly Cooked Thoroughly Cooked

No

12. Eat Radish or Turnip?

Yes → **Please specify the type:** Raw Lightly Cooked Thoroughly Cooked

No

13. Eat Celery?

Yes → **Please specify the type:** Raw Lightly Cooked Thoroughly Cooked

No

14. Eat Sauerkraut?

Yes

No

Continue to Next Page

15. Eat Horseradish, Mustard, or Wasabi?

Yes

No

16. Take any antibiotic prescription medications (e.g., Cipro®, Septra®, penicillins, or other)?

Yes

No

17. Smoke cigarettes?

Yes → Please specify the total number of cigarettes: _____

No

18. Consume any alcoholic drink?

Yes → Please specify the total number of drinks: _____

No

Date this questionnaire was completed |_____|_____| / |_____|_____| / |_____|_____|_____|
Month Day Year

Thank you very much for your time!

Appendix E Participant Interview Phone Script

POW-R Health: Power to Redefine your Health Program PHONE SCREENING Paper Copy

Today's Date _____ Time _____

Leave the following message on the A/M of potential participants (do not say Roswell Park Cancer Institute)

Hi, this message is for _____. This is _____ calling from the POW-R Health: Power to Redefine your Health Program to follow-up on your call expressing interest in our study. I would like to take a few minutes to explain the study in more detail to you. Please call me back between the hours of 8:30am and 5 pm at _____. If you cannot reach me, please leave a message including your name, telephone number, and a convenient time to call. Thank you and I hope to speak to you soon.

Speaking to participants:

“This is _____ calling from Roswell Park Cancer Institute. I’m calling to follow-up on your call expressing interest in our POW-R Health: Power to Redefine your Health Program being conducted here at Roswell Park. I would like to take a few minutes to explain the study in more detail to you. Is this a good time to do that?”

If NO: When would be the best day and time to call you back?

If YES, or if first contact with respondent:

“We are conducting a study here at Roswell Park Cancer Institute to see if someone’s diet can reduce their risk of bladder cancer coming back in those who had bladder cancer. We are specifically interested in testing whether a vegetable intervention can improve health in those who had bladder cancer.

Your participation will last a total of 6 months (about 24 weeks) and includes the following:

We will ask you to complete two assessments. One before the study begins, and one after the study ends. Each assessment will consist of:

- A 45-60-minute survey over the phone
- Telling us what you’ve eaten over the past 24-hours. This is called a dietary recall. This will be done on 3 randomly selected days. Each time it will take about 15-20 minutes over the phone.
- Sending us urine samples through the mail.

- Being part of a 6-month program to improve your diet. The program will consist of:

- Receiving educational materials about a healthy diet
- One 20-minute phone call with a Roswell staff member to talk to you about a healthy diet
- 11 interactive voice response automated phone calls, where you will receive a phone call from a machine that will ask you how many vegetables you ate during a certain time period.

To thank you for your time and participation, you will be given a \$40 gift card to Tops Markets for completing the phone survey and sending the urine sample; and a \$20 gift card from Tops Markets for completing each dietary recall. So, for each assessment you will have the opportunity to receive a total of \$100 in gift cards to Tops Markets. Across both assessments you will have the opportunity to receive a total of \$200 in gift cards to Tops Markets.

Are you still interested in being a part of the study?

May we get your verbal consent to complete the baseline

If NO: Thank you for your time.

Demographics

New Applicant Introduction Form

I want you to know that everything said during this conversation is confidential and will only be shared with our research team. I would like to share some information with you about our program. POW-R Health: Power to Redefine your Health is a healthy eating program that focuses on eating more vegetables to improve health. We are currently recruiting adults who live in Western New York. During this call I will gather information to determine your eligibility to participate in the program and whether the program might work for you. This conversation could take up to 15 minutes. Is that ok?

(circle one) Yes No

If YES, continue.

If NO, read this script: Ok Mr./Mrs. _____. When would be a good day and time for me to call you back? _____

Let's begin with your name and address.

1. First: _____ **Middle:** _____ **Last:** _____

2. Are you male or female? **Male** **Female**

3. Are you Hispanic or Latino/a or Spanish in origin?

Yes

Are you (check all that apply): Mexican, Mexican American, Chicano/a
Puerto Rican
Cuban
Another Hispanic, Latino/a, or Spanish origin

No

4. Which one or more of the following would you say is your race?

(Check all that apply)

- White
- Black or African American
- American Indian or Alaska Native
- Asian Indian
- Native Hawaiian
- Chinese
- Filipino
- Japanese
- Korean
- Vietnamese
- Other Asian
- Other Pacific Islander

5. What is your address?

Street: _____

City: _____ Zip Code: _____

6. I would like to get your phone numbers:

Daytime Phone: (____)	_____	(circle one)	home	work	cell
Evening Phone: (____)	_____	(circle one)	home	work	cell
Other: _____		(circle one)	home	work	cell

6a. Do you have an email address? _____

7. What is your date of birth?:

Month: _____ Day: _____ Year: _____

Note: _____

If individual will turn 18 BEFORE the current round of recruitment closes, age ineligibility applies and this script is read:

Applicant Turning 18 Soon

I'm sorry _____, you are not eligible to participate in the program. The program is made for those aged 18 and older.

Would you like to continue with the questionnaire? Yes No

If answer is YES, continue to Question 8.

If answer is NO, thank applicant for his/her interest in the program and End Interview.

IF THE INDIVIDUAL PASSES THESE SET OF QUESTIONS CONTINUE TO THE NEXT SECTION.

Cancer

8. Have you been diagnosed with stage Tis, Ta, or T1 bladder cancer? These are early stages of bladder cancer where the cancer lesion stays in the superficial layer of the bladder wall and does not invade the muscle layer. Sometimes they are called superficial bladder cancer or non-muscle invasive bladder cancer.

If YES, continue to Question 9.

If DON'T KNOW, continue to Question 9.

If NO, read this script:

I'm sorry, _____, you are not eligible to participate in the program. The program is designed for people who have been diagnosed with stage Tis, Ta, or T1 bladder cancer. Thank you for your interest, but we will not be able to enroll you.

9. Have you received a partial or radical cystectomy? A cystectomy is surgery where a part or the entire bladder is removed.

If NO, continue to Question 10.

If YES, read this script:

I'm sorry, _____, you are not eligible to participate in the program. The program is designed for people who have NOT received a partial or radical cystectomy. Thank you for your interest, but we will not be able to enroll you.

10. Have you had been diagnosed with another cancer (other than bladder cancer) during the past 12 months?

If NO, continue to Question 11.

If YES, read this script:

I'm sorry, _____, you are not eligible to participate in the program. The program is designed for people who have NOT been diagnosed with another cancer in the past 12 months of your being diagnosed with bladder cancer. Thank you for your interest, but we will not be able to enroll you.

11. Have you had chemotherapy or radiotherapy within the last 2 months?

If NO, continue to Question 12.

If YES, read this script:

I'm sorry, _____, you are not eligible to participate in the program. The program would not be safe for those who have had chemotherapy or radiotherapy within the last 2 months. Thank you for your interest, but we will not be able to enroll you.

Medications/Health

12. Have you been told by a doctor that you have any of the following health conditions?
(circle one)

- a. Ongoing or active infection;
- b. Crohn's disease;
- c. Inflammatory Bowel Disease;
- d. Other (specify: symptomatic heart failure, unstable angina pectoris, cardiac arrhythmia)
- e. Psychiatric or social situations that would affect your participation

No – Skip to the Consent Section

Yes – Go to question 12a

12a. Please tell me more about your limitations? _____

12b. Record eligibility based on health condition (circle one):

Ineligible

Questionable- refer to PI

Acceptable to continue

If debilitating or such that the individual would have a hard time completing the program, then ineligibility applies and this script should be read:

I'm sorry, _____ you are not eligible to participate in the program. Thank you for your interest, but we will not be able to enroll you.

If questionable and referring to PI, then this script should be read:

_____, based on the information you have given me, I can't tell for sure if you are eligible for the program. I need to talk with the Program Coordinator about whether you are eligible or not. Someone from our team will call you to see if you are eligible. If you are eligible, the remaining screening questions will be asked at that time.

The interview is STOPPED and the individual will be called back.

Consent

Congratulations, Mr./ Ms Applicant. You are eligible to participate in POW-R Health: Power to Redefine your Health Program. Are you still interested in being a part of study?

If Yes, continue to the consent section.

If No, read this script:

For below: Ok Mr./Ms. _____, Thank you for your interest in the Program. We appreciate your time.

I would like to now go over the consent form for the study with you.
(go over consent form).

I will mail you a copy for you to keep.

Before the program begins, you will need to complete the first assessment. Our team will call you to collect general information about your health. Our team will also call you on three different days to ask what you've eaten in the last 24 hours. So in total, you will receive 4 separate phone calls from our team to collect this information. We will also mail you a urine sample collecting kit for you to mail back to us. After we collect this information, you will receive your gifts cards for the first assessment. The POW-R Health: Power to Redefine your Health program materials will also be sent to you in the mail and one of our interventionists will call you.

If you would like to complete the first assessment now, can we get your verbal consent before we proceed? [Ask participant to indicate a Yes or No] Do you have any questions?

[If participant chooses to do the survey at another time, we will review the script at that time]
Welcome to POW-R Health! Someone will be in touch with you soon.

Appendix F Participant Baseline Bladder Questionnaire

Hi, my name is _____ . I'm calling because you kindly agreed to participate in the POW-R Health: Power to Redefine your Health Program. If you recall, part of being in the study is completing a survey—once before the study starts, and a final time after the study ends. The survey information will be used to see if our dietary intervention worked to improve your health. This phone survey will take about 45-60 minutes to complete. Do you have time to take the survey now?

If no: What would be a good day and time for me to call you? (please use Telephone Disposition Sheet)

If yes: Thank you! Please remember that everything you say here will be confidential. Your information won't be identified by name (proceed to questions below).

Let's start off with some information about you.

DEMOGRAPHICS

1. What is your marital status?

- 1 Married
- 2 Living as married
- 3 Divorced
- 4 Widowed
- 5 Separated
- 6 Single, never been married

2. What is the highest grade or level of schooling you completed?

- 1 Less than 8 years
- 2 8-11 years
- 3 12 years or completed high school
- 4 Post high school training other than college (vocational or technical)
- 5 Some college
- 6 College graduate
- 7 Postgraduate

3. Thinking about members of your family living in this household, what is your combined annual income, meaning the total pre-tax income from all sources earned in the past year?

- 1 \$0- \$9,000
- 2 \$10,000-\$14,999
- 3 \$15,000-\$19,999
- 4 \$20,000-\$34,999
- 5 \$35,000-\$49,999
- 6 \$50,000-\$74,999
- 7 \$75,000-\$99,999
- 8 \$100,000-199,999
- 9 \$200,000 or more

4. What is your occupational status?

- 1 Employed
- 2 Unemployed
- 3 Homemaker
- 4 Retired
- 5 Disabled
- 6 Other (Specify) _____

5. How many people currently live in your home (include yourself)? _____

6. Do you have any kind of health care coverage, including health insurance, prepaid plans such as HMOs or government plans such as Medicare, or Indian Health Service?

- 1 Yes (if yes, go to 6a)
- 2 No

6a. What is the primary source of your health care coverage?

- 1. A plan purchased through an employer or union (including plans purchased through another person's employer)
- 2. A plan that you or another family member buys on your own
- 3. Medicaid (primarily for people over age 65) or other state program
- 4. Medicare
- 5. TRICARE (formerly CHAMPUS), VA, or Military
- 6. Alaska Native, Indian Health Service, Tribal Health Service
- 7. Some other source

7. We would like to confirm your current address. Do you still live at _____? Read address from database.

1 Yes

0 No (please specify current address):

(Name of street, city, state, zip) update if necessary

BLADDER CANCER DIAGNOSIS

The next set of questions is about your bladder cancer diagnosis.

8. We would like to confirm the date of your bladder cancer diagnosis. According to our records, you were first diagnosed on _____. Is that correct?

1 Yes

0 No →

8 Don't Know

9 Refused

8a. What was the date? _____

8 Don't Know

9 Refused

9. Did your doctor use a scope to remove the bladder tumor? This procedure is called a transurethral resection.

1 Yes → 9a. What was the date? _____

0 No 8 Don't Know

8 Don't Know 9 Refused

9 Refused

10. Have you received any additional treatment for bladder cancer since your diagnosis?

1 Yes

0 No

8 Don't Know

9 Refused

If No, Don't Know or Refused, go to Question 14.

11. Did you receive chemotherapy (e.g., mitomycin C, thiotepa, doxorubicin)?

1 Yes

0 No

8 Don't Know

9 Refused

12. Did you receive immunotherapy (e.g., bacillus Calmette-Guerin [BCG], interferon)?

1 Yes

0 No

8 Don't Know

9 Refused

13. Did you receive any other treatment?

1 Yes → 13a. Specify: _____

0 No

8 Don't Know

9 Refused

CURRENT LIFESTYLE

The next section is about your current lifestyle. Again, this information is completely confidential.

14. What is your present height without shoes?

____ ft. ____ inches

8 Don't Know
9 Refused

15. How much do you currently weigh?

____ pounds

8 Don't Know
9 Refused

	Excellent	Very Good	Good	Fair	Poor	Don't Know	Refused
16. In general, would you say your health is:	5 <input type="checkbox"/>	4 <input type="checkbox"/>	3 <input type="checkbox"/>	2 <input type="checkbox"/>	1 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>
17. In general, would you say your quality of life is:	5 <input type="checkbox"/>	4 <input type="checkbox"/>	3 <input type="checkbox"/>	2 <input type="checkbox"/>	1 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>

18. What is the primary source of drinking water at your current residence?

1 Private Well
2 Community Supply (tap water, water filtered at home)
3 Bottled Water
4 Other (specify): _____
8 Don't Know
9 Refused

19. Over the past 30 days, how many glasses of water per day do you usually drink?

1 Less than 1 glass
2 1-2 glasses
3 3-4 glasses
4 5 or more glasses
8 Don't Know
9 Refused

20. Over the past 30 days, how often did you typically feel the need to empty your bladder during the day?

- 1 More frequently than once an hour
- 2 Once an hour
- 3 Once every 2 hours
- 4 Once every 3-5 hours
- 5 Only once or twice a day
- 8 Don't Know
- 9 Refused

21. Are you currently following any special diet?

- 1 Yes
- 0 No
- 8 Don't Know
- 9 Refused

If No, Don't Know or Refused, go to Question 23.

22. What type of special diet (check all that apply):

- 1 Vegetarian (with fish)
- 1 Vegetarian (no fish)
- 1 Vegan (no meat, chicken, fish, dairy, or eggs)
- 1 Macrobiotic
- 1 Paleo
- 1 Gluten-free
- 1 Atkins
- 1 Low Carb
- 1 Other (specify) _____
- 1 Don't Know
- 1 Refused

23 Do you currently smoke?

- 1 Yes, every day
- 2 Yes, some days →

23a. On how many of the past 30 days did you smoke a cigarette?

____|____| Days
8 Don't Know
9 Refused

24. On average, how many cigarettes do/did you smoke each day? (Note to interviewer: 1 pack=20 cigarettes)

____ Cigarettes per day

8 Don't Know
9 Refused

25. Over the last 30 days, how many days per week did you exercise for 20 minutes or more?

None
 1-2 days
 3-4 days
 5 or more days

26. Compared to other people your age, how would you rate the level of your usual physical activity? (If currently ill, think about your activity during the past 30 days before your illness).

Much more active
 More active
 About the same
 Less active
 Much less active

DIETARY INTAKE

These next questions are about the fruits and vegetables you ate or drank during the **past 30 days**. Please think about all forms of fruits and vegetables including cooked or raw, fresh, frozen or canned. Please think about all meals, snacks, and food consumed at home and away from home.

27. During the past month, how many times per week did you drink 100% PURE fruit juices? Do not include fruit-flavored drinks with added sugar or fruit juice you made at home and added sugar to. Only include 100% juice.

____ times per week

28. During the past month, not counting juice, how many times per week did you eat fruit? Count fresh, frozen, or canned fruit.

____ times per week

29. During the past month, how many times per week did you eat cooked or canned beans, such as refried, baked, black, garbanzo beans, beans in soup, soybeans, edamame, tofu or lentils. Do NOT include long green beans.

____ times per week

30. **During the past month, how many times per week did you eat dark green vegetables for example broccoli or dark leafy greens including romaine, chard, collard greens or spinach?**

 times per week

31. **During the past month, how many times per week did you eat orange-colored vegetables such as sweet potatoes, pumpkin, winter squash, or carrots? (write number)**

32. **Not counting the vegetables mentioned, about how many times per week did you eat OTHER vegetables? Examples of other vegetables include tomatoes, tomato juice or V-8 juice, corn, eggplant, peas, lettuce, cabbage, and white potatoes that are not fried such as baked or mashed potatoes. (write number)**

 times per week

These next questions are about other vegetables you ate during the **past 30 days**. Please think about all meals, snacks, and food consumed at home and away from home.

(Go through table. Frame questions as, “How often did you eat raw arugula? Never, a few times per year, once per month, 2-3 times per month, once a week, twice per week, 3-4 times per week, 5-6 times per week, or every day.” If they answer never, go to the next vegetable. If they ate any amount, ask, “About how much raw arugula did you eat each time? The medium serving size is one cup of the vegetable, about the size of a baseball. Lightly cooked generally includes stir fry, sauté, microwave, short-term, e.g. less than 10 minutes, steam or bake, and thoroughly cooked includes stew, biol, or long-term, e.g. more than 10 minutes, steam or bake.)

Vegetables

		Never	A Few Times Per Year	Once per month	2-3 Times per month	Once per week	Twice per week	3-4 Times per week	5-6 Times per week	Every day	How much each time?		
											S	M	L
Arugula	raw	<input type="checkbox"/>											
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>											
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>											
Broccoli	raw	<input type="checkbox"/>											
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>											
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>											
Broccoli sprout	raw	<input type="checkbox"/>											
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>											
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>											
Broccolini	raw	<input type="checkbox"/>											
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>											
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>											
Corn	raw	<input type="checkbox"/>											
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>											
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>											

Green cabbage	raw (e.g. coleslaw)	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Red/Purple cabbage	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Sauerkraut	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Carrots	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Cauliflower	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Brussels sprouts	raw	<input type="checkbox"/>										

	lightly cooked (e.g. stir fry)	<input type="checkbox"/>									
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>									
Kale	raw	<input type="checkbox"/>									
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>									
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>									
Kohlrabi	raw	<input type="checkbox"/>									
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>									
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>									
Collard greens	lightly cooked (e.g. stir fry)	<input type="checkbox"/>									
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>									
Peas	raw	<input type="checkbox"/>									
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>									
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>									
Mustard greens	raw	<input type="checkbox"/>									
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>									
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>									
Turnip	lightly cooked (e.g. stir fry)	<input type="checkbox"/>									
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>									

Turnip greens	lightly cooked (e.g. stir fry)	<input type="checkbox"/>									
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>									
Bok/ Pak choy	raw	<input type="checkbox"/>									
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>									
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>									
Chinese cabbage/ Napa	raw	<input type="checkbox"/>									
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>									
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>									
Daikon root	raw	<input type="checkbox"/>									
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>									
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>									
Celery	raw	<input type="checkbox"/>									
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>									
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>									
Garden cress	raw	<input type="checkbox"/>									
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>									
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>									
Water cress	raw	<input type="checkbox"/>									

	lightly cooked (e.g. stir fry)	<input type="checkbox"/>									
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>									
Radicchio	lightly cooked (e.g. stir fry)	<input type="checkbox"/>									
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>									
Radishes	raw	<input type="checkbox"/>									
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>									
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>									

We're going to finish the survey by asking some final questions about sauces and condiments you ate during the **past 30 days**. Please think about all meals, snacks, and food consumed at home and away from home.

(Go through table. Frame questions as, "How often did you eat mayonnaise? Never, a few times per year, once per month, 2-3 times per month, once a week, twice per week, 3-4 times per week, 5-6 times per week, or every day." If they answer never, go to the next food. If they ate any amount, ask, "About how much mayonnaise did you eat each time? The size of your thumb from knuckle to tip or less? About two thumbs worth? Or more than 2 thumbs worth?"

For **horseradish**, if they consume any amount, ask, "about how much horseradish did you eat each time? Smaller than an egg, about the size of egg, or more than the size of an egg?")

SAUCES AND CONDIMENTS											
	Never	A Few Times Per Year	Once per month	2-3 Times per month	Once per week	Twice per week	3-4 Times per week	5-6 Times per week	Everyday	Medium Serving	Serving Size
											S
											M L
Mayonnaise and mayonnaise-type spreads	<input type="checkbox"/>	2 Tbsp.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>								
Horseradish	<input type="checkbox"/>	1/4 cup	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>								
Mustard	<input type="checkbox"/>	2 Tbsp.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>								
Wasabi	<input type="checkbox"/>	2 Tbsp.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>								

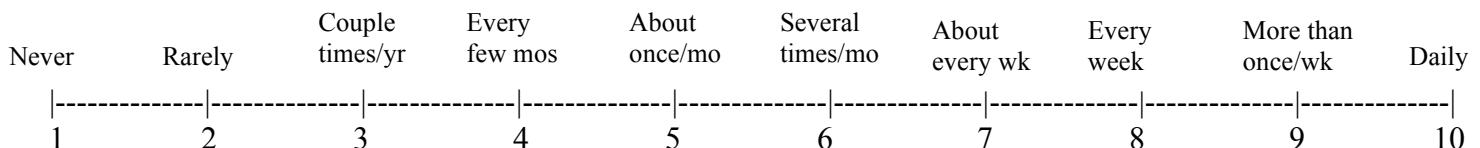
Belief into Action Scale

Circle a single number for each question below:

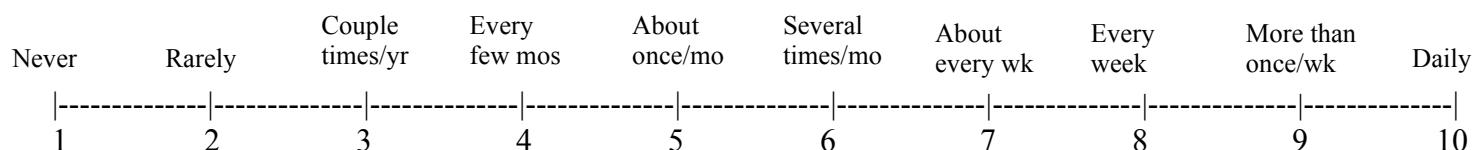
1. Please circle the highest priority in your life now? (most valued, prized)

1. My health and independence
2. My family
3. My friendships
4. Job, career or business
5. My education
6. Financial security
7. Relationship with God
8. Ability to travel & see the world
9. Listening to music and partying
10. Freedom to live as I choose

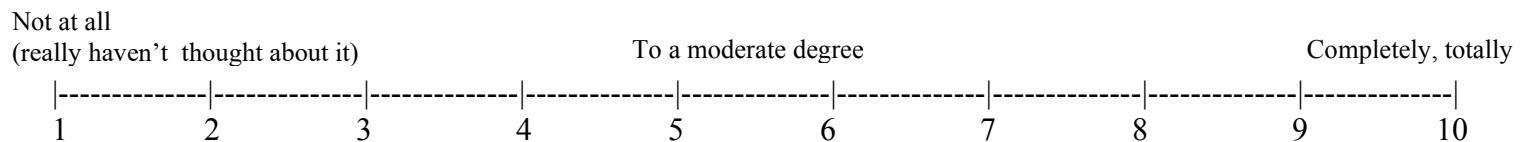
2. How often do you attend religious services? (circle a number below)



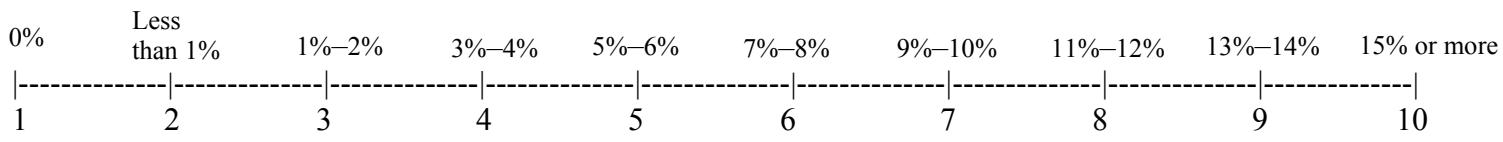
3. Other than religious services, how often do you get together with others for religious reasons (prayer, religious discussions, volunteer work, etc.)?



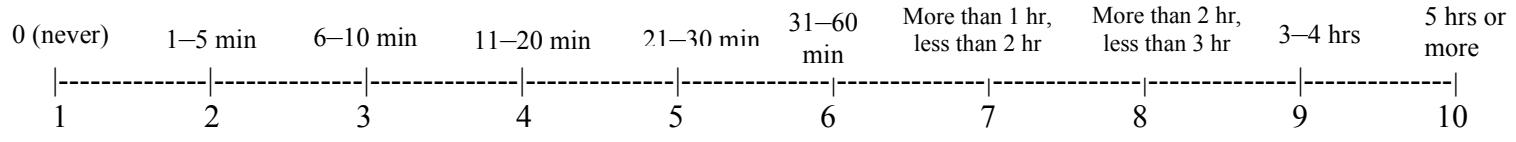
4. To what extent (on a 1 to 10 scale) have you decided to place your life under God's direction?



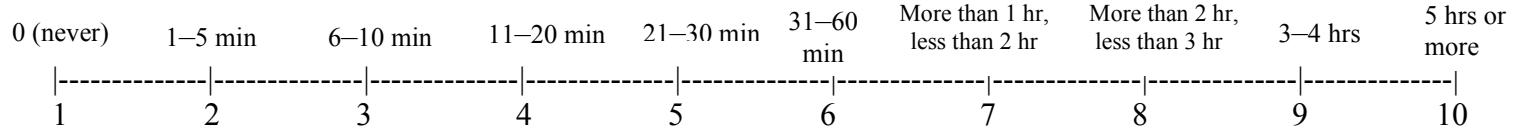
5. What percentage of your gross annual income do you give to your religious institution or to other religious causes each year?



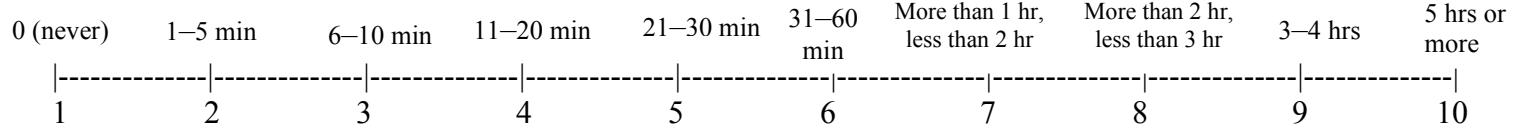
6. On average, how much time each day (in 24 hrs) do you spend listening to religious music or radio, or watching religious TV?



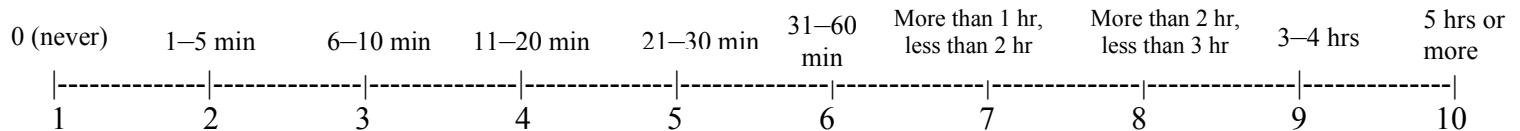
7. On average, how much time each day do you spend reading religious scriptures, books, or other religious literature?



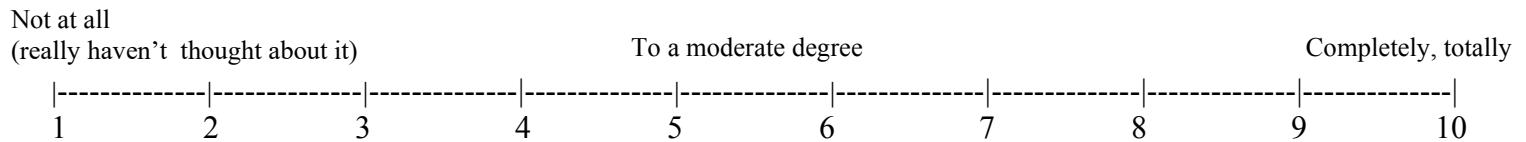
8. On average, how much time each day do you spend in private prayer or meditation?



9. On average, how much time each day do you spend as a volunteer in your religious community or to help others for religious reasons?



10. To what extent (on a 1 to 10 scale) have you decided to conform your life to the teachings of your religious faith?



You have finished the survey! Thank you so much for your time. Do you have any questions?

Again, welcome to POW-R Health Program!

Appendix G Participant Follow-up

Appendix G1. Participant 6-month Follow-up Questionnaire

Hi, my name is _____. I'm calling because you kindly agreed to participate in the POW-R Health: Power to Redefine your Health Program. If you recall, part of being in the study is completing a survey—once before the study starts, and a final time after the study ends. The survey information will be used to see if our dietary intervention worked to improve your health. This phone survey will take about 45-60 minutes to complete. Do you have time to take the survey now?

If no: What would be a good day and time for me to call you? (please use Telephone Disposition Sheet)

If yes: Thank you! Please remember that everything you say here will be confidential. Your information won't be identified by name (proceed to questions below).

BLADDER CANCER FOLLOW-UP

Let's begin the survey with questions about your bladder cancer status. These questions refer to the time period since we last talked with you, which is approximately the past 6 months.

1. In the last 6 months, have you had a clinical assessment, or cystoscopy, for your bladder cancer?

1 <input type="checkbox"/>	Yes	
0 <input type="checkbox"/>	No	→ Skip to Question 2 (cystectomy)
8 <input type="checkbox"/>	Don't Know	→ Skip to Question 2 (cystectomy)
9 <input type="checkbox"/>	Refused	→ Skip to Question 2 (cystectomy)

1a. What was the date of your last assessment? _____

2. In the last 6 months, have you had a cystectomy (surgery to remove the bladder)?

1 <input type="checkbox"/>	Yes	
0 <input type="checkbox"/>	No	→ Skip to Question 3 (recurrence)
8 <input type="checkbox"/>	Don't Know	→ Skip to Question 3 (recurrence)
9 <input type="checkbox"/>	Refused	→ Skip to Question 3 (recurrence)

2a. What was the date of the cystectomy? _____

3. In the last 6 months, have you had a recurrence of your bladder cancer (i.e., did your doctor say that the original cancer came back or that you had a new lesion/mass/tumor)?

1 Yes → Skip to Question 10 (other cancer)
0 No → Skip to Question 10 (other cancer)
8 Don't Know → Skip to Question 10 (other cancer)
9 Refused → Skip to Question 10 (other cancer)

3.1 How many recurrences have you had? _____ (Number)

[Note to Interviewer: If more than 1 recurrence, record the date of the most recent (last) recurrence here.]

3.1a. What was the date of your recurrence? _____

4. Did your recurrent bladder cancer progress to muscle-invasive disease?

1 Yes
0 No
8 Don't Know
9 Refused

5. Did your doctor use a scope to remove the recurrent bladder tumor? This procedure is called a transurethral resection.

1 Yes → Specify Date in 5a
0 No
8 Don't Know
9 Refused

5a. What was the date of transurethral resection (TURBT)? _____

6. Did you receive chemotherapy (e.g., mitomycin C, thiotapec, doxorubicin) for your bladder cancer recurrence/progression?

1 Yes
0 No
8 Don't Know
9 Refused

7. Did you receive immunotherapy (e.g., bacillus Calmette-Guerin [BCG], interferon) for your bladder cancer recurrence/progression?

1 Yes
0 No
8 Don't Know
9 Refused

8. Did you receive radiation therapy for your bladder cancer recurrence/progression?

1 Yes
0 No
8 Don't Know
9 Refused

9. Did you receive any other treatment for your bladder cancer recurrence/progression?

1 Yes → Specify treatment in 9a
0 No
8 Don't Know
9 Refused

9a. Specify other treatment received:

10. In the last 6 months, have you been diagnosed with any other types of cancer since your original bladder cancer diagnosis?

1 Yes
0 No → Skip to Question 11
8 Don't Know → Skip to Question 11
9 Refused → Skip to Question 11

10a. When did you receive this diagnosis?

10b. What was your diagnosis?

11. Overall, how would you rate your satisfaction with your current understanding of bladder cancer and its treatment?

1 Excellent
2 Very Good
3 Good
4 Fair
5 Poor
8 Don't Know
9 Refused

Now that we've gone over your bladder cancer status, we're now going to talk about your current lifestyle.

CURRENT LIFESTYLE

12. What is your present height without shoes?

 |__| ft. |__| inches

8 Don't Know
9 Refused

13. How much do you currently weigh?

_____ pounds

8 Don't Know
9 Refused

	Excellent	Very Good	Good	Fair	Poor	Don't Know	Refused
14. In general, would you say your health is:	5 <input type="checkbox"/>	4 <input type="checkbox"/>	3 <input type="checkbox"/>	2 <input type="checkbox"/>	1 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>
15. In general, would you say your quality of life is:	5 <input type="checkbox"/>	4 <input type="checkbox"/>	3 <input type="checkbox"/>	2 <input type="checkbox"/>	1 <input type="checkbox"/>	8 <input type="checkbox"/>	9 <input type="checkbox"/>

16. What is the primary source of drinking water at your current residence?

1 Private Well
2 Community Supply (tap water or water filtered at home)
3 Bottled Water
4 Other (specify): _____
8 Don't Know
9 Refused

17. Over the past 30 days, how many glasses of water per day do you usually drink?

1 Less than 1 glass
2 1-2 glasses
3 3-4 glasses
4 5 or more glasses
8 Don't Know
9 Refused

18. Over the past 30 days, how often did you typically feel the need to empty your bladder during the day?

1 More frequently than once an hour
2 Once an hour
3 Once every 2 hours
4 Once every 3-5 hours
5 Only once or twice a day
8 Don't Know
9 Refused

19. Other than being a part of the POW-R Health Program, are you currently following any other special diet?

1 Yes
0 No
8 Don't Know
9 Refused

If No, Don't Know or Refused, go to Question 21.

20. What type of special diet (check all that apply):

1 Vegetarian (with fish)
2 Vegetarian (no fish)
3 Vegan (no meat, chicken, fish, dairy, or eggs)
4 Macrobiotic
5 Paleo
6 Gluten-free
7 Atkins
10 Low Carb
11 Other (specify) _____
8 Don't Know
9 Refused

21. Do you currently smoke?

1 Yes, every day
2 Yes, some days →

21a. On how many of the past 30 days did you smoke a cigarette?

____|____| Days
8 Don't Know
9 Refused

22. On average, how many cigarettes do/did you smoke each day? (Note to interviewer: 1 pack=20 cigarettes)

____|____| Cigarettes per day

8 Don't Know
9 Refused

23. Over the last 30 days, how many days per week did you exercise for 20 minutes or more?

0 None
1 1-2 days

2 3-4 days
3 5 or more days

24. Compared to other people your age, how would you rate the level of your usual physical activity? (If currently ill, think about your activity during the years before your illness).

1 Much more active
2 More active
3 About the same
4 Less active
5 Much less active

DIETARY INTAKE

These next questions are about the fruits and vegetables you ate or drank during the **past 30 days**. Please think about all forms of fruits and vegetables including cooked or raw, fresh, frozen or canned. Please think about all meals, snacks, and food consumed at home and away from home.

25. During the past month, how many times per week did you drink 100% PURE fruit juices? Do not include fruit-flavored drinks with added sugar or fruit juice you made at home and added sugar to. Only include 100% juice.

____ times per week

26. During the past month, not counting juice, how many times per week did you eat fruit? Count fresh, frozen, or canned fruit.

____ times per week

27. During the past month, how many times per week did you eat cooked or canned beans, such as refried, baked, black, garbanzo beans, beans in soup, soybeans, edamame, tofu or lentils. Do NOT include long green beans.

____ times per week

28. During the past month, how many times per week did you eat dark green vegetables for example broccoli or dark leafy greens including romaine, chard, collard greens or spinach?

____ times per week

29. During the past month, how many times per week did you eat orange-colored vegetables such as sweet potatoes, pumpkin, winter squash, or carrots? (write number)

30. Not counting the vegetables mentioned, about how many times per week did you eat OTHER vegetables? Examples of other vegetables include tomatoes, tomato juice or V-8 juice, corn, eggplant, peas, lettuce, cabbage, and white potatoes that are not fried such as baked or mashed potatoes. (write number)

____ times per week

These next questions are about other vegetables you ate during the **past 30 days**. Please think about all meals, snacks, and food consumed at home and away from home.

(Go through table. Frame questions as, “How often did you eat raw arugula? Never, a few times per year, once per month, 2-3 times per month, once a week, twice per week, 3-4 times per week, 5-6 times per week, or every day.” If they answer never, go to the next vegetable. If they ate any amount, ask, “About how much raw arugula did you eat each time? The medium serving size is one cup of the vegetable, about the size of a baseball. Lightly cooked generally includes stir fry, sauté, microwave, short-term, e.g. less than 10 minutes, steam or bake, and thoroughly cooked includes stew, biol, or long-term, e.g. more than 10 minutes, steam or bake.)

Vegetables		Never	A Few Times Per Year	Once per month	2-3 Times per month	Once per week	Twice per week	3-4 Times per week	5-6 Times per week	Every day	How much each time?	S	M	L
Arugula	raw	<input type="checkbox"/>												
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>												
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>												
Broccoli	raw	<input type="checkbox"/>												
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>												
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>												
Broccoli sprout	raw	<input type="checkbox"/>												
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>												
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>												
Broccolini	raw	<input type="checkbox"/>												
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>												
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>												
Corn	raw	<input type="checkbox"/>												
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>												
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>												

Green cabbage	raw (e.g. coleslaw)	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Red/Purple cabbage	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Sauerkraut	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Carrots	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Cauliflower	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Brussels sprouts	raw	<input type="checkbox"/>										

	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Kale	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Kohlrabi	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Collard greens	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Peas	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Mustard greens	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Turnip	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										

Turnip greens	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Bok/ Pak choy	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Chinese cabbage/ Napa	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Daikon root	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Celery	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Garden cress	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Water cress	raw	<input type="checkbox"/>										

	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Radicchio	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										
Radishes	raw	<input type="checkbox"/>										
	lightly cooked (e.g. stir fry)	<input type="checkbox"/>										
	thoroughly cooked (e.g. stew)	<input type="checkbox"/>										

I am now going to ask some questions about sauces and condiments you ate during the **past 30 days**. Please think about all meals, snacks, and food consumed at home and away from home.

(Go through table. Frame questions as, “How often did you eat mayonnaise? Never, a few times per year, once per month, 2-3 times per month, once a week, twice per week, 3-4 times per week, 5-6 times per week, or every day.” If they answer never, go to the next food. If they ate any amount, ask, “About how much mayonnaise did you eat each time? The size of your thumb from knuckle to tip or less? About two thumbs worth? Or more than 2 thumbs worth?”

For **horseradish**, if they consume any amount, ask, “about how much horseradish did you eat each time? Smaller than an egg, about the size of egg, or more than the size of an egg?)

SAUCES AND CONDIMENTS											Serving Size		
	Never	A Few Times Per Year	Once per month	2-3 Times per month	Once per week	Twice per week	3-4 Times per week	5-6 Times per week	Everyday	Medium Serving	S	M	L
	<input type="checkbox"/>	2 Tbsp.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>								
	<input type="checkbox"/>	1/4 cup	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>								
Mayonnaise and mayonnaise-type spreads	<input type="checkbox"/>	2 Tbsp.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>								
Horseradish	<input type="checkbox"/>	1/4 cup	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>								
Mustard	<input type="checkbox"/>	2 Tbsp.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>								
Wasabi	<input type="checkbox"/>	2 Tbsp.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>								

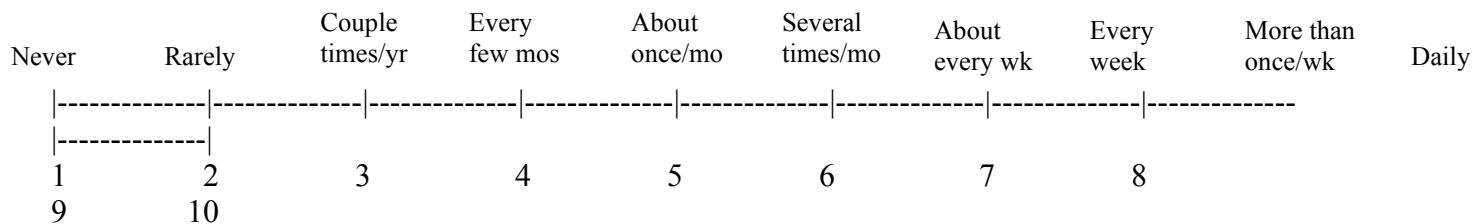
Belief into Action Scale

Circle a single number for each question below:

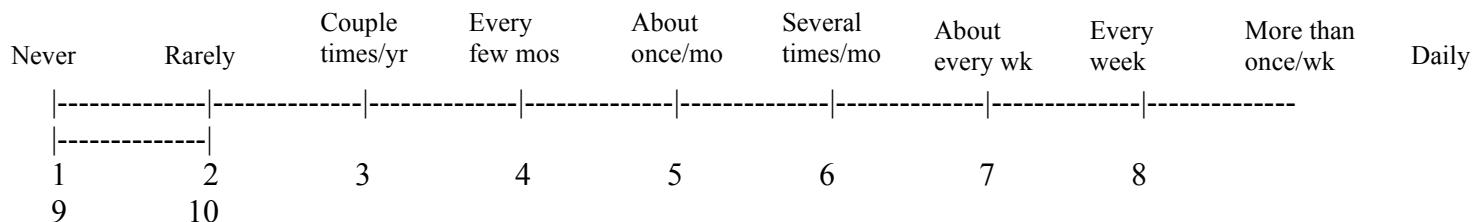
1. Please circle the highest priority in your life now? (most valued, prized)

1. My health and independence
2. My family
3. My friendships
4. Job, career or business
5. My education
6. Financial security
7. Relationship with God
8. Ability to travel & see the world
9. Listening to music and partying
10. Freedom to live as I choose

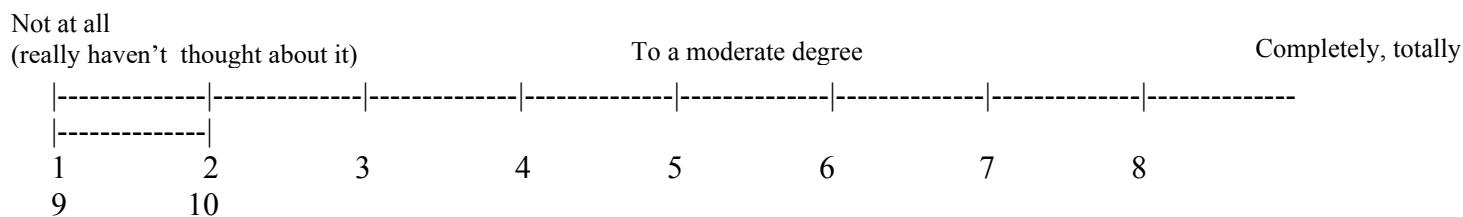
2. How often do you attend religious services? (circle a number below)



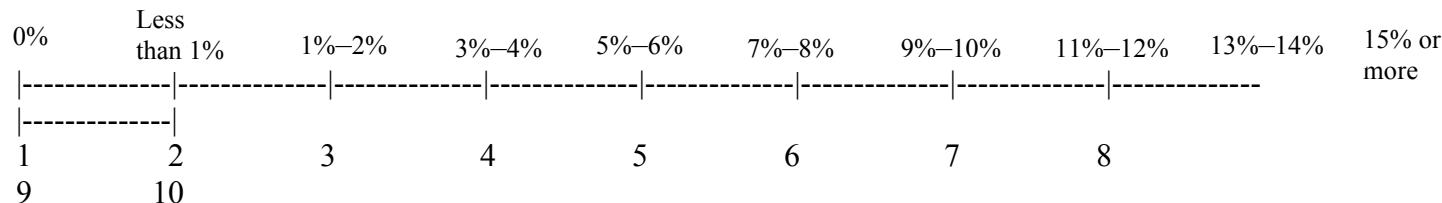
**3. Other than religious services, how often do you get together with others for religious reasons
(prayer, religious discussions, volunteer work, etc.)?**



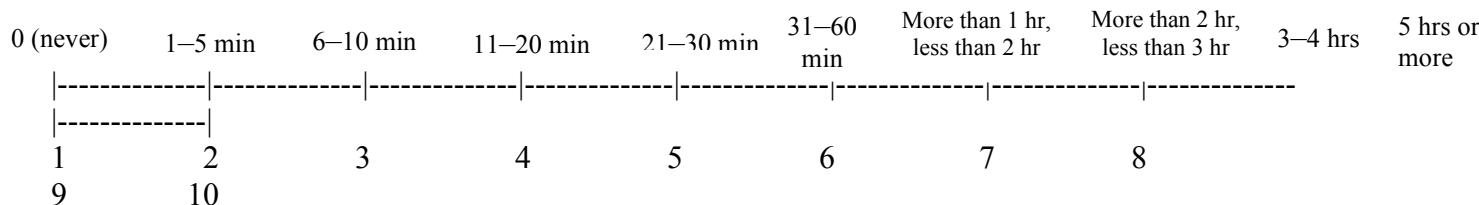
4. To what extent (on a 1 to 10 scale) have you decided to place your life under God's direction?



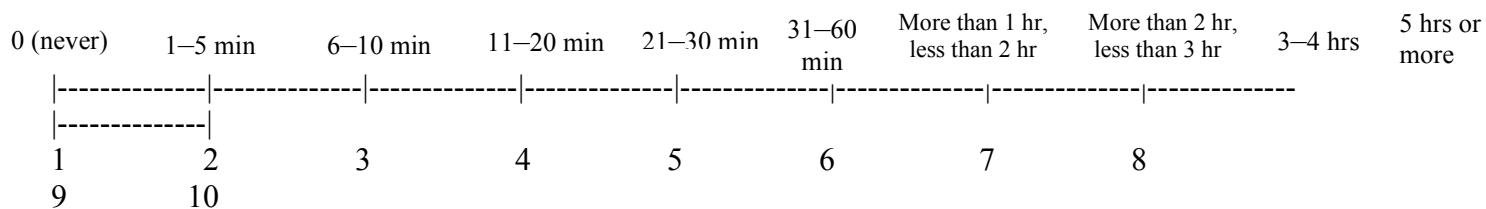
5. What percentage of your gross annual income do you give to your religious institution or to other religious causes each year?



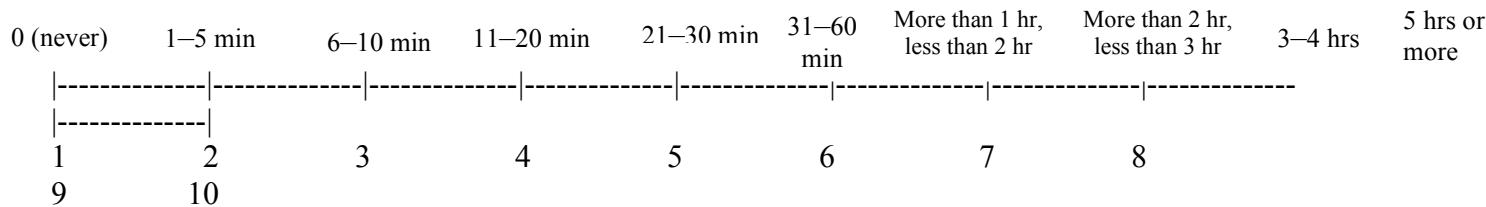
6. On average, how much time each day (in 24 hrs) do you spend listening to religious music or radio, or watching religious TV?



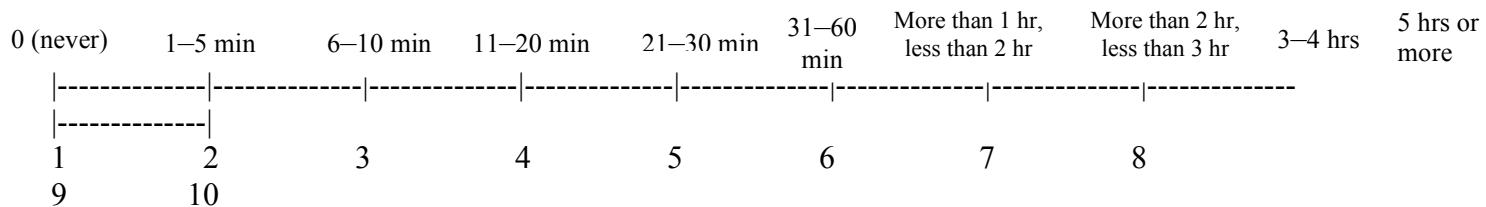
7. On average, how much time each day do you spend reading religious scriptures, books, or other religious literature?



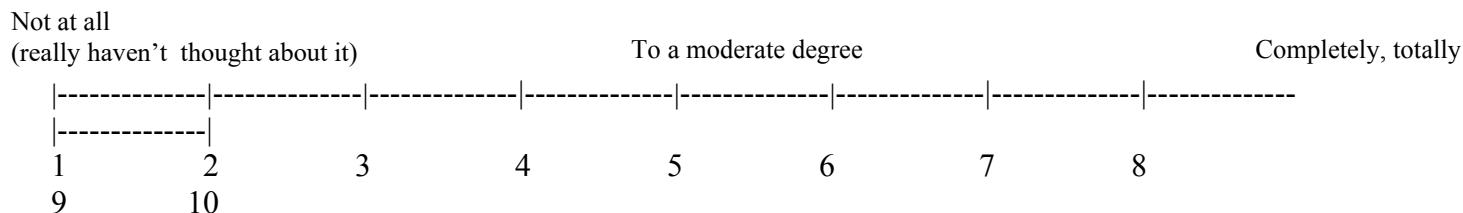
8. On average, how much time each day do you spend in private prayer or meditation?



9. On average, how much time each day do you spend as a volunteer in your religious community or to help others for religious reasons?



10. To what extent (on a 1 to 10 scale) have you decided to conform your life to the teachings of your religious faith?



We're going to finish the survey by asking your opinion about the dietary program you got.

I'm going to read some statements about the dietary program you got. Please let me know whether you completely disagree with the statement, disagree with the statement, neither agree nor disagree with the statement, agree with the statement, or completely agree with the statement.

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The diet program I received met my approval.	①	②	③	④	⑤
2. The diet program I received was appealing to me.	①	②	③	④	⑤
3. I liked the diet program I received.	①	②	③	④	⑤
4. I welcomed the diet program I received.	①	②	③	④	⑤

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The diet program I received fit into my lifestyle.	①	②	③	④	⑤
2. The diet program I received was suitable to my lifestyle.	①	②	③	④	⑤
3. The diet program I received was applicable to my lifestyle.	①	②	③	④	⑤
4. The diet program I received was a good match with my lifestyle.	①	②	③	④	⑤

Feasibility of Intervention Measure (FIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The diet program I received was implementable in my life.	①	②	③	④	⑤
2. The diet program I received was possible to do in my life.	①	②	③	④	⑤
3. The diet program I received was doable.	①	②	③	④	⑤
4. The diet program I received was easy to use.	①	②	③	④	⑤

If you are a part of Group A, there are a few feedback questions we would like to ask you at this time, is this okay?

If you are a part of Group B, you have finished the survey! Thank you so much for your time. Do you have any questions? Again, thank you for your participation in POW-R Health!

Appendix G2. POW-R Participant Additional Questions to Follow-Up Questionnaire

These questions will be given to those in the cruciferous arm only.

Thank you so much for being a part of the POW-R study. The program you went through consisted of a mailed magazine, a phone call with one of our Roswell staff, and then 11 automated phone calls. We would like to ask the feedback questions regarding the study at this time.

1. What did you think about the magazine?

- a. What did you like about it?
- b. What would you change?

2. What did you think about the phone call with the Roswell staff person?

- a. What did you like about it?
- b. What would you change?

3. What did you think of the 11 automated calls?

- a. What did you like about it?
- b. What would you change?

4. What do you think having this program as a phone app?

You have finished the survey! Thank you so much for your time. Do you have any questions? Again, thank you for your participation in POW-R Health!

Appendix H New York State Cancer Registry Contact Materials and Procedures

POW-R Health: Power to Redefine your Health Program NYS Cancer Registry Patient Contact and Data Handling Procedures

The procedures described in this document are standard procedures the New York State Cancer Registry (NYSCR) follows for patient contact studies.

I. Approval Process

1. Roswell Park Cancer Institute IRB approval
2. NY State Health Department Administrative approval

II. NYSCR Patient Consenting Process (i.e., physician notification and patient consent to release name, contact information, and diagnostic information to Roswell Park Cancer Institute)

Using ICD-O-3 codes provided in the study protocol, the NYSCR will conduct a search of its database to identify eligible patients who were diagnosed with stage Tis, Ta, or T1 bladder cancer in 2018 or later, who resided in one of eight counties of interest at diagnosis (Niagara, Orleans, Genesee, Erie, Wyoming, Chautauqua, Cattaraugus, and Allegany), who are 18 years of age or older, who did not receive a cystectomy, who did not have a prior cancer diagnosis within 12 months of their bladder cancer diagnosis, who did not have a subsequent more advanced bladder cancer diagnosis, and who have not died or opted out of research studies. This search will be repeated if needed until the recruitment goal is reached. The NYSCR will contact reporting facilities to obtain the patients' physician information, if missing in the database.

The NYSCR will send a letter to the physician of record for selected cases notifying him/her that the patient was identified for the study, requesting that the NYSCR be notified if the patient is deceased, too ill or otherwise unable or ineligible to participate in the study, and requesting information about the case's primary care physician if different from the contacted physician. The physician will have three weeks to respond.

If no contraindication is received from the physician or if the physician has not responded within three weeks, the NYSCR will send an informational packet to the patient. The packet will contain: 1) a letter explaining the study and requesting permission to release their name, contact information, and diagnostic information to the study's principal investigator at Roswell Park Cancer Institute; 2) a participant information sheet; and 3) a release of information consent form. If the NYSCR has not received any response after two weeks a reminder packet of information will be sent. Again, if no response is forthcoming after two more weeks, five telephone calls will be attempted by the NYSCR (three during regular business hours, and two during non-business hours) to describe the study and receive a response (either consent or refusal). If the patient consents verbally, NYSCR staff will fill out the consent form and document that the consent was obtained via phone. If the Registry is unable to contact the patient via telephone, and no written response has been received, no other contact will be attempted, and the patient will be considered a refusal.

Upon receipt of the consent form, the patient's name, contact information, and diagnostic information will be provided by the NYSCR to the study's principal investigator at Roswell Park Cancer Institute via Roswell's secure File Transfer Solution (sFTP). The NYSCR will receive a unique user name and password in separate emails to transfer the data via sFTP.

III. Roswell Park Patient Contact Procedures

Upon receipt of the patient information from the NYSCR, the Roswell Park research team will contact the patient by telephone. All members of the Roswell Park research team will have completed Collaborative Institutional Training Initiative (CITI training). If the patient is not reached during the first attempt, the research team will make additional attempts using the following algorithm: five additional attempts at varying dates and times, for a total of six attempts over three weeks. Each attempt will be documented in the call manager portion of the Electronic Data Capture system. After all phone attempts are exhausted, a traceable Hard to Reach Letter will be mailed to the patient's address listed in the patient profile. The patient will be asked to contact the Roswell Park research team if they are interested in learning more about the study.

Upon contact with the patient, the Roswell Park research team member will again explain the study, administer the screening interview, and obtain consent for the patient's participation. The Roswell Park research team will record the patient's real time responses in the corresponding Patient Phone Screening Interview Form in the Electronic Data Capture system. The patient will be mailed a consent form for them to keep. For respondents who do not wish to participate, the telephone contact will be terminated, and they will be ineligible for the study. Information on non-participants will be provided to the NYSCR, as well as any information for any individuals who indicate that they do not want to be contacted about any future research studies.

IV. Data Handling, Dissemination and Storage Procedures

After receipt of the patient information from the NYSCR, the data will be entered and stored in REDCap. REDCap is a secure application supported by Partners Research Computing, Enterprise Research Infrastructure & Services (ERIS). ERIS has all the necessary physical and operational securities in place to meet or exceed Federal and State security and privacy regulations for data transmission and storage using REDCap. The dataset containing patient contact information will be separated from the research dataset including survey data and urine sample tracking data. The data will only be accessed by key members of the Roswell Park research team who are in charge of contacting patients. All the data communications between NYSCR and Roswell Park will be transferred via Roswell's secure File Transfer Solution (sFTP). A unique username and password will be used for each data transfer and sent in separate emails.

Exhibit A

The following information will be provided to Roswell Park for each bladder cancer case identified for possible inclusion in the study:

1. Reporting source
2. Patient name
3. Patient address and telephone number
4. Physician name and contact information
5. Basic demographic information (race, ethnicity, date of birth, county of residence)
6. Primary site
7. Summary stage
8. Histology
9. Laterality
10. Date of diagnosis
11. Age at diagnosis
12. First course of treatment
13. Primary surgical procedure
14. Chemotherapy
15. Date of last contact

Materials used by the New York State Cancer Registry for the

POW-R Health: Power to Redefine your Health Program
[Letter from NYS Cancer Registry to Physician]

Month, Day, Year

{Physician Name}
{Physician Address}
{Physician City, State Zip}

Dear Dr. "M.D._LAST NAME":

We are writing to inform you that the New York State Department of Health's Cancer Registry is collaborating with Roswell Park Comprehensive Cancer Center on a pilot study of a dietary intervention with a goal to reduce the risk of recurrence in individuals diagnosed with non-muscle invasive bladder cancer. Patients diagnosed with non-muscle invasive bladder cancer (including Tis, Ta, and T1 disease) who did not receive cystectomy and who live in the counties of Niagara, Orleans, Genesee, Erie, Wyoming, Chautauqua, Cattaraugus, and Allegany may be eligible for the study.

Our records show that one of your patients was recently diagnosed with bladder cancer and meets the study criteria. The patient's name and other identifying information reported to the Cancer Registry are on the enclosed form. We would like to contact your patient to assess their interest in participating in the study.

Patients will be sent an introductory letter describing the study and requesting their consent for their name, contact information, and some information about their diagnosis to be shared with Roswell Park Comprehensive Cancer Center. Patients who consent will be contacted by phone regarding participation in the study. Patient participation in the study includes participation in a 6-month phone-based dietary intervention that will consist of educational materials mailed to the patient's home, one 20-minute phone call with Roswell Park staff to go over the educational materials, and 11 automated telephone calls asking participants to report the number of vegetable servings they have consumed in the prior week, followed by tailored feedback based on the servings reported. Patients will also be asked to complete two assessments, one at the beginning of the study, and one at the end. These assessments will include a 45-60-minute phone survey, self-collection of a urine sample, and three 24-hour dietary recalls. All information that could identify the patient will be kept confidential. Names and other identifying information will not be used in any publication about the study.

If you do not object to our contacting your patient, you do not need to do anything further. However, there may be some reason why your patient cannot or should not be contacted about

participation in this study; therefore, we would like to hear from you within the next three weeks if you prefer that we do not contact your patient.

If you prefer that we do not contact your patient please complete the enclosed form and fax it to "Attn: bladder cancer study" at (518) 473-6789 or mail it back to us in the enclosed self-addressed, stamped envelope. If you have any questions about the study or the form, please contact Dr. Maggie Kuliszewski at the New York State Cancer Registry at (518) 474-2255. Thank you very much for your assistance.

Sincerely,

Maria J. Schymura, Ph.D.
Director, New York State Cancer Registry

New York State Cancer Registry
POW-R Health: Power to Redefine your Health Program

Patient Information Sheet for Physician

Name of Physician

Address

Address

Address

Telephone number

If information below is incorrect please provide correct information.

Patient Name

Patient Address

Telephone number

Patient DOB _____ Sex _____

Race _____

Diagnosed with non-muscle invasive Tis, Ta, or T1 bladder cancer?

Yes _____ No _____

If yes, date first diagnosed _____

Any medical contraindications to patient contact for the study? Yes _____ No _____

If yes, please explain _____

Physician signature _____ Date _____

Please fax the completed form to "Attn: bladder cancer study" at (518) 473-6789. Or mail the form in the enclosed self-addressed, stamped envelope to:

POW-R Health: Power to Redefine your Health Program, New York State Cancer Registry,
NYS Department of Health, Suite 361, Riverview Center, 150 Broadway, Albany, NY 12204

Thank you for your assistance.

Date sent

[Letter from NYS Cancer Registry to Patient]

{Patient Name}

{Patient Street Address}

{Patient City, State, ZIP}

Dear _____:

The New York State Department of Health's Cancer Registry is contacting patients who may be eligible for a research study. The study is being done in collaboration with researchers at Roswell Park Cancer Institute. The purpose of the study is to learn more about how diet may reduce the risk of recurrence in individuals with early-stage bladder cancer. Men and women who were recently diagnosed with early-stage bladder cancer and who live in the counties of Niagara, Orleans, Genesee, Erie, Wyoming, Chautauqua, Cattaraugus, and Allegany may be eligible for the study.

Under New York State Public Health Law, hospitals and doctors must report all cases of cancer that they find to the New York State Cancer Registry. This is how we learned about your diagnosis.

Please take the time to read the enclosed information about this study. We would like to send your name, contact information, and some information about your diagnosis to researchers at Roswell Park Cancer Institute, so that they can contact you to see if you are eligible for the study and interested in participating. However, we need your consent in order to release your name and contact information. Please fill out the enclosed consent form to let us know if we can share your information with Roswell Park Cancer Institute.

Please mail the completed consent form back to us in the enclosed self-addressed, stamped envelope. If we do not receive the form, someone from our office will call you to make sure you received this letter and to discuss the study with you.

If you have any questions about this study, please call Dr. Maggie Kuliszewski at the New York State Cancer Registry at (518) 474-2255.

If you have any questions about your rights as a participant in this study or think you have been harmed by the study, please contact Mr. Tony Watson, the Administrator of the Institutional Review Board at the New York State Department of Health at (518) 474-8539.

We greatly appreciate your help with this study.

Sincerely,

Dr. Maria Schymura, Director
New York State Cancer Registry

Enclosures

POW-R Health: Power to Redefine your Health Program New York State Department of Health Cancer Registry

Participant Information Sheet

The New York State Department of Health's Cancer Registry and Roswell Park Cancer Institute are collaborating on a research study of individuals with bladder cancer in New York State. The purpose of the study is to better understand how diet may reduce the risk of recurrence in men and women diagnosed with early-stage bladder cancer.

Procedure: A researcher from Roswell Park Cancer Institute will contact you to see if you are eligible for the study and would like to participate. If you decide to participate, you will receive a 6-month dietary intervention that may improve your health. The intervention will include educational materials mailed to your home, a 20-minute phone call with Roswell Park staff to go over the educational materials, and 11 automated phone calls that will give you feedback on your diet based on how many vegetables you report eating during the past week. To see if our dietary intervention improves health, we will also ask you to complete two assessments, one at the beginning of the study, and one at the end of the study. The assessment will include a 45-60-minute survey, a self-collected urine sample, and three dietary recalls. Individuals who are eligible for and participate in the study will receive up to \$200 in gift cards at a local retail store as a token of appreciation for their participation.

Voluntary Participation: Taking part in this study is up to you. You may stop taking part at any time. You may refuse to answer any question. If you decide not to take part, you will not lose any benefits that you would normally receive.

Confidentiality: We will keep all of your answers and health information private, as required by law. If you decide to participate in the study, we will assign a code to you and use the code instead of your name. Any records that include your name and could link you to the coded information will be kept in electronic files accessible only to assigned study staff and will be password-protected on the computer. Access will be allowed only to the researchers involved in the study who have signed a confidentiality agreement. Your name and other identifying information will not appear in any reports of this study. Your address will not be used to send any additional promotional information whatsoever.

Benefits: You may or may not benefit from the study intervention. Information about your experience in the study may contribute to our understanding of factors that reduce the risk of recurrence of early-stage bladder cancer and may help other people in the future.

Risks: There are no known risks to being part of this study. Talking about your health and your bladder cancer diagnosis may cause you some stress. There is also the potential (but unlikely) loss of confidentiality regarding your responses to questions. We have many procedures in place to prevent this. Please see the above section on confidentiality.

Questions about the Study:

If you have any questions about this study, please call Dr. Maggie Kuliszewski at the New York State Cancer Registry at (518) 474-2255.

If you have any questions about your rights as a participant in this study or think you have been harmed by the study, please contact Mr. Tony Watson, the Administrator of the Institutional Review Board at the New York State Department of Health at (518) 474-8539.

[NYS CANCER REGISTRY PATIENT CONSENT FORM]

INFORMED CONSENT FOR FURTHER CONTACT
POW-R Health: Power to Redefine your Health Program

I understand that by checking the first statement and by signing this form below I am agreeing to allow the New York State Cancer Registry to release my name, contact information, and some information about my bladder cancer diagnosis to Roswell Park Cancer Institute.

Please check one of the following statements. Please sign and return in the enclosed envelope.

1. I consent to the release of my name, contact information, and some information about my bladder cancer diagnosis to Roswell Park Cancer Institute. I understand that a researcher from that organization will contact me to see if I am eligible for the study and would like to participate.

Name (please print)

Signature

Address

Telephone #

Date

2. I do not consent to the release of my name, contact information, or information about my bladder cancer diagnosis to Roswell Park Cancer Institute. I do not want anyone from that organization to contact me.

(Name of patient pre-printed on the bottom – in case above is illegible)

STATEMENT TO BE READ REGARDING THE STUDY PURPOSE, PROCEDURES INVOLVED, RISKS AND BENEFITS INVOLVED, AND CONFIDENTIALITY
NYS Cancer Registry Patient Contact – (if mailed response was not obtained)

Hello, my name is _____. May I please speak with _____)?

I'm from the New York State Department of Health's Cancer Registry. We're collaborating with Roswell Park Cancer Institute on a research study of individuals with bladder cancer in New York State. The purpose of the study is to better understand how diet may reduce the risk of recurrence in men and women diagnosed with early-stage bladder cancer. Men and women who were recently diagnosed with early-stage bladder cancer and who live in the counties of Niagara, Orleans, Genesee, Erie, Wyoming, Chautauqua, Cattaraugus, and Allegany may be eligible for the study. Recently, we sent you a letter asking for your consent for us to share your name, contact information, and some information about your bladder cancer diagnosis with Roswell Park Cancer Institute. Did you receive the letter?

IF "YES", PROCEED WITH SCRIPT BELOW.

IF "NO", ASK IF THEY WOULD LIKE TO CONTINUE OR HAVE YOU SEND ANOTHER LETTER.

IF "ANOTHER LETTER", VERIFY ADDRESS.

IF "CONTINUE", PROCEED WITH SCRIPT BELOW.

As the letter explains, the purpose of the study is to better understand certain factors that may reduce the risk of recurrence in men and women diagnosed with early-stage bladder cancer. If you consent for us to share your name and contact information with Roswell Park Cancer Institute, a researcher will contact you to see if you are eligible for the study and would like to participate. If you decide to participate, you will receive a 6-month dietary intervention that may improve your health. The intervention will include educational materials mailed to your home, a 20-minute phone call with Roswell Park staff to go over the educational materials, and 11 automated phone calls that will give you feedback on your diet based on how many vegetables you report eating during the past week. To see if our dietary intervention improves health, we will also ask you to complete two assessments, one at the beginning of the study, and one at the end of the study. The assessment will include a 45-60-minute survey, a self-collected urine sample, and three dietary recalls.

Taking part in this study is up to you. You may stop taking part at any time. You may refuse to answer any question. If you decide not to take part, you will not lose any benefits that you would normally receive. Individuals who are eligible for and participate in the study will receive up to \$200 in gift cards at a local retail store as a token of appreciation for their participation.

All of your answers will be kept private as required by law. All records that include your name will be kept in locked file cabinets. All records on the computer will be password-protected. Access will be allowed only to the researchers involved in the study. Your name and other identifying information will not appear in any reports of this study.

You may or may not benefit from the study intervention. Information about your experience in the study may contribute to our understanding of factors that reduce the risk of recurrence of early-stage bladder cancer and may help other people in the future. There are no known risks from being a part of the study. Talking about your health and your bladder cancer diagnosis may cause you some stress. There is also the potential (but unlikely) loss of confidentiality regarding your responses to questions. We have many procedures in place to prevent this.

If you have any questions about this study, please call Dr. Maggie Kuliszewski at the New York State Cancer Registry at (518) 474-2255.

If you have any questions about your rights as a participant in this study or think you have been harmed by the study, please contact Mr. Tony Watson, the Administrator of the Institutional Review Board at the New York State Department of Health at (518) 474-8539.

Do you consent to the release of your information to Roswell Park Cancer Institute? If so, someone from that organization will contact you by phone.

**CHECK THE APPROPRIATE RESPONSE BOX ON THE PATIENT CONSENT FORM.
SIGN AND DATE THE FORM IN THE BLANK SPACE ABOVE THE PATIENT
SIGNATURE LINE AND ADD “BY TELEPHONE” AFTER THE DATE.**

Appendix I Physician Interview Guide

Physician Semi-Structured Interview

To be administered right after verbal consent.

Thank you for agreeing to be a part of this study.

Our dietary intervention consists of giving bladder cancer patients 3 things: 1) educational materials by mail, 2) One 20 minute phone call with a trained staff member to go over the educational materials, and 3) 11 automated phone calls that ask patients to report the servings of vegetables they ate in the previous week, with automated feedback based on the number of servings reported.

If our study shows that this intervention significantly reduces bladder cancer recurrence in bladder cancer patients:

1. To what extent would you welcome such an intervention?
Probe: What would make you like this intervention more?
2. To what extent would you think the intervention would be a good match for your clinic?
Probe: What would make this intervention fit better within your clinic?
3. To what extent do you think the intervention would be doable in your clinic?
Probe: What would make this intervention easier for your clinic to use?

That concludes the interview. Thank you so much for your time.

Appendix J Physician Research Study Information Sheet for Structured Interviews

Please keep a copy of this form for your reference.

I am (fill in name/role), with the Division of Prevention & Population Sciences at Roswell Park Comprehensive Cancer Center. I am working with a team at Roswell Park to learn about the barriers and facilitators of intervention implementation within clinical practice. The goal is to gain feedback and develop the intervention for “real-world” implementation.

To accomplish this, we would like to conduct a semi-structured interview with a total of 20 physicians or health care providers within the area in Western New York. This study is funded by the National Cancer Institute.

I would like to tell you more about it before you decide whether or not to participate in this one-time interview study. Please stop me at any time if you have any questions. Your participation is completely voluntary; you do not have to participate.

During the interview, I will provide you with a brief overview of our dietary intervention for bladder cancer patients. I will then ask questions regarding facilitators and barriers of intervention adoption within clinical practice. I will ask your opinion on the needed implementation strategies to sustain the intervention, in addition to intervention modifications to maximize sustained clinic adoption. The interview should last approximately 15 minutes. I may ask your permission to electronically record the discussion so we can capture information accurately. If you object to electronically recording the conversation, please let me know now.

This information will be collected anonymously (without linking it to your name or identity, or identifying any patients; all data will be aggregated). We will not be using your name on any of the forms or any information that is gathered.

Your involvement in this study does not involve any physical risk to you. The possible risks include feeling uncomfortable answering questions, embarrassment, or someone identifying you as a participant in the project, although this would be rare. You will not receive any direct health benefit from participating in this study.

Participants that complete the interview will receive a \$100 gift card to a local retail store.

You do not have to take part in this one-time contact research study. If you decide to participate, you can stop your participation at any time. You may refuse to answer any questions and you may leave at any time.

Results of this study will yield important information on the feasibility of a dietary behavioral intervention to improve bladder cancer outcomes among bladder cancer patients. These results have the potential to improve the survivorship outcomes of a group at elevated risk of cancer recurrence, as well as for teaching, for research, for scientific publications and/or for presentations at scientific meetings. You will not be identified in any way. Your participation is completely anonymous because I am not collecting your name (or taking photographs of you).

If you have any questions, you are free to ask them now. If you have questions or concerns about the study at any time, you can call the Roswell Park Office of Research Subject Protection at (716) 845-3455. You may contact me at the telephone number I will provide in a few minutes. This study has been reviewed and approved by the Roswell Park Institutional Review Board.

CONTACT INFORMATION:

If you have any questions about this study, you may contact me:

Cassy Dauphin
Roswell Park Comprehensive Cancer Center
Elm & Carlton Streets
Buffalo, NY 14263
716-845-8319

Or you may contact the Principal Investigator, who is the Director of this study:

Karen Yeary, PhD
Roswell Park Comprehensive Cancer Center
Elm & Carlton Streets
Buffalo, NY 14263
716-845-1300 Ext 6231

Li Tang, PhD
Roswell Park Comprehensive Cancer Center
Elm & Carlton Streets
Buffalo, NY 14263
716-845-8247

Appendix K Community Advisory Board (CAB) Research Study Information Sheet

Please keep a copy of this form for your reference.

I am (fill in name/role), with the Division of Cancer Prevention and Control at Roswell Park Comprehensive Cancer Center. I am working with a team at Roswell Park to adapt materials and methods from current evidence-based fruit and vegetable interventions in order to develop a dietary intervention for bladder cancer survivors. The goal is to gain feedback and develop the intervention for “real-world” implementation. This study is funded by the National Cancer Institute.

I would like to tell you more about it before you decide whether or not to participate. Please stop me at any time if you have any questions. Your participation is completely voluntary; you do not have to participate.

In this study, you will be asked to attend three meetings (in person or virtual) as a Community Advisory Board (CAB) member to help develop a dietary intervention that will be relevant for bladder cancer survivors. You will be asked to review intervention materials and messages and provide feedback for improvements. We will also ask you some demographic questions. Each meeting will last approximately 90 minutes. We may ask your permission to electronically record the discussion so we can capture information accurately. If you object to electronically recording the conversation, please let us know.

This information will be collected anonymously (without linking it to your name or identity or identifying any patients; all data will be aggregated). We will not be using your name on any of the forms or any information that is gathered.

Your involvement in this study does not involve any physical risk to you. The possible risks include feeling uncomfortable answering questions, embarrassment, or someone identifying you as a participant in the project, although this would be rare. You will not receive any direct health benefit from participating in this study.

CAB members will be asked to complete a structured 60 minute interview, will receive \$50 for interview, compensated \$100 per meeting attended, up to three meetings, and interviews will be conducted over the phone.

You do not have to take part in this one-time contact research study. If you decide to participate, you can stop your participation at any time. You may refuse to answer any questions and you may leave at any time.

Results of this study will yield important information on the feasibility of a dietary behavioral intervention to improve bladder cancer outcomes among bladder cancer patients. These results have the potential to improve the survivorship outcomes of a group at elevated risk of cancer recurrence, as well as for teaching, for research, for scientific publications and/or for presentations at scientific meetings. You will not be identified in any way. Your participation is completely anonymous because I am not collecting your name (or taking photographs of you).

If you have questions or concerns about the study at any time, you can call the Roswell Park Office of Research Subject Protection at (716) 845-3455. You may contact me at the telephone number I will provide in a few minutes. This study has been reviewed and approved by the Roswell Park Institutional Review Board.

CONTACT INFORMATION:

If you have any questions about this study, you may contact me:

Nikia Clark
Roswell Park Comprehensive Cancer Center
Elm & Carlton Streets
Buffalo, NY 14263
716-845-4888

Or you may contact the Principal Investigators, who are the Directors of this study:

Karen Yeary, PhD
Roswell Park Comprehensive Cancer Center
Elm & Carlton Streets
Buffalo, NY 14263
716-845-1300 Ext 6231

Li Tang, PhD
Roswell Park Comprehensive Cancer Center
Elm & Carlton Streets
Buffalo, NY 14263
716-845-8247

Appendix L Bladder Community Advisory Board (CAB) Interview Guide

Thank you for being willing to be a part of helping us make a healthy eating program for bladder cancer survivors to improve their health. We're going to start by asking some questions about you.

1. (Administer demographic survey, page 2)
2. When were you first diagnosed with bladder cancer?
 - What type of treatment did you receive after your bladder cancer diagnosis?
 - How long did the treatment last?
3. Have you had any recurrence since your initial bladder cancer diagnosis?
 - If yes, when did it happen and what treatment did you receive?
4. What is the biggest concern you have regarding your bladder cancer diagnosis?
5. Since your bladder cancer diagnosis, did you change your eating habits?
 - If yes, how did you change your eating habits?
6. Do you think what you eat can make a difference in terms of bladder cancer prevention or recurrence?
 - If yes, how?
7. Recent research has shown that eating more cruciferous vegetables can reduce the chances of bladder cancer coming back in bladder cancer survivors. Cruciferous vegetables include broccoli, arugula, brussels sprouts, green or white cabbage, and turnips.
 - What do you think about this information? Is this helpful? Have you heard this before?
8. In your day-to-day life, what might make it easier for you to eat more cruciferous vegetables?
 - Probes: Help from your family, help from the healthcare system, help from friends, any particular information
9. Who does most of the shopping for food in your family?
 - If self: What affects the kinds or amount of vegetables you buy?
 - If not self: What role do you play in what they shop for?
10. Who does most of the planning or preparing of meals in your family?
 - If not self: What role do you play in how meals are planned or prepared?
11. How do other people in your life impact the kinds and amounts of vegetables you eat?

Demographic Survey

• **Are you male or female?**

- 1 Male
- 2 Female

• **Are you Hispanic or Latino/a or Spanish in origin?**

- 1 Yes

Are you:
(circle all that apply)

- 1 Mexican, Mexican American, Chicano/a
- 2 Puerto Rican
- 3 Cuban
- 4 Another Hispanic, Latino/a, or Spanish origin

- 2 No

• **Which one or more of the following would you say is your race? (Circle all that apply)**

- 1 White
- 2 Black or African American
- 3 American Indian or Alaska Native
- 4 Asian
- 5 Other (please specify)_____

• **How old are you?**

_____ years

• **What is your marital status?**

- 1 Married
- 2 Living as married
- 3 Divorced
- 4 Widowed
- 5 Separated
- 6 Single, never been married

• **What is the highest grade or level of schooling you completed?**

- 1 Less than 8 years
- 2 8-11 years
- 3 12 years or completed high school
- 4 Post high school training other than college (vocational or technical)
- 5 Some college
- 6 College graduate
- 7 Postgraduate

• **What is your occupational status?**

- 1 Employed

- 2 Unemployed
- 3 Homemaker
- 4 Retired
- 5 Disabled
- 6 Other (Specify) _____

- **How many people currently live in your home (include yourself)? _____**
- **In the past 12 months, have you received food stamps, also called SNAP, the Supplemental Nutrition Assistance Program on an EBT card?**
 - 1 Yes
 - 2 No
 - 3 Don't know
- **Do you have any kind of health care coverage, including health insurance, prepaid plans such as HMOs or government plans such as Medicare, or Indian Health Service?**
 - 1 Yes (if yes, go to 11a)
 - 2 No

11a. What is the primary source of your health care coverage?

- 35. A plan purchased through an employer or union (including plans purchased through another person's employer)
- 36. A plan that you or another family member buys on your own
- 37. Medicaid (primarily for people over age 65) or other state program
- 38. Medicare
- 39. TRICARE (formerly CHAMPUS), VA, or Military
- 40. Alaska Native, Indian Health Service, Tribal Health Service
- 41. Some other source

I'm going to read you several statements that people have made about their food situation. For these statements, please tell me whether the statement was often true, sometimes true, or never true for (you) in the last 12 months—that is, since last (name of current month). The first statement is:

- **“The food that I bought just didn’t last, and I didn’t have money to get more.” Was that often, sometimes, or never true for you in the last 12 months?**
 - 1 Often true
 - 2 Sometimes true
 - 3 Never true
 - 4 DK or Refused
- **“I couldn’t afford to eat balanced meals.” Was that often, sometimes, or never true for you in the last 12 months?**
 - 1 Often true

- 2 Sometimes true
- 3 Never true
- 4 DK or Refused

Appendix M Participant 24-hour Dietary Recall Instructions

24-Hour Recalls

What's a 24-Hour Recall?



24-hour recalls are a way of figuring out what you usually eat and drink. We will get this

information through talking to you on the telephone, where we will ask you to remember what you ate and drank during the previous day.

The telephone recalls will occur on 3 separate days at the start of the study, and 3 separate days at the end of the study. The days will be selected at random so that weekdays (Monday through Thursday) and one weekend day (Friday through Sunday) is included. This will help us figure out your *average* diet.

Scheduling the Calls

A person from Roswell Park Cancer Institute, Buffalo, NY will be calling you to do the recalls. They will call you during the times you said would work best with your schedule when you signed up to be a part of the study. At this time, they will call and ask you for details of **everything** -- all foods and liquids (including water) -- that you ate or drank during the past 24 hours *from midnight to midnight of the previous day*.

The person will ask you the amount you actually ate or drank, not how much was put into the dish, cup, or bowl. Please use the "**Food Amounts Booklet**" that we sent you with this sheet. The following tips will also help you estimate how much you eat and drink.

Measuring Tips



Use measuring cups and spoons to help you tell the Roswell person the exact amount you ate or drank.

Instead of telling the Roswell person you had breakfast cereal, give more details like: 1 cup of wheat flakes with 1/2 cup of lowfat milk, and 1/2 of a large (8-inch) banana.

- Measure the volume of dishes, bowls, cups, and glasses that you use a lot. This will help you to figure out and report the correct volume of food/drink each time you use that container.
- For pieces of food that do not fit into a cup or spoon, describe the size using the "**Food Amounts Booklet**".

For example, 1 corn tortilla (6 inches across), and 1 cube of cheese (2" long x 1" wide x 1/2" high). You can use weight or dimensions for reporting meat, fish, poultry, cheese, pizza, and baked goods. Include thickness, length, and width of food using a ruler. Indicate if the weight was obtained before or after cooking.

Be Specific. When naming the food or drink that you ate/drank, give the Roswell person details. For example, if you ate meat, details such as the part eaten are important. If you ate chicken, tell the person whether it was from the thigh or breast, or if it was white or dark meat.

Brand Names & Labels. Brand names of prepared foods are very useful for the Roswell person, as are labels from the prepared foods you have eaten.

Mixed Foods. Be prepared to tell the Roswell person what is in a mixed food. For example, rather than just saying 1 cup of stew, do your best to give the amount of each major item in the stew, such as 1/4 cup stewed beef, 1/4 cup potato, 1/4 cup carrot, 1/4 cup gravy. If you made a dish at home, report the recipe used including all ingredients, and the number of servings from the recipe or what portion of the total you actually ate.

Preparation Method. It is also important for you to describe how the food was cooked, such as baked, boiled, broiled, fried, breaded and fried. For example, one chicken drumstick (fried in shortening, no flour or batter).



Add-ONS. Remember to tell your Roswell person the little things added to foods like butter, margarine, mustard, jelly, sugar, gravy, or salad dressing.

Nonfat Items. Don't forget to report nonfat items. Just because they are nonfat does not mean they are not important to include.

Time & Place. The Roswell person will ask you to say about what time the food or drink was eaten or drank, and whether it was eaten at a meal or a snack. It is also very helpful if you can say where the food or drink was eaten/drunk, for example at home, work, school, restaurant, store, etc. *For example, at 2:00 PM, I ate a snack at home. The snack was 2 tablespoons of raisins and 8 whole-grain crackers (2-inch diameter).*

also ask you what vitamin and/or mineral or herbal supplements you took during the prior day. **It is important that you have these supplements handy**, as the Roswell person will ask you for specific information about the supplement ingredients.

For those supplements with more than one ingredient, **the Roswell person will ask you for the brand name, the manufacturer, and the manufacturer's contact information (address, phone number, and/or website).**

We have information on the contents of many of these. However, we may need to ask you to read off all the ingredients for some supplements, along with the amount per tablet or capsule, and how many you ate during the previous day.

Thank you for being a part of this very important study. We look forward to talking with you.

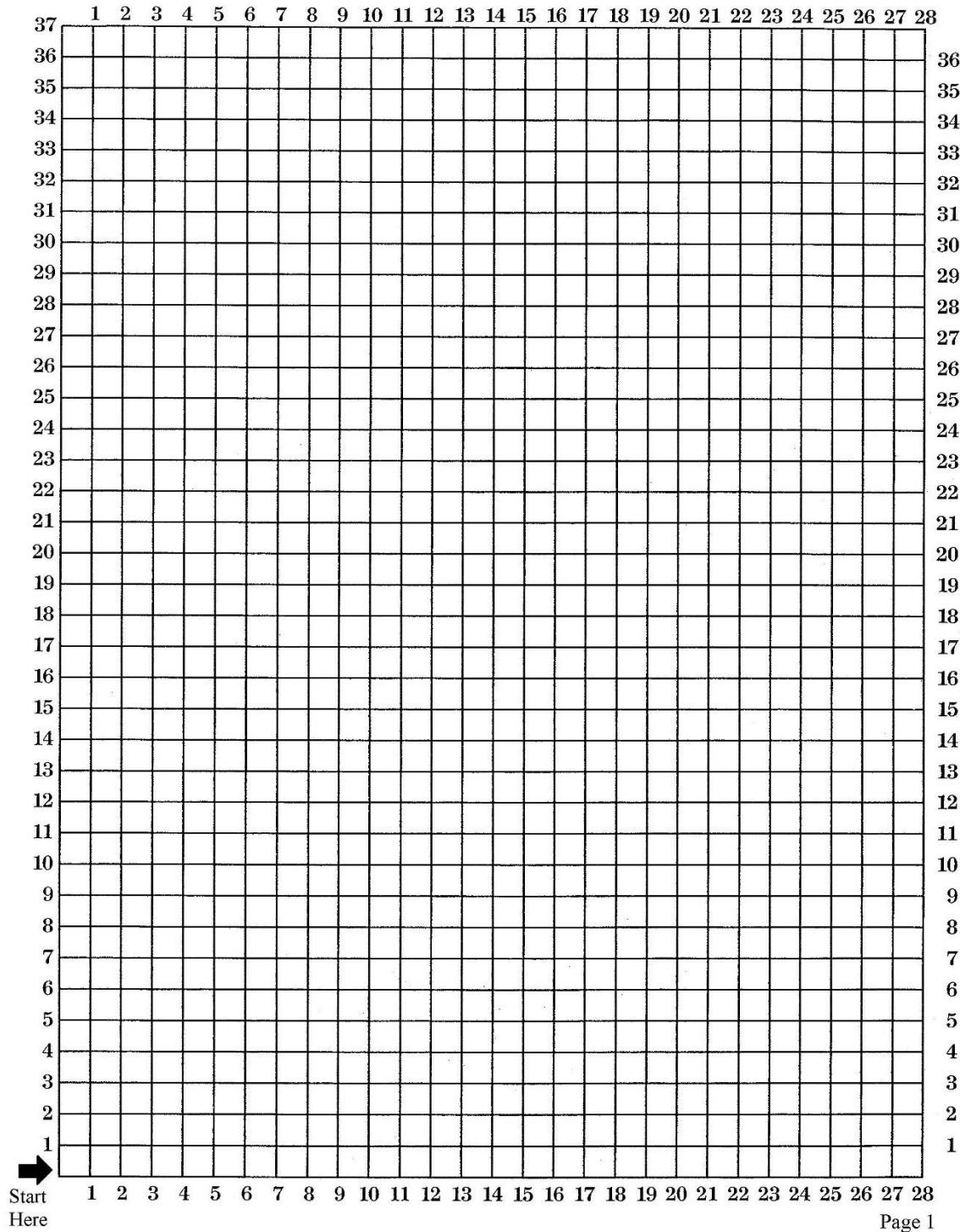


Supplements. The Roswell person will

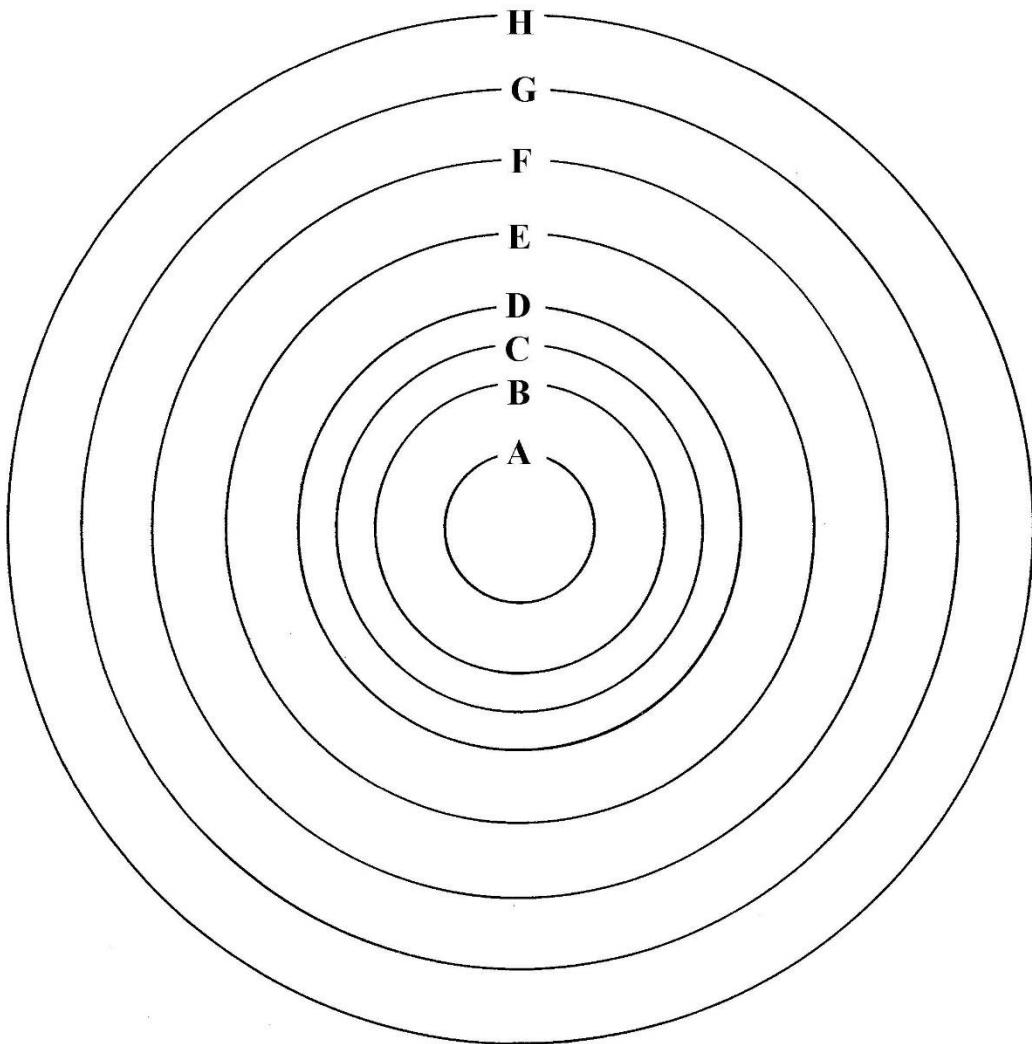
Food Amounts Booklet

**You will use this booklet
during the phone interview.**

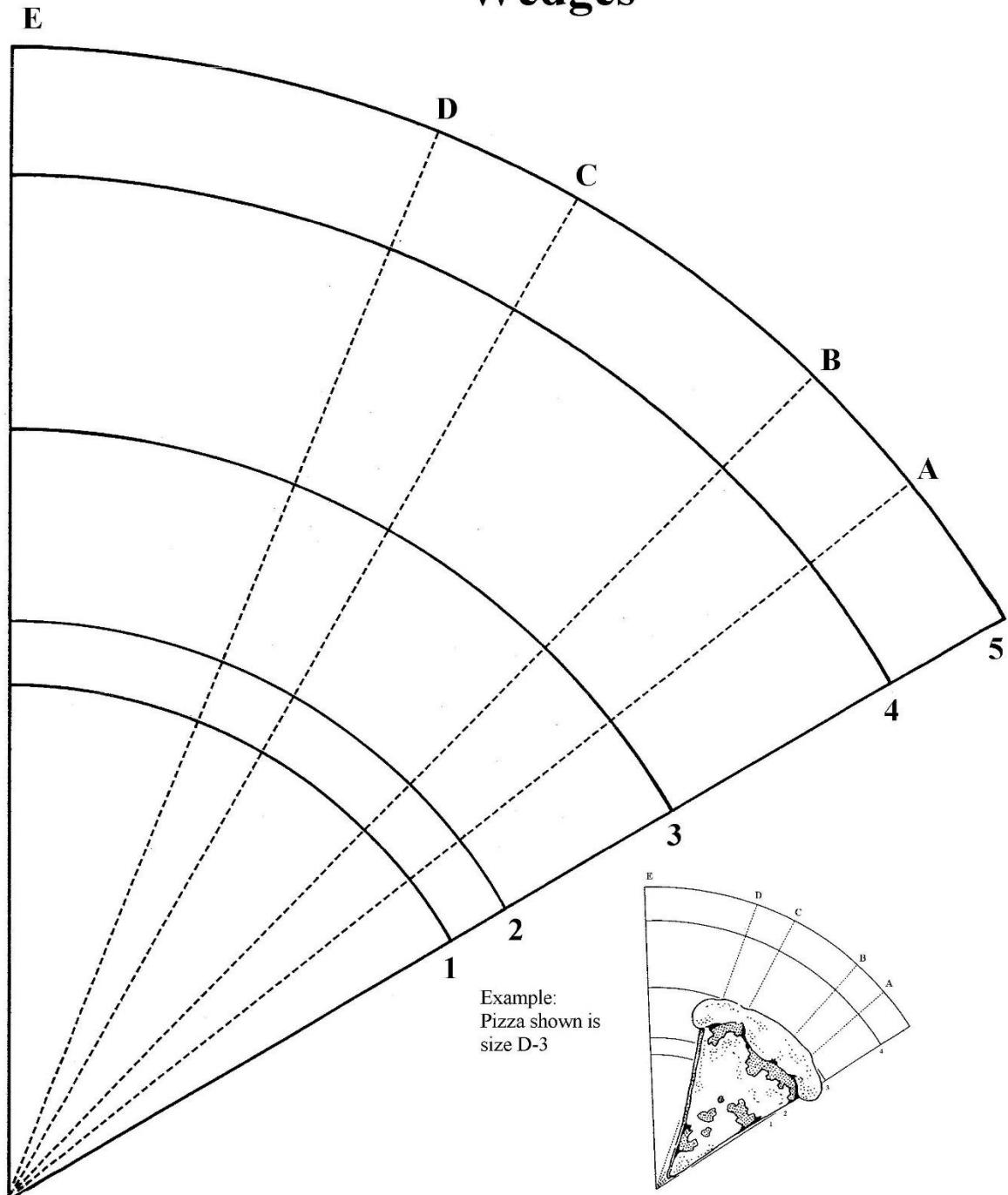
Squares and Rectangles



Circles

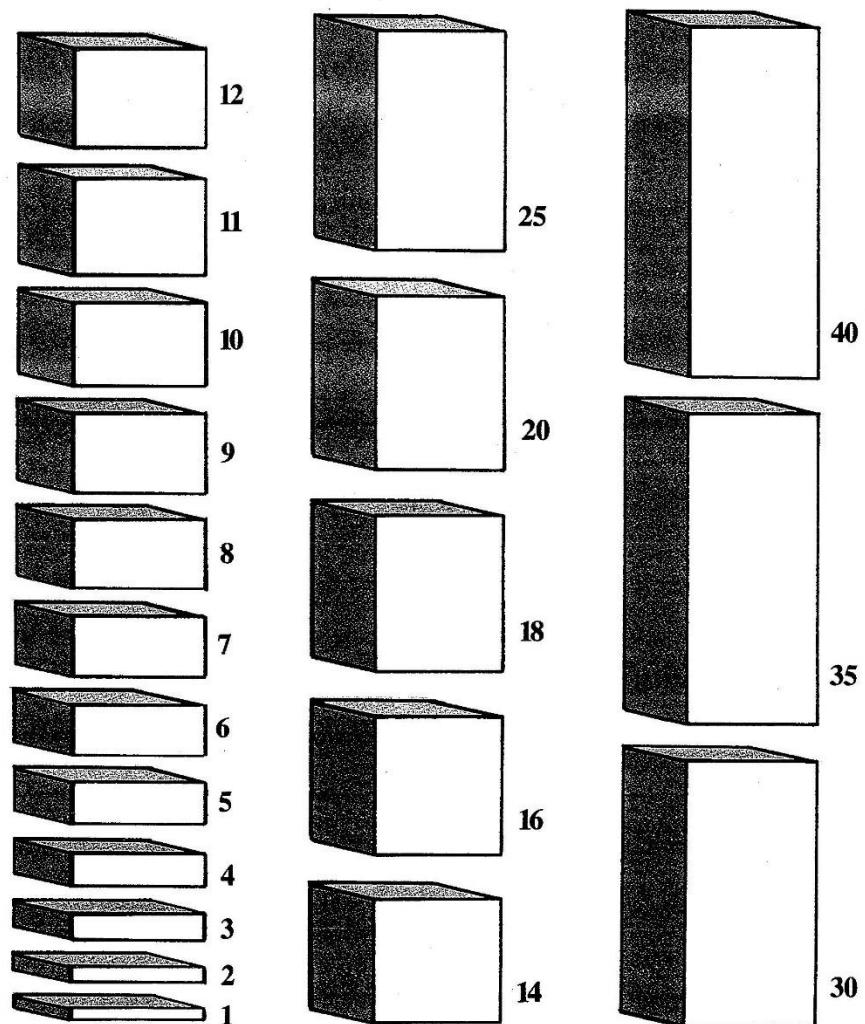


Wedges

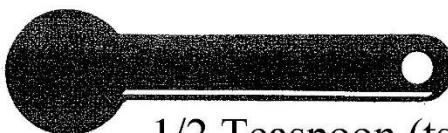


Page 3

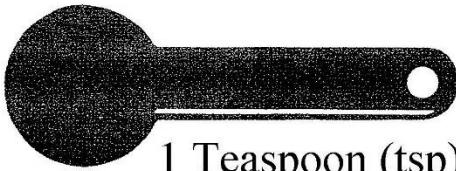
Thickness



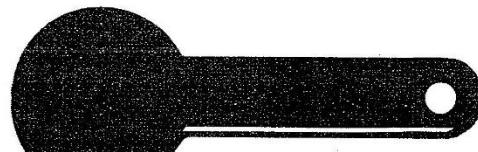
Measuring Spoons



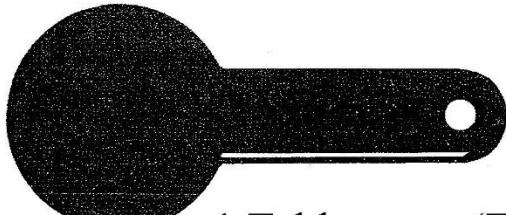
1/2 Teaspoon (tsp)



1 Teaspoon (tsp)

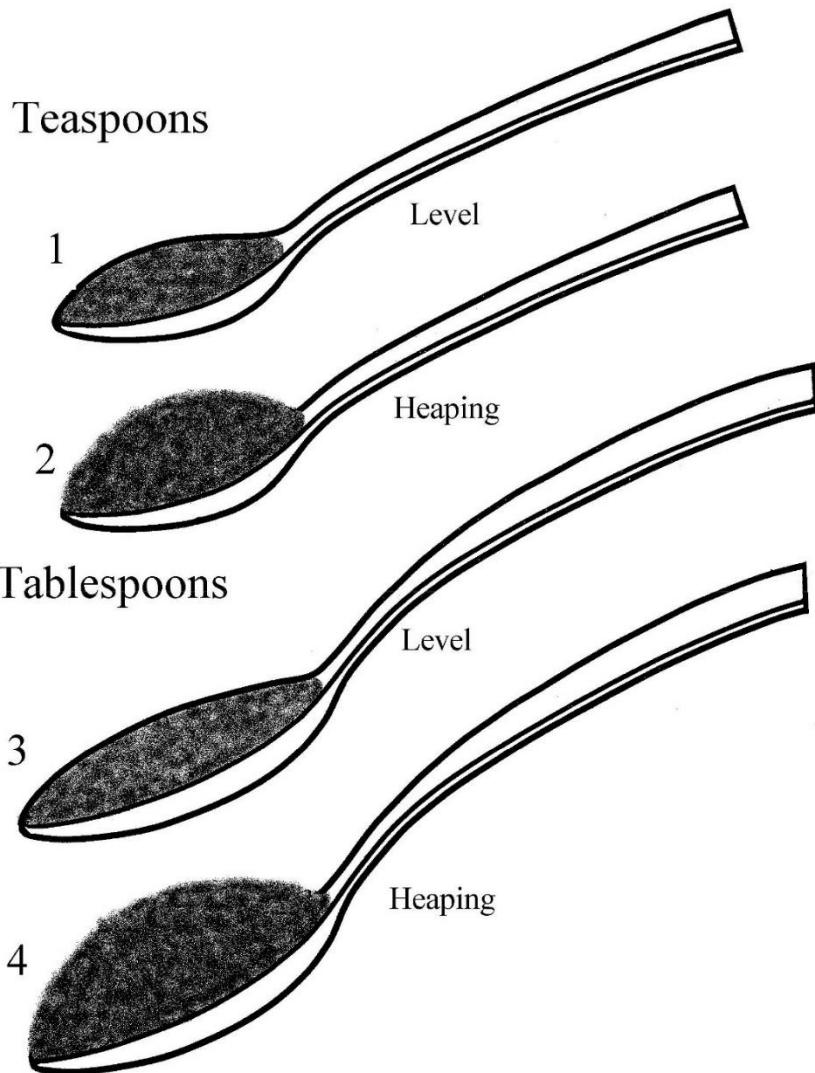


1/2 Tablespoon (Tbsp)

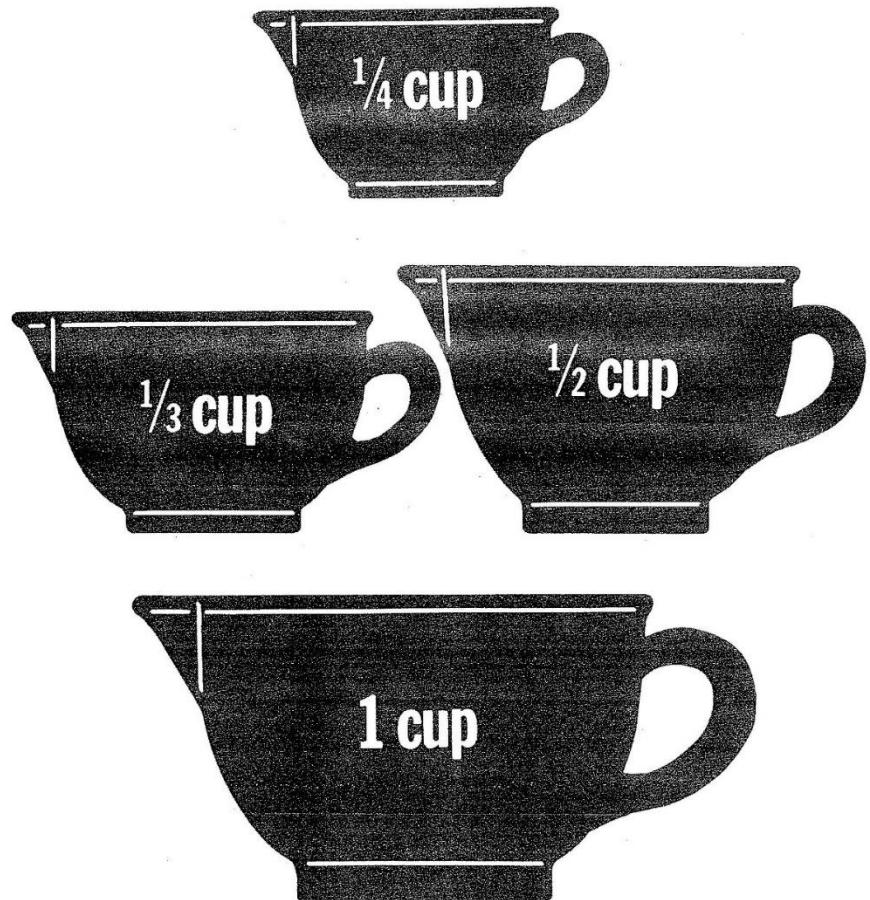


1 Tablespoon (Tbsp)

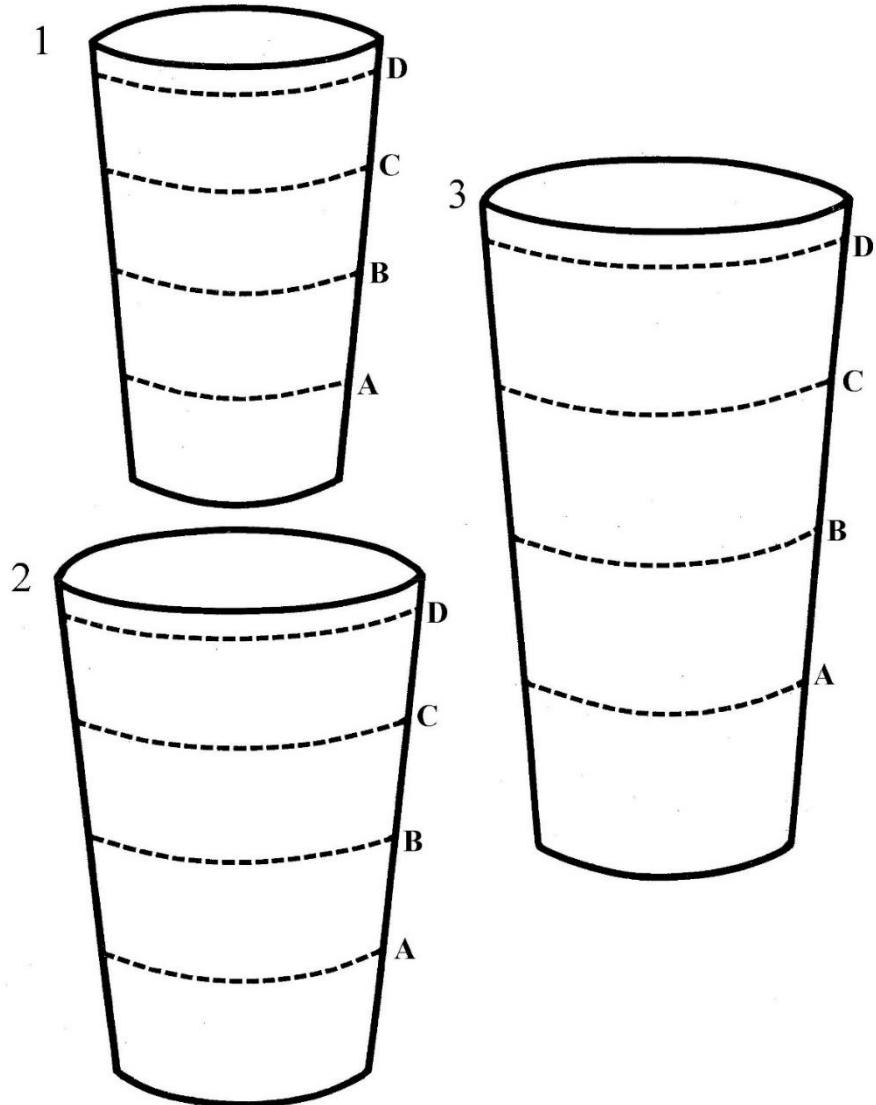
Eating and Serving Spoons



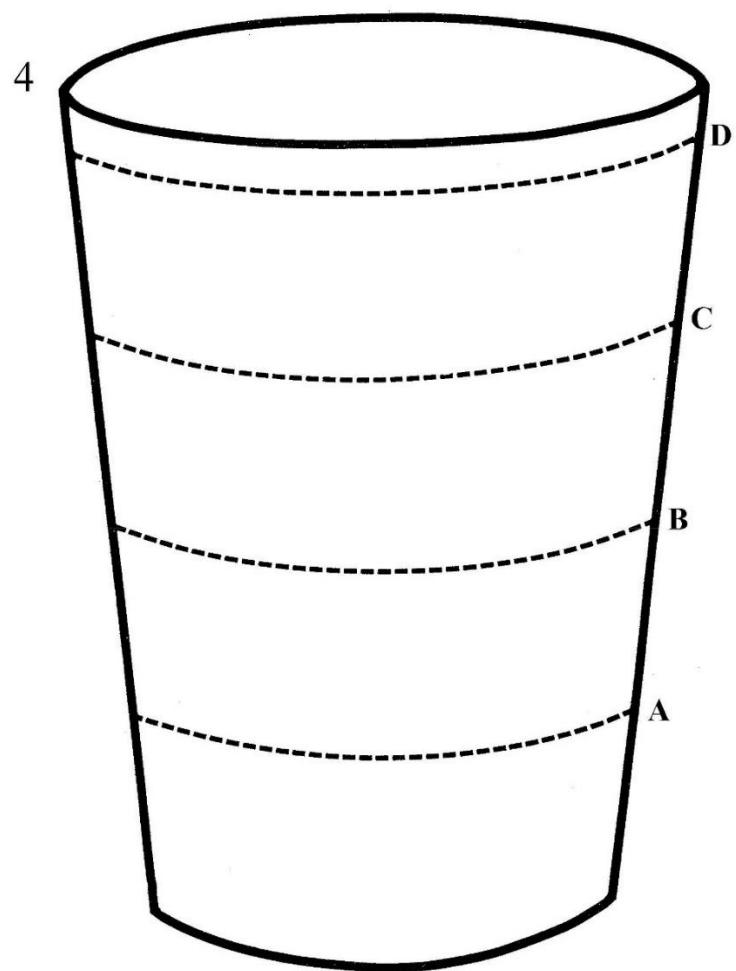
Measuring Cups



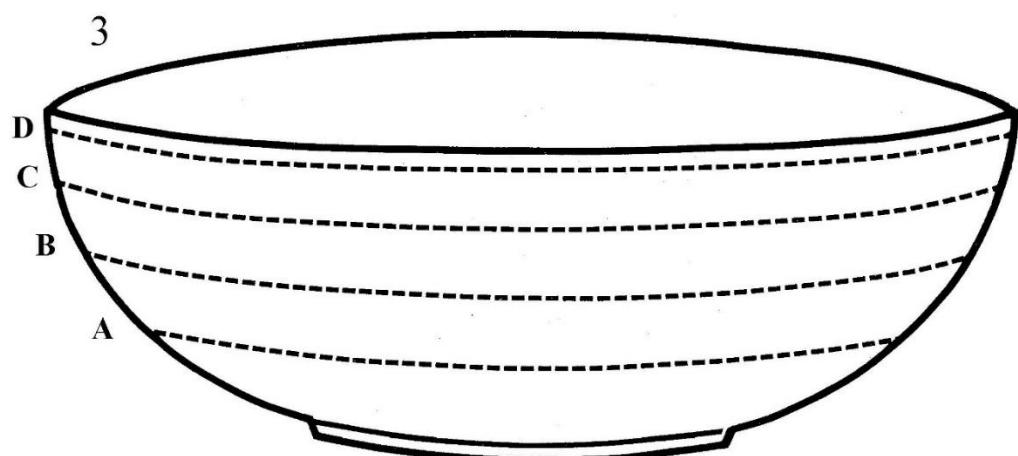
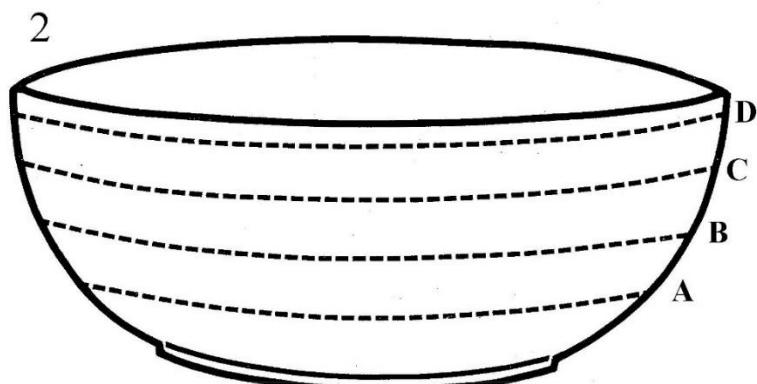
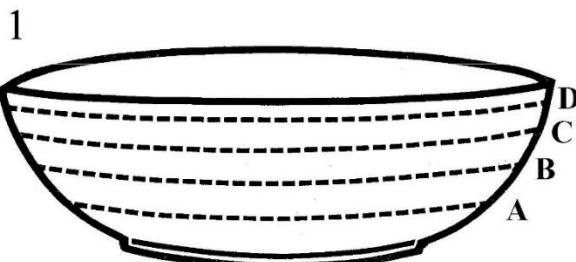
Glasses



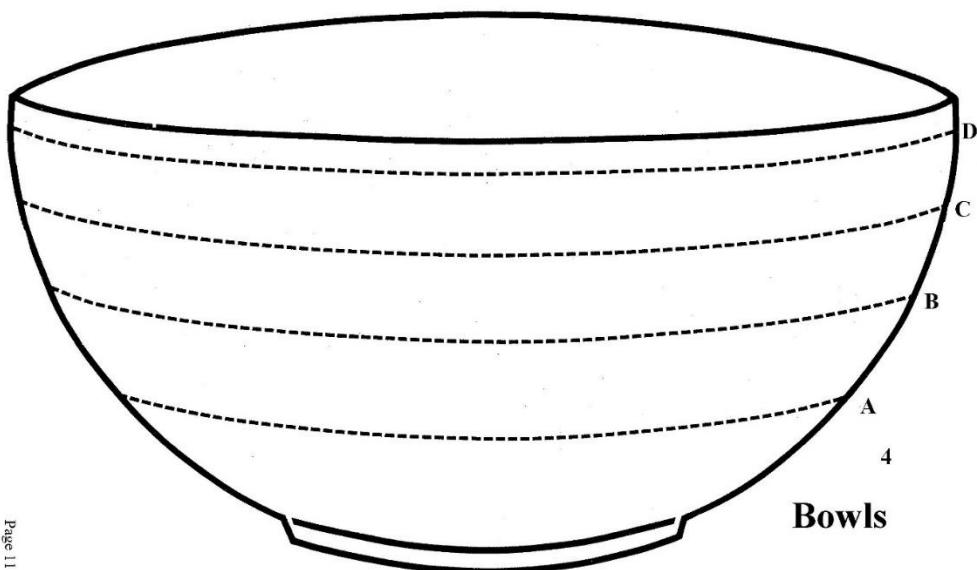
Glasses



Bowls

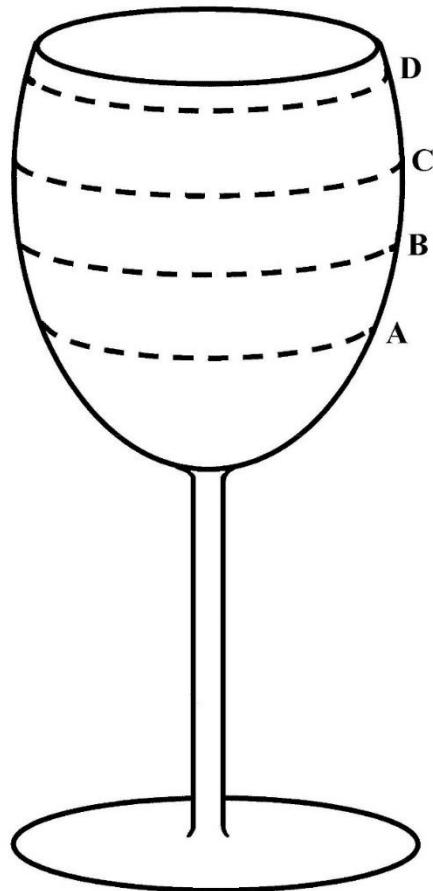


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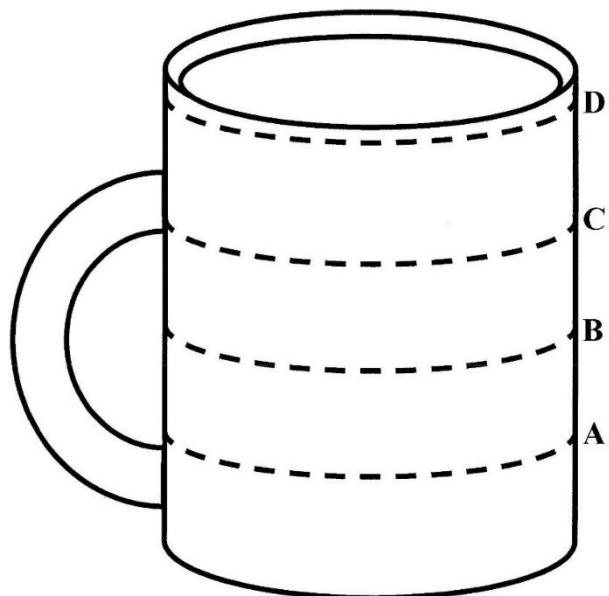


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Wine Glass

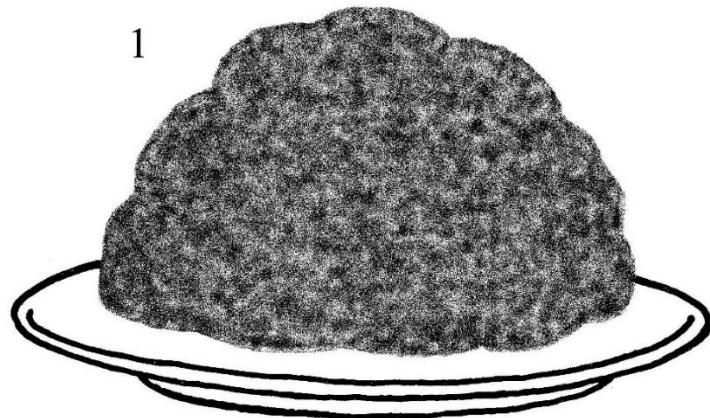


Mug

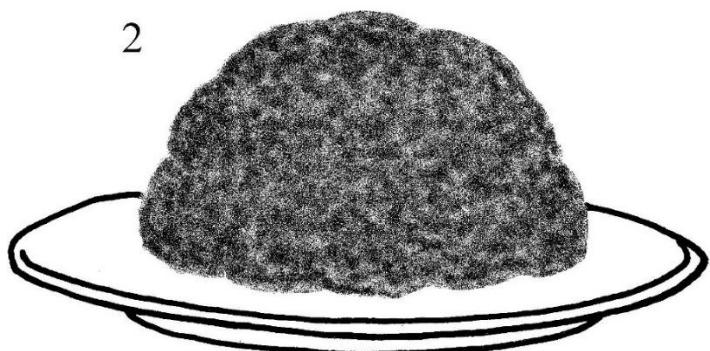


Mounds

1

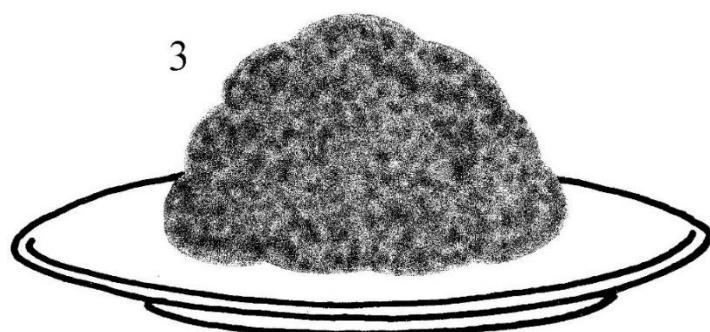


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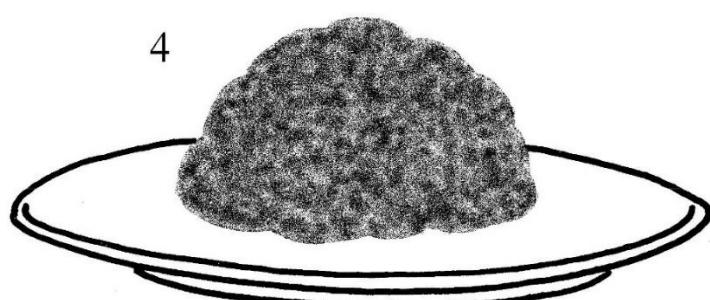


Mounds

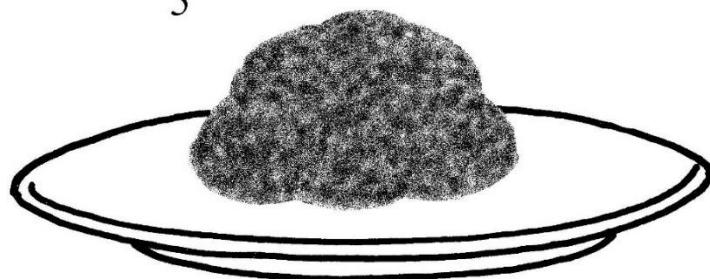
3



4

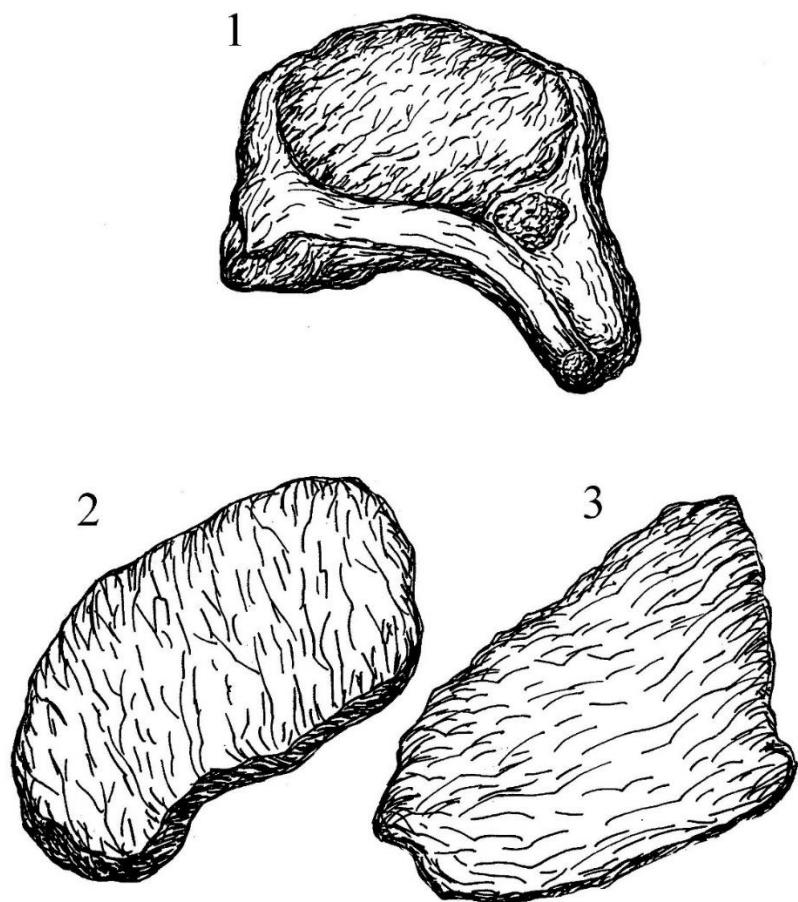


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Meats

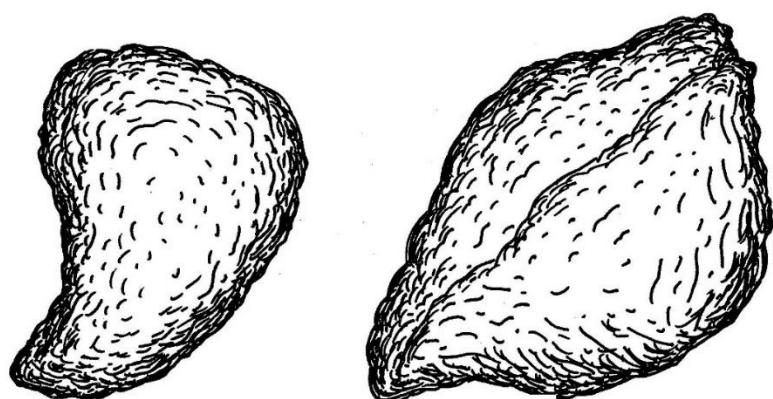


Chicken



1 Wing

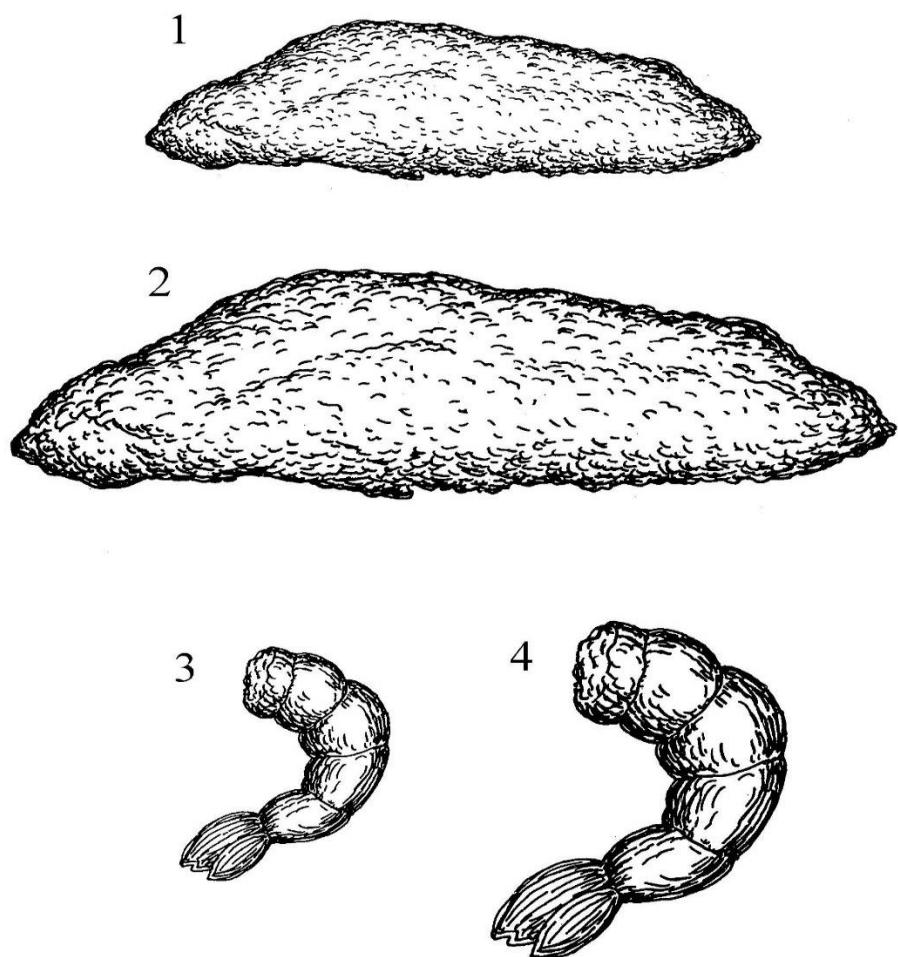
2 Drumstick



3 Thigh

4 Breast

Fish



Adapted from: Van Horn LV, Stumbo P, Moag-Stahlberg A, Obarzanek E, Hartmuller VW, Farris RP, Kimm SY, Frederick M, Snetselaar L, Liu K. The Dietary Intervention Study in Children (DISC): dietary assessment methods for 8- to 10-year-olds. J Am Diet Assoc. 1993 Dec;93(12):1396-403.
Modified by Alejandra Valencia, Mary Stevens, Nutrition Coordinating Center, University of Minnesota for the Hispanic Community Health Study, Study of Latinos, 2007.

Appendix O. Participant Welcome Letter

Dear POW-R Health Participant,

Welcome to the POW-R Health Program! A group of doctors and bladder cancer survivors have made this program to help you live a long and healthy life.

This mailing should include:

- 2 consent forms (1 for you to sign and mail back to us; 1 for you to keep)
- 1 Gender, Race, and Ethnicity Form (please mail back to us)
- 1 envelope (to place the signed consent form and the Gender, Race, and Ethnicity Form)
- 1 Food Amounts Booklet (Keep this for later)
- 1 Urine collection kit with one pre-paid FedEx urine shipping box

If you did not receive ALL of these things, please call us right away at: 716-845-1300, Ext 7221.

Please complete all of the forms that are white in color and mail them back to us. Place the signed consent form and the Gender, Race, and Ethnicity Form in the envelope. Place the envelop in the urine shipping box with your urine sample and mail together.

In about a week, someone will call you to ask you what you ate and drank for the past day. These are called dietary recalls. You will be asked to do 3 dietary recalls.

After you complete your dietary recalls, and mail in the white forms (signed consent form; the gender, race, and ethnicity form) and the urine collection kit, you will receive the program.

Thank you again for being a part of this important study. If you have any questions, please don't hesitate to contact us at: 716-845-1300, Ext 7221.

Sincerely,



Karen Yeary, PhD



Li Tang, PhD

Appendix P. Participant Health Magazine for Intervention and Control Arm

Intervention Magazine





Welcome to the POW-R Health Program

As a bladder cancer survivor, you know that taking care of your health is important. You probably go and get your bladder checked often or get other treatments to keep your bladder healthy. But did you know that among bladder cancer survivors like you, there is still a 50%-80% chance that the bladder cancer could come back within 5 years? Compared to all types of cancers, bladder cancer has the highest chance of coming back.

Most bladder cancer survivors like you are doing well and don't think about the cancer coming back. Most survivors weren't even aware that they had bladder cancer to begin. When bladder cancer is in the body, most can't tell because there are no symptoms. Most survivors didn't go through intense treatment (like chemotherapy) as other cancer survivors. Many bladder cancers are caught at early stages so intense treatment is not needed.

It is good that for many survivors, the bladder cancer didn't affect their life that much. But not having a lot of symptoms and not going through a lot of treatments may make some survivors think of bladder cancer as a lesser cancer.

2 POW-R HEALTH: Power to Redefine Your Health

RECIPES

Spicy Skillet Turnip Greens Recipe

A quick recipe for spicy skillet turnip greens for a comforting, home-cooked meal.

Yield: 6 servings

Prep Time: 5 mins

Cook Time: 20 mins

Total Time: 25 mins

INGREDIENTS

1 tablespoon olive oil

1 medium onion, cut into wedges

1 pound turnip greens, cleaned and chopped

½ cup water

Pinch brown sugar

½ teaspoon red pepper flakes, adjust to preference

INSTRUCTIONS

1. Drizzle olive oil into skillet over medium heat.
2. Add onion and cook until just tender, about 3 minutes. Then add half of turnip greens. Allow to cook down and add the remainder of the greens.
3. Add water, brown sugar and red pepper flakes. Adjust the amount of red pepper to your personal taste.

Source: adapinch.com



POW-R HEALTH: Power to Redefine Your Health

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RECIPES

Simple Arugula Salad

Yield: 4 to 6 servings

INGREDIENTS

2 tablespoons olive oil

2 tablespoons freshly squeezed lemon juice

¼ teaspoon kosher salt

Freshly ground black pepper

5 ounces arugula (about 5 packed cups)

2 ounces shaved Parmesan cheese (about 2/3 cup)

INSTRUCTIONS

Whisk the olive oil, lemon juice, salt, and a few grinds of black pepper together in a large bowl. Add the arugula and toss to combine. Top with the shaved Parmesan and serve immediately.

RECIPE NOTES

Make ahead: The dressing can be made up to 5 days ahead of time and stored in an airtight container in the refrigerator. Rewhisk again before using.

Source: theadt.com



Can I take a
vitamin pill instead
of eating power
vegetables?

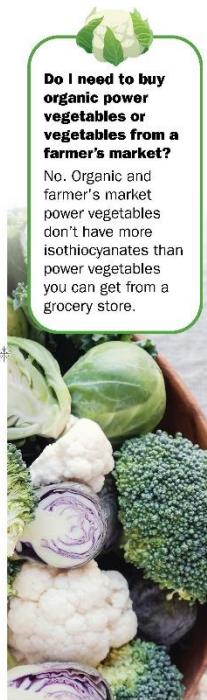
Vitamin pills don't
have the anti-cancer
isothiocyanates that
power vegetables
have. So, vitamin
pills can't replace
power vegetables.



POW-R HEALTH: Power to Redefine Your Health

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Do I need to buy organic power vegetables or vegetables from a farmer's market?

No. Organic and farmer's market power vegetables don't have more isothiocyanates than power vegetables you can get from a grocery store.

What are power vegetables?

Power vegetables are **cruciferous vegetables**: a group of vegetables where the flowers on the vegetables form the shape of a cross (in Latin, *Cruciferae* means "cross bearing"). Power vegetables include:

- Broccoli
- Turnips
- Green or white cabbage
- Brussels sprouts
- Radishes
- Arugula
- Mustard greens, and
- Other vegetables listed below

Humans have eaten power vegetables for many years. But the anti-cancer parts of power vegetables were not known until lately. Power vegetables are rich in many vitamins and minerals, such as folate, vitamins C, E, and K, and are a good source of fiber. Best for cancer survivors, power vegetables have a group of unique things called glucosinolates. Glucosinolates give power vegetables their strong smell and bitter taste. When power vegetables are cooked and eaten, glucosinolates are broken down into some active things. One of these active things is isothiocyanates. Doctors have found that isothiocyanates have strong anti-cancer actions against many types of cancer, including bladder cancer.

Why are power vegetables good at fighting bladder cancer?

When we eat power vegetables, isothiocyanates go to the bladder through the urine and build-up in the urine. Bladder cancer cells mostly form on the inside surface of the bladder and are exposed to the urine. When the isothiocyanates builds up in the urine, bladder cancer cells get soaked in isothiocyanates that are in the urine. Being exposed to isothiocyanates in the urine help kill bladder cancer cells and stop them from growing.

4 POW-R HEALTH: Power to Redefine Your Health

RECIPES

Healthy No Mayo Coleslaw

This Healthy No Mayo Coleslaw recipe is the perfect middle ground between creamy, deli-style coleslaws and tangy vinegar slaws. It features a lightened-up Greek yogurt coleslaw dressing that needs just a few simple ingredients. Even better? It only takes about 5 minutes to toss together!

Yield: 9 servings, $\frac{1}{2}$ cup each

Total Time: 30 Minutes or Less



INGREDIENTS

- ½ cup nonfat plain Greek yogurt
- 3 ½ tablespoons cider vinegar
- 3 tablespoons sugar
- 1 teaspoon kosher salt
- ½ teaspoon black pepper
- 16 ounces (about 6 ¼ cups) bagged coleslaw blend or shredded cabbage

INSTRUCTIONS

1. In a small bowl, combine Greek yogurt, vinegar, sugar, salt, and pepper, whisking until smooth and thoroughly combined.
2. Place slaw blend/cabbage in a large bowl and pour Greek yogurt dressing mixture over top. Stir to coat cabbage thoroughly.
3. Cover and refrigerate until using (preferably at least 30 minutes).

NOTES

Make-ahead tips: This coleslaw keeps well, covered in the refrigerator, and can easily be made several hours in advance. In fact, we prefer to let it sit for at least half an hour before serving, so that the cabbage softens a bit and the whole salad melds together. We find that it's at its best, though, if eaten within a day or two.

Source: twohealthykitchens.com

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RECIPES

Lemon Arugula Rigatoni Pasta Recipe

Yield: 4

Prep Time: 15 minutes

Cook Time: 10 minutes

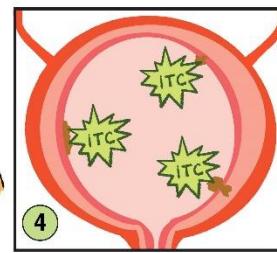
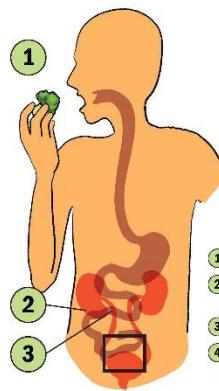
INGREDIENTS

- ¾ pound whole wheat or gluten-free rigatoni
- 4 cups baby arugula
- 15-ounce can cannellini beans
- 1 lemon (zest and juice)
- 2 tablespoons extra-virgin olive oil, divided
- 1 teaspoon kosher salt
- ¼ cup grated Pecorino (or Parmesan) cheese, plus more for serving (optional)
- Fresh ground black pepper

INSTRUCTIONS

1. Bring a large pot of salted water to a boil. Cook the pasta according to package instructions.
2. Meanwhile, drain and rinse the cannellini beans and place them in a large bowl with 4 cups arugula. Add the lemon zest and juice of the lemon to the bowl, then add 1 tablespoon olive oil, the kosher salt, and a few grinds of black pepper. Toss gently to combine all flavors.
3. When pasta is done, drain it and add immediately to the large bowl with beans and arugula. Add another 1 tablespoon olive oil and ¼ cup Pecorino cheese and stir to combine (the warm pasta will wilt the arugula and warm the beans).
4. Serve immediately, topped with additional cheese, salt, pepper, olive oil and/or lemon zest if desired.

Source: acouplecooks.com, adapted from Martha Stewart



- 1 Fresh or lightly cooked power vegetable eaten
- 2 Isothiocyanates released from power vegetable through digestion
- 3 Isothiocyanates are delivered to the bladder in urine
- 4 Isothiocyanates in urine soak bladder wall and directly affect abnormal bladder cells to stop any cancer from coming back

Science studies have shown that isothiocyanates from power vegetables have stopped bladder cancer from growing in animals. Isothiocyanates may fight bladder cancer through stopping chemicals that fuel cancer, guarding cells from DNA damage, killing cancer cells, stopping cancer from growing, boosting the immune system, stopping the tumor from making blood vessels, and stopping the tumor cells from moving.

Recent studies in bladder cancer survivors like you have shown that eating a lot of power vegetables, especially raw or fresh power vegetables, could help reduce death from bladder cancer by 57%, maybe by stopping or slowing down cancer growth and return. Other studies have found that if made right, eating 1 serving of power vegetables each day would make enough isothiocyanates in the urine to stop the growth or kill at least 50% of bladder cancer cells. So, there is proof that eating power vegetables can help stop bladder cancer from coming back.

Power vegetables are not only good at fighting bladder cancer. They have lots of fiber or roughage to keep you regular. They can help you have a healthy weight. Power vegetables can also be a part of a healthy diet, which can help keep you young and strong.

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How can you get the most anti-cancer power from power vegetables?

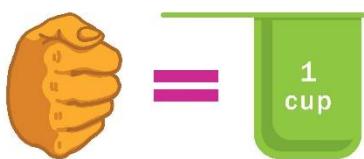
The key to getting the most anti-cancer power from power vegetables is to have enough isothiocyanates in the urine and to have the inner surface of the bladder fully soaked in the isothiocyanates as long as it can. The chart on the next page lists power vegetables that are easy to find in the grocery store along with their isothiocyanates amounts when they are fresh or raw.

What types of power vegetables should I choose?

Choose power vegetables with medium to high isothiocyanates, such as arugula, broccoli, broccoli sprouts, cabbage, mustard greens, water cress, daikon, or turnip.

How many power vegetables should I eat?

Eat at least one serving of power vegetables per day. One serving size is 1 cup at the time you eat it. So if you have a salad with arugula, it would be 1 cup raw. If you cook the arugula, it would 1 cup cooked. 1 cup is about the size of your fist.



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RECIPES

Sautéed Greens

These sautéed greens are a breeze to make on your stove top. A little chopping and a few ingredients like garlic and tamari or soy sauce are all it takes. It's a great way to eat more greens!

Servings: 2 people
Prep Time: 10 minutes
Cook Time: 10 minutes

INGREDIENTS

2 bunches Swiss chard or other greens, roughly chopped
3 cloves garlic, chopped
1 tsp. low-sodium tamari or soy sauce (or to your liking)

INSTRUCTIONS

- Water sauté the chopped garlic for a few minutes. Then add the chopped stems and a little water and sauté a few minutes. Then add the rest of the greens.
- Continue sautéing the greens, turning frequently. Add more water if it dries out.
- Add the tamari or soy sauce to your taste and continue to sauté until softened, about 10 minutes.
- Serve with whole grains such as brown rice or quinoa, adding more soy sauce as needed.

Source: plantbasedcooking.com



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RECIPES

Salatet Malfouf (Lebanese Cabbage Salad)

A simple cabbage salad made with lemon juice, olive oil, garlic, and mint.

Servings: 4
Total Time: 15 minutes

INGREDIENTS

½ medium head of cabbage, thinly sliced
1 medium clove garlic, minced
2 Tbsp. fresh lemon juice
2 Tbsp. olive oil
¼ tsp. salt
2 Tbsp. chopped fresh dried mint leaves

INSTRUCTIONS

- In a large bowl mix the garlic, lemon juice, olive oil, salt, and mint until thoroughly combined.
- Add the shredded cabbage to the bowl and toss to coat.
- Let the salad sit at room temperature for 10 minutes to allow flavors to meld or cover and refrigerate to allow the flavors to meld a little more and serve at later time. Served room temperature or cold, it's a tasty salad either way.

NOTES & TIPS

Drying out fresh mint leaves:

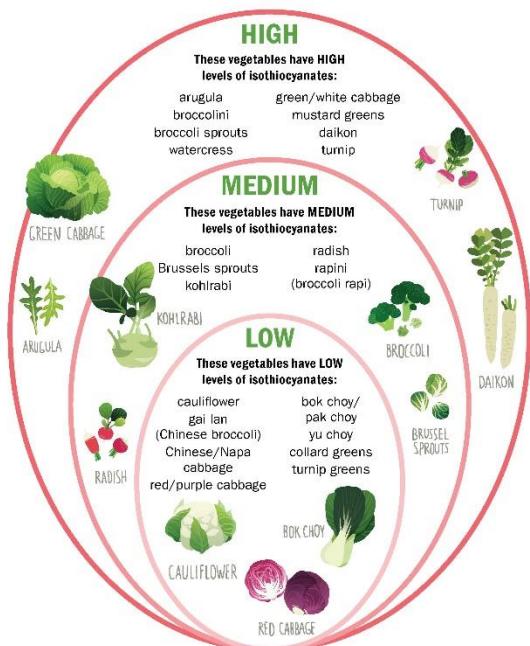
- Separate the leaves from the stems and lay on a microwave safe plate in a single layer. Cook for 10 second intervals until mint begins to curl. Should only take about 30 seconds to dry.
- Alternatively you can dry them out in your oven at the lowest possible temperature, place the leaves in the oven on a baking sheet for about 5 to 10 minutes.
- Either way you want the mint to be dry but still green.

Source: yeprecipes.com

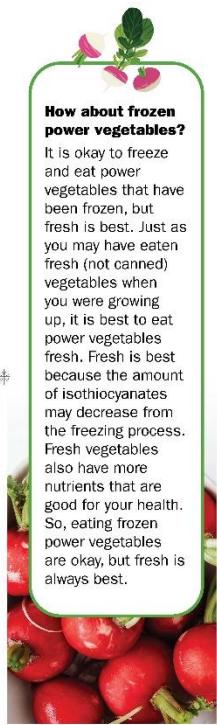


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Which power vegetables are high in ITCs?



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How about frozen power vegetables?

It is okay to freeze and eat power vegetables that have been frozen, but fresh is best. Just as you may have eaten fresh (not canned) vegetables when you were growing up, it is best to eat power vegetables fresh. Fresh is best because the amount of isothiocyanates may decrease from the freezing process. Fresh vegetables also have more nutrients that are good for your health. So, eating frozen power vegetables are okay, but fresh is always best.

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What is the best way to eat power vegetables?

It is best to eat power vegetables fresh, or raw. Just like the good old days, when most vegetables were eaten fresh, it is best to eat power vegetables fresh. They can be lightly cooked too. How you cook and how long you cook will affect how much isothiocyanates a power vegetable will give you. Cooking power vegetables too much can reduce isothiocyanates. Don't use canned power vegetables. Just like in the old days when vegetables were homegrown and not canned, stay away from canned power vegetables.

DO eat power vegetables fresh or raw, or cooked a little bit (less than 10 minutes), such as:

- stir frying
- sautéing
- microwaving
- steaming

DON'T overcook (more than 10 minutes):

- stewing
- boiling
- baking



My personal action plan to eat more power vegetables

Today's Date: _____

My reasons for wanting to eat more power vegetables

The most important reasons I _____ want to eat more power vegetables are:

My power vegetable eating goals

In 6 months, I pledge to eat _____ serving(s) of power vegetables each day. My short-term goal is to eat _____ serving(s) this week, between (dates) _____ and _____.

Who can help me

This person can help me eat more power vegetables:

Obstacles and strategies

The obstacles that may make it harder for me to reach my goals and the strategies I can use to overcome them are:

Obstacles	Strategies
Obstacle 1	Strategy 1
	Strategy 2
	Strategy 3
Obstacle 2	Strategy 1
	Strategy 2
	Strategy 3

My plan this week to eat more power vegetables

The next time I go to the grocery store, I will buy these power vegetables with medium or high isothiocyanates:

The next time I plan to eat power vegetables, I will make them this way:

<input type="checkbox"/> Raw	<input type="checkbox"/> Sauté	<input type="checkbox"/> Steam
<input type="checkbox"/> Microwave	<input type="checkbox"/> Stir-fry	



When is the best time of day to eat power vegetables?

Eat power vegetables at dinner time or as a late-night snack before bed. When you eat power vegetables, the isothiocyanates from the power vegetables can get in the urine within 1 hour and slowly build up in the urine over 8 hours. If you eat power vegetables during the day, the isothiocyanates could be quickly passed out of the body from peeing a lot throughout the day. If you eat power vegetables at dinner time or as a late-night snack, your body will be able to build up the isothiocyanates in your bladder. Although you may pee a few times before you go to bed, a fair amount of the isothiocyanates can still build up in the urine and increase the time the inside of the bladder is soaked in isothiocyanates.

Is coleslaw a power vegetable?

Yes. Coleslaw is made of raw cabbage. Make sure you choose healthier coleslaw that is lower in fat, calories, and sodium. Please see our coleslaw recipe on page 17.

Is sauerkraut a power vegetable?

No. Sauerkraut is fermented cabbage with very little isothiocyanates.



Tips on how to eat more power vegetables

To get the most out of power vegetables' anti-cancer effects, it's best to eat power vegetables every day. Eating power vegetables every day can be hard, above all if you don't like vegetables. You may not like the taste, texture, or how power vegetables look. But it is vital to try. It is okay to slowly start adding more power vegetables to your diet. Eating better can also be hard because of the food ads of less healthy foods on TV. These ads are made by those who don't care about your health. You can work towards making your diet better by having more power vegetables without giving up the foods you love. If some of the foods you love are less healthy, you can still eat them a little bit AND eat more power vegetables at the same time. Ask your spouse, partner, or other people to help you.

- Make power vegetables in different ways. Cut them up in small pieces and put them in soup or pasta.
- Blend power vegetables up with fruit to make a smoothie.
- Keep power vegetables in your fridge where you can easily see them.
- Try out the recipes in this **POW-R Health magazine** (see page 13). These are recipes were chosen by doctors because they include power vegetables with high isothiocyanates and are easy to make.
- Ask your spouse, partner, or someone else to make meals with power vegetables for you. Ask them to help you eat more power vegetables.



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- Add a little sauce and/or seasonings to power vegetables to make them taste better.
- Store power vegetables in the crisper section of your fridge to make them last longer.
- Get power vegetables from the frozen foods section in the grocery store and store at home for easy access (for example, frozen broccoli)
- Buy already washed and cut power vegetables to eat as a snack (for example, broccoli or cauliflower)
- Make healthy eating a family and friends affair! The more support and help that you get from loved ones can make eating better simpler and more fun. Let people close to you know about your power vegetable eating goals and why you are making the change. Ask them to join you and show support. They can bring power vegetables over to you.

Do you have questions?

In about a week, someone from the POW-R Health Team will call you to go over this magazine, answer any questions you have, and work with you to fill out your action plan (please see action plan on next page). They will also show you how to use the POW-R Health Book. Please have your copy of the magazine handy for when we call!

After talking with one of our POW-R Health Team members, you will then receive automated phone calls from the POW-R Health program. POW-R Health phone calls will show up on your phone with the phone number 716-333-7697 (POWR), so please accept phone calls from this number. This phone number is on the POW-R Health fridge magnet, and on the POW-R Health Book.

If you have any questions,
please call 716-845-1300, Ext 7221.

If you need to access the POW-R automated phone system,
call 716-333-7697 (POWR).



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If you have any questions,
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If you need to access the POW-R automated phone system,
call 716-333-7697 (POWR).

**POW-R
HEALTH**

Power to Redefine Your Health

INSIDE: Learn about the Health Powers of Fruits and Vegetables - Easy, Delicious Recipes



Welcome to the POW-R Health Program

You probably already know that eating fruits and vegetables is an important part of eating healthy and staying healthy. Eating fruits and vegetables may have come easier to you because you grew up with fresh fruit and vegetables at the kitchen table. You may already be eating a lot of fruits and vegetables to stay young and strong, especially since your diagnosis.

Most bladder cancer survivors like you are doing well. Most survivors weren't even aware that they had bladder cancer to begin. When bladder cancer is in the body, most can't tell because there are no symptoms. Most survivors didn't go through intense treatment (like chemotherapy) as other cancer survivors. Many bladder cancers are caught at early stages so intense treatment is not needed. Not having a lot of symptoms and not going through a lot of treatments may make some survivors think of bladder cancer as a lesser cancer. The truth is that bladder cancer is a dangerous disease. No matter what your personal experience with bladder cancer is, living a healthy lifestyle is very important to all cancer survivors.

Apples and Peanut Butter (Apple Slices)

Yield: 1 serving

INGREDIENTS

1 firm eating apple (I like Gala the best)
2-4 tablespoons peanut butter (crunchy or creamy)

INSTRUCTIONS

1. Core and slice apple into wedges.
2. Divide the peanut butter evenly among the slices. I usually spread mine along the inner edge.

Source: food.com





Avocado Fruit Salad

Yield: 6 servings
Total Time: 20 minutes

INGREDIENTS

- ½ cup plain yogurt
- 2 tablespoons honey
- 1 teaspoon grated lemon zest
- 1 teaspoon plus 2 tablespoons lemon juice, divided
- 3 medium ripe avocados, peeled and cubed
- 1 medium apple, chopped
- 1 cup halved seedless grapes
- 1 can (11 ounces) mandarin oranges, drained
- 1 medium firm banana, cut into ¼-inch slices

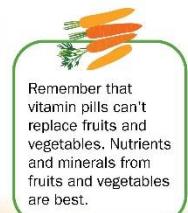
INSTRUCTIONS

For dressing, mix yogurt, honey, lemon zest and 1 teaspoon lemon juice. Toss avocados with remaining lemon juice.

In a large bowl, combine remaining ingredients; gently stir in avocados. Serve with dressing.

Source: tasteofhome.com

That's why a group of medical professionals, including doctors, nurses, scientists, and nutritionists, have made the POW-R Health Program. We want to make sure you live the longest, healthiest life possible. We are here to support you. Share these materials with your spouse, partner, friends, family and others to support you too.



What are fruits and vegetables?

Fruit and vegetables are plants that have lots of minerals, vitamins, and other healthy things that are good for the human body. A fruit develops from the flower of a plant, while the other parts of the plant are known as vegetables. Fruits have seeds, while vegetables can have roots, stems and leaves.

Some common fruits are:

- Apples and pears
- Citrus – oranges, grapefruits, mandarins and limes
- Stone fruit – nectarines, apricots, peaches and plums
- Tropical and exotic – bananas and mangos
- Berries – strawberries, raspberries, blueberries, kiwi, and passionfruit
- Melons – watermelons and honeydew
- Tomatoes and avocados

Some common vegetable types are:

- Leafy green – lettuce and spinach
- Cruciferous – cabbage, cauliflower, Brussels sprouts and broccoli
- Marrow – pumpkin, cucumber, and zucchini
- Root – potato, sweet potato and yam
- Edible plant stem – celery and asparagus
- Allium – onion, garlic, and shallot



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How are fruits and vegetables good for you?



Having a healthy diet full of fruits and vegetables is very important. Research has shown that eating fruits and vegetables can help you live longer. Eating fruits and vegetables reduces the risk of getting some cancers, high blood pressure (hypertension), heart disease, and diabetes. A recent study said that eating about 2 cups (200 g) of fruits and vegetables each day can reduce the risk of heart disease by up to 16%, stroke by 18%, and cancer by 4%. Cancer survivors who eat at least 5 servings of fruits and vegetables report better overall well-being.

Fruits and vegetables have all of these great health benefits because they have a lot of vitamins C and A, electrolytes, and antioxidants. Vitamin C protects the immune system and protects the body from harmful effects of pollutants and toxins. Vitamin C protects cells and molecules from damage that causes many diseases, including cancer. Fruits and vegetables are also a great source of fiber. The fiber in fruits and vegetables lowers cholesterol, which reduces heart disease risk. The fiber in fruits and vegetables can also help control the body's blood sugar, which reduces risk of diabetes. Fruits and vegetables can also help you have a healthy weight by giving you lots of fiber and water, which can fill you up without giving too many calories.

How can you get the best health benefits from eating fruits and vegetables?

What kinds of fruits and vegetables should I eat?

VEGETABLES

- Fresh, frozen, and canned vegetables can all be a part of healthy eating.
- **Fresh** vegetables are best! Fresh vegetables usually give your body the most nutrients. Try to eat as many different types of vegetables as you can.
- **Frozen** vegetables have the same amount of nutrients as fresh vegetables and can be cheaper to buy. If you buy frozen vegetables, look for types that don't have added butter, sauces, or cheese. These will have added calories and fat that can make it harder to have a healthy diet.
- **Canned** vegetables can be high in salt, so if you buy canned vegetables make sure you look for the 'no salt' ones.

Baked Parmesan Zucchini

Crisp, tender Parmesan zucchini sticks oven-roasted to absolute perfection. It's healthy, nutritious and completely addictive!

Yield: 4 servings
Prep Time: 10 Minutes
Cook Time: 20 Minutes

INGREDIENTS

- 4 zucchini, quartered lengthwise
- ½ cup freshly grated Parmesan
- ½ teaspoon dried thyme
- ½ teaspoon dried oregano
- ½ teaspoon dried basil
- ¼ teaspoon garlic powder
- Kosher salt and freshly ground black pepper, to taste
- 2 tablespoons olive oil
- 2 tablespoons chopped fresh parsley leaves

INSTRUCTIONS

1. Preheat oven to 350 degrees F. Coat a cooling rack with nonstick spray and place on a baking sheet; set aside.
2. In a small bowl, combine Parmesan, thyme, oregano, basil, garlic powder, salt and pepper, to taste.
3. Place zucchini onto prepared baking sheet. Drizzle with olive oil and sprinkle with Parmesan mixture. Place into oven and bake until tender, about 15 minutes. Then broil for 2-3 minutes, or until crisp and golden brown.
4. Serve immediately, garnished with parsley, if desired.

Source: damdelicious.net



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Butter Parmesan Corn

Total Time: Under 30 minutes

INGREDIENTS

- 6 half ears corn, cleaned, husked
- 2 tablespoons butter, softened
- 1/2 cup Parmesan cheese, grated
- Salt, to taste
- Pepper, to taste

INSTRUCTIONS

1. Preheat oven to 375°F (190°C).
2. Coat each ear of corn in a thin layer of butter and roll in the parmesan cheese to coat.
3. Place corn in a square baking dish and sprinkle with salt and pepper.
4. Bake for 25 minutes.
5. Enjoy!

Source: tasty.co

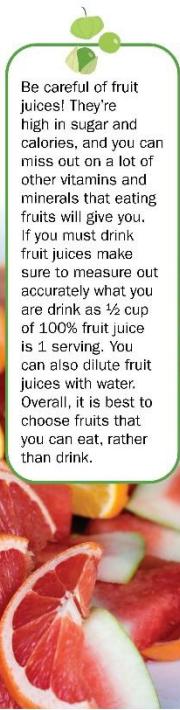
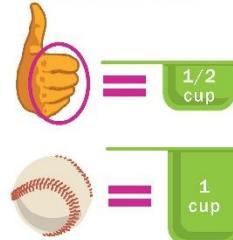
FRUIT

- Fresh, frozen, and canned fruit can all be a part of healthy eating.
- **Fresh** fruit is best! Fresh fruit usually gives your body the most nutrients. Try to eat as many different types of fruit as you can.
- **Frozen** fruit can last longer than fresh fruit and can be cheaper to buy.
- **Canned** fruit can be high in sugar and calories, so buy canned fruit in 100% fruit juice with no sugar added.

How many fruits and vegetables are you supposed to eat?

- Eat **2 1/2 to 3 cups of vegetables** and **1 1/2 to 2 cups of fruit** each day. 1/2 cup is about the size of the front part of your fist. 1 cup is about the size of a baseball.

SERVING SIZES



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How to prepare fruits and vegetables

You can eat a lot of fruits and vegetables raw. You can also cook them in many different ways:

- sautéeing
- microwaving
- steaming
- baking
- stir-frying
- stewing
- boiling



Tips on how to eat more fruits and vegetables

You can buy fruits and vegetables from many different places. You can buy them from your local grocery store, farmer's market, and online. Here are some tips on how to eat more fruits and vegetables:

- Have a healthy morning. Add sliced fruit, like a sliced banana, to your cereal for breakfast.

Source: simplyrecipes.com

Cucumber Salad with Grapes and Almonds

Cucumber salad with grapes, toasted almonds and a little garlic—essentially a deconstructed white gazpacho! Perfectly balanced, cool and refreshing summer salad.

Servings: 4 people

Prep Time: 30 minutes

Cook Time: 5 minutes

INGREDIENTS

- 1/4 cup slivered and blanched almonds
- 1 pound cucumbers, peeled if the peel is bitter, unpeeled if not
- Kosher salt
- 1 teaspoon minced garlic
- About 20 green grapes, sliced in half
- 2 tablespoons extra-virgin olive oil
- 1 teaspoon sherry or white wine vinegar
- 2 teaspoons minced chives, for garnish

INSTRUCTIONS

1. Prep the cucumbers: Slice the cucumbers in half lengthwise. Use a spoon to scoop out the seeds in the middle, discard the seeds. If using rather large cucumbers, slice them again lengthwise. Then cut them crosswise into 1/4-inch to 1/2-inch slices.
- Place in a large bowl and sprinkle with a teaspoon of kosher salt. Toss to distribute the salt evenly around the cucumber pieces.
- Let sit for 20 to 25 minutes while the salt helps pull excess moisture out of the cucumbers.
2. Toast the slivered almonds in a small pan over medium-high heat, tossing them often, until they start to brown and smell good. Move to a bowl to cool.
3. Combine: Mix the cucumbers, almonds, garlic, grapes, olive oil, and vinegar together in a large bowl and add more salt to taste. Garnish with chives and serve.

Source: simplyrecipes.com

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Tangy Carrot Slaw

Servings: 6 as a side dish

INGREDIENTS

1/4 cup Dijon mustard
1/4 cup olive oil
3 tablespoons red wine vinegar or freshly squeezed lemon juice
1 teaspoon kosher salt
Freshly ground black pepper
2 pounds carrots, peeled and shredded (about 6 cups)
1/4 cup thinly sliced scallion

INSTRUCTIONS

1. Place the mustard, oil, vinegar or lemon juice, salt, and a few generous grinds of pepper in a large bowl and whisk to combine. Add the carrots and scallions and toss well to evenly coat.
2. Cover and refrigerate for at least 30 minutes or overnight to allow the flavors to meld. Taste and season with more salt and pepper as needed before serving.

STORAGE

Leftovers can be stored in an airtight container in the refrigerator for up to 3 days.

Source: thekitchn.com

- Bag it! Toss an apple, banana or other fruit in your bagged lunch.
- Put pizza in your soup. Add some grated carrots or canned or frozen vegetables in a soup, casserole, or other main dish.
- Save time cooking! Buy canned or frozen vegetables to have easy access to vegetables for meals.
- Toss it! Have more tossed salads with a lot of different vegetables and low-fat dressing.
- Don't have time? Drink 100% vegetable juices.
- Make them last. Store fruits and vegetables in the crisper in your refrigerator to make them last longer. Freeze fruits and vegetables to keep them from spoiling.
- Save money! Buy in-season fruits and vegetables, or buy less expensive fruits and vegetables like apples, oranges, bananas, carrots, and green beans.
- Add chopped up vegetables to your eggs or potatoes. Try onions, celery, green or red bell peppers, or spinach.
- Put vegetables in your sandwich, like cucumber, sprouts, tomato, lettuce or avocado.
- Have a piece of fruit or raw vegetables handy, such as green or red bell peppers, green beans, celery or carrots.
- Carry dried fruit, such as raisins, dates or dried apricots, in your pocket or purse.
- On hot days, munch on a bowl of frozen fruits or vegetables, such as grapes, peas or bananas.
- Add a side of steamed or microwaved vegetables – frozen veggies are fine!
- When making rice, add some frozen peas for the last three minutes of cooking.
- If you don't like how some fruits or vegetables taste, look, or feel, try cooking or seasoning them in different ways. You will most likely find a new way to enjoy them! Be creative!



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- Don't give up your favorite foods. You can still eat your favorite foods in moderation, while still eating more fruits and vegetables.
- TV and media advertise a lot of less healthy food choices. If you find yourself being tempted to eat foods that are less healthy, think of ways to make those foods healthier by adding vegetables or enjoying a smaller portion size.

Do you have questions?

In about a week, someone from the POW-R Health Team will call you to go over this magazine, answer any questions you have, and work with you to fill out your action plan (please see action plan on next page). They will also show you how to use the POW-R Health Book. Please have your copy of the magazine handy for when we call!



After talking with one of our POW-R Health Team members, you will then receive automated phone calls from the POW-R Health program. POW-R Health phone calls will show up on your phone with the phone number 716-333-7697 (POWR), so please accept phone calls from this number. This phone number is on the POW-R Health fridge magnet, and on the POW-R Health Book.

If you have any questions, please call 716-845-1300, Ext 7221.

If you need to access the POW-R automated phone system, call 716-333-7697 (POWR).

My personal action plan to eat more fruits and vegetables

Today's Date: _____

My reasons for wanting to eat more fruits and vegetables

The most important reasons I _____, want to eat more fruits and vegetables are:

My fruit eating goals

In 6 months, I pledge to eat _____ cups of fruit each day.
My short-term goal is to eat _____ cups of fruit this week, between (dates) _____ and _____

My vegetable eating goals

In 6 months, I pledge to eat _____ cups of vegetables each day.
My short-term goal is to eat _____ cups of vegetables this week, between (dates) _____ and _____

Who can help me

This person can help me eat more fruits and vegetables:

Obstacles and strategies

The obstacles that may make it harder for me to reach my goals and the strategies I can use to overcome them are:

Obstacles	Strategies
Obstacle 1	Strategy 1
	Strategy 2
	Strategy 3
Obstacle 2	Strategy 1
	Strategy 2
	Strategy 3

My plan this week to eat more fruits and vegetables

The next time I go to the grocery store, I will buy these fruits and vegetables:

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POW-R HEALTH: Power to Redefine Your Health

Appendix Q. Live Call Scripts (Intervention and Control)

Intervention

Participant ID: _____ Staff Initials: _____ Date: _____

Start Time: _____ End Time: _____ Treatment Control

Materials that should have been sent to participant

Cover Letter/Welcome Letter

POW-R Health Magazine

POW-R Track Book (24 copies)

Refrigerator Magnet

PART A: Getting participant on the phone, call intro, packet receipt

Note: Only make three attempts to reach the participant

Phone Answered

Hello, this is [staff name] from the POW-R Health program calling for [participant name], she/he is expecting my call. Is [participant name] home/available right now?

Yes

Hi [participant name] I'm calling to review the POW-R Health program materials with you. It should take about 60 minutes; do you have time to complete it right now?

No

That's okay, can we schedule a time that would work better for you? Thanks, I will give you a call then.

Time to call back

Leaving Message

1st Attempt

This is [staff name] from the POW-R Health program calling for [participant name]. I'm calling to review the POW-R Health program materials with you, which should take about 60 minutes. I'll try calling you again, but if you would like to call me back and let me know a good time for us to chat, I can be reached at 716-697-4615/716-720-2308. Thanks, and I hope I catch up with you soon!

2nd Attempt

Hello again, this is [staff name] from the POW-R Health program calling for [participant name]. I left a message with you on _____ [date] and I am calling you back to review the POW-R Health program materials with you, which should take about 60 minutes. I'll try calling you one more time, but if you would like to call me back and let me know a good time for us to chat, I can be reached at 716-697-4615/716-720-2308. Thanks, and I hope I catch up with you soon!

3rd Attempt

Hello again, this is [staff name] from the POW-R Health program calling for [participant name]. I left a message with you on _____ [date], and I am calling you back to review the POW-R Health program materials with you, which should take about 60 minutes. If you would like to call me back and let me know a good time for us to chat, I can be reached at 716-697-4615/716-720-2308. Thanks, and I hope I catch up with you soon!

Confirm Intervention Packet Receipt

We are glad you are a part of the program. We put a program packet in the mail for you about the POW-R Health Program. The packet should have included a magazine, booklets, and a magnet.

A1. Did you receive the program packet in the mail?

If YES: (Go to Question A2)

If NO: It's really important that you have your packet before we go over it. Let me make a note to send you the packet again. What is your mailing address? I'll call you again after your packet is sent. Thank you for taking the time to talk with me. I'll talk to you again soon.

END CALL.

A2. If so, did you have time to review the information in this packet?

No Yes

Mailing Address

No Yes

If YES: Okay great, I'm glad you got a chance to review the material. Just to make sure that the magazine clearly conveyed the information, I will now ask you some questions to go over the main points of the magazine. We will then work together to create your personal action plan to eat more power vegetables. Before we begin, please pull out the packet we sent. It would really help to have them with you for the later part of the call. Please have a pen handy too (Go to PART D).

If NO: That is okay. We can still go over what is in the packet right now. Before we begin, please pull out the packet we sent. It would really help to have them with you for the later part of the call. Please have a pen handy too. (Go to PART B)

PART B: OVERVIEW

I'm going to begin by going over the POW-R Magazine. After I go over the magazine's contents, we'll complete your personal action plan (page 12). I'll then go over the POW-R Books and the magnet. So, let's start with the POW-R Magazine. Please have your POW-R Magazine next to you so you can follow along what I'm going to review.

PART C: MAGAZINE CONTENT

Welcome to the POW-R Health Program (page 2)

- Among bladder cancer survivors like you, there is still a 50%-80% chance that the bladder cancer could come back within 5 years
- Compared to all types of cancers, bladder cancer has the highest chance of coming back
- If the cancer comes back and is not caught at early stages, there is a risk of losing the bladder
- Going to your routine check-ups with doctors is good to catch bladder cancer coming back at early stages. But they are not enough.
- Doctors made the **POW-R Health Program** to make sure you live the longest, healthiest life possible
- Certain vegetables that can help stop bladder cancer from coming back. These vegetables are called power vegetables
- Power vegetables help reduce death from bladder cancer by 57%

Interesting convo points

What are Power Vegetables? (page 4)

- Power vegetables are cruciferous vegetables
- Examples of power vegetables are Broccoli, Turnip, Cabbage, and Arugula
- When power vegetables are eaten, they break down into active things. One of these active things is isothiocyanates (eye-so-thye-oh-sigh-nates) or ITCs.
- ITCs have strong anti-cancer actions against many types of cancer, including bladder cancer.
- Do you have any questions about what I've covered so far?

Interesting convo points

How are Power Vegetables Good at Fighting Bladder Cancer? (pages 4 and 5)

- (Refer participant to picture in magazine on page 5)
- (Go through Steps 1-4 of the picture)
- There is proof that eating power vegetables can help stop bladder cancer from coming back

How Can You Get the Most Anti-Cancer Power From Power Vegetables

- The key to getting the most anti-cancer power from power vegetables is to have enough ITCs in the urine and to have the bladder inner surface fully soaked in the isothiocyanates as long as it can.
- Choose power vegetables that are high or medium in ITCs (look at page 7 in magazine for medium and high ITC power vegetables)
- Eat at least one serving of power vegetables per day. One serving size is 1 cup of power vegetables at the time you eat it. So if you eat one cup of arugula raw, that would be 1 cup raw. If you eat arugula cooked, that would be 1 cup of cooked arugula. One cup is about the size of your fist.
- It is best to eat power vegetables fresh, or raw. They can be lightly cooked too, for no more than 10 minutes. If you cook power vegetables too much it will reduce their anti-cancer power. Don't use canned power vegetables.
- Eat power vegetables at dinner time or as a late-night snack before bed. When you eat power vegetables, the ITCs from the power vegetables can get in the urine within 1 hour and slowly build up in the urine over 8 hours. If you eat power vegetables during the day, you could lose a lot of ITCs in your urine from going to the bathroom throughout the day. If you eat power vegetables at dinner time or as a late-night snack, your body will be able to build up the ITCs in your bladder. Although you may go to the bathroom a few times before you go to the bed, a fair amount of the ITCs can still build up in the urine and increase the time the bladder is soaked in ITCs.

Tips to Eat More Power Vegetables (page 10)

- Look at pages 10 and 11 in your magazine for tips on how to eat more power vegetables

□ Part D: Going over Magazine Components: Teach Back Opportunity #1

Just to make sure that the magazine clearly conveyed the information, I am now going to ask you a few questions to review some of the main points of the magazine. You may feel like I'm testing you, but the purpose of this is to make sure that the magazine communicated the information to you clearly. Are you ready? Let's go!

Note: For a question to be answered correctly, all parts of the question must be answered correctly.

TB1 What is a power vegetable?

Correct: A cruciferous vegetable

Correct

No

Yes

CORRECT: Yes, that's right! A power vegetable is a certain type of vegetable called cruciferous vegetables.

INCORRECT: Power vegetables are cruciferous vegetables.

TB2 Please give me three examples of power vegetables.

Correct Answer: Anything listed in the POW-R Health magazine.

Correct

No

Yes

1) _____

2) _____

3) _____

CORRECT: Yes, that's right- good job! There are a lot of vegetables that are considered cruciferous vegetables. More cruciferous vegetables are listed in your POW-R Health Magazine.

INCORRECT: Ok, no problem, you missed *[state answers that are incorrect and correct]*. Your POW-R Health Magazine lists some power vegetables on page 7.

TB3 How many power vegetable servings do you need to eat each day.

Correct Answer: 1 serving/day

Correct

No

Yes

CORRECT: Excellent, you're right. You only need to eat one power vegetable serving a day to help stop bladder cancer from coming back.

INCORRECT: Okay, no problem, the correct answer is 1 serving or cup a day. You only need to eat one power vegetable serving a day to help stop bladder cancer from coming back.

TB4 What is the amount of 1 serving of a power vegetable?

Correct Answer: 1 cup at time of eating/consumption

Correct

No Yes

CORRECT: Excellent, you're right. 1 serving of a power vegetable is 1 cup at the time you eat it. 1 cup is about the size of your fist.

INCORRECT: Okay, no problem, the correct answer is 1 serving of a power vegetable is 1 cup at the time you eat it. 1 cup is about the size of your fist.

TB5 **QUESTION:** What is an isothiocyanate or ITC?

Correct Answer: An active compound in power vegetables that has strong anti-cancer properties

Correct

No Yes

CORRECT: Ok great, you really seem to understand what an isothiocyanate/ITC is.

INCORRECT: Isothiocyanates/ITCs are an active compound in power vegetables that has strong anti-cancer properties.

TB6 What is the best way to prepare power vegetables so they give you most isothiocyanates/ITCs?

Correct Answer: It is best to eat power vegetables fresh or raw. You can also lightly cook them too (cook for less than 10 minutes).

Correct

No Yes

CORRECT: Yes, that's right- good job!

INCORRECT: It's best to eat power vegetables fresh or raw. If you want to cook them, it's best to eat them lightly cooked, where you cook them for less than 10 minutes.

TB7 Why is it important to eat power vegetables at dinner or as a late-night snack before bedtime?

Correct Answer: Isothiocyanates from power vegetables go to the urine. The isothiocyanates in the urine soak the inside of the bladder; the longer the isothiocyanates in the urine are in the bladder, the longer the bladder will be exposed to the anti-cancer activities. Many people urinate several times throughout the day, and less often at night. If you eat power vegetables later at night, there is a greater chance that the isothiocyanates from the power vegetables will stay in your bladder longer.

Correct

No Yes

CORRECT: Yes, that's right- good job!

INCORRECT: Isothiocyanates/ITCs from power vegetables goes to your urine. The urine then goes to your bladder. The isothiocyanates in your urine will work to kill any cancer cells in your bladder. The longer the bladder is exposed to the isothiocyanates in your urine, the longer it will be exposed to anti-cancer activities. Many people urinate several times a day a less often at night. So, there is a greater chance that the isothiocyanates from the power vegetables will stay in your bladder longer if you eat power vegetables at night.

Scoring Circle all questions that were answered incorrectly.

none	TB1	TB2	# Incorrect
TB3	TB4	TB5	
TB6	TB7		

ALL CORRECT: Excellent job! You understand the main points of the POW-R Magazine and you got all of those questions correct. Now let's move on and put together an Action Plan! *[Go to Part F]*

ANY INCORRECT: *[GO TO PART E]*

Part E: Going over Magazine Components: Teach Back Opportunity #2

Only ask questions that were answered incorrectly in Part D. SKIP if all questions were answered correctly in Part D.

Is this part applicable?

No Yes

You did a good job remembering information that I just covered. I know there was a lot of information covered. So, let's just briefly recap the ones you missed.

TB1.2 What is a power vegetable?

Correct: A cruciferous vegetable

Correct

No Yes

CORRECT: Yes, that's right! A power vegetable is a certain type of vegetable called cruciferous vegetables.

INCORRECT: Power vegetables are cruciferous vegetables.

TB2.2 Please give me three examples of power vegetables.

Correct Answer: Anything listed in the POW-R Health magazine.

Correct

No Yes

1) _____

2) _____

3) _____

CORRECT: Yes, that's right- good job! There are a lot of vegetables that are power vegetables.

INCORRECT: Ok, no problem, you missed *[state answers that are incorrect and correct]*. There is a list of power vegetables in your POW-R Magazine on page 7.

TB3.2 How many power vegetable servings do you need to eat each day.

Correct Answer: 1 serving/day

Correct

No Yes

CORRECT: Excellent, you're right. You only need to eat one power vegetable serving a day to help stop bladder cancer from coming back.

INCORRECT: Okay, no problem, the correct answer is 1 serving a day. You only need to eat one power vegetable serving a day to help stop bladder cancer from coming back.

TB4.2 What is the amount of 1 serving of a power vegetable?

Correct Answer: 1 cup at time to eating/consumption

Correct

No **Yes**

CORRECT: Excellent, you're right. 1 serving of a power vegetable is 1 cup at the time you eat it. 1 cup is about the size of your fist.

INCORRECT: Okay, no problem, the correct answer is 1 serving of a power vegetable is 1 cup at the time you eat it. 1 cup is about the size of your fist.

TB5.2 **QUESTION:** What is an isothiocyanate/ITC?

Correct

No **Yes**

Correct Answer: An active compound in power vegetables that has strong anti-cancer properties

CORRECT: Ok great, you really seem to understand what an isothiocyanate is.

INCORRECT: Isothiocyanates/ITCs is an active compound in power vegetables that has strong anti-cancer properties.

TB6.2 What is the best way to prepare power vegetables so they give you most isothiocyanates/ITCs?

Correct Answer: It is best to eat power vegetables fresh or raw. You can also lightly cook them too (cook for less than 10 minutes).

Correct

No **Yes**

CORRECT: Yes, that's right- good job!

INCORRECT: It's best to eat power vegetables fresh or raw. If you want to cook them, it's best to eat them lightly cooked, where you cook them for less than 10 minutes.

TB7.2 Why is it important to eat power vegetables at dinner or as a late night snack before bedtime?

Correct Answer: Isothiocyanates from power vegetables go to the urine. The isothiocyanates in the urine soak the inside of the bladder; the longer the isothiocyanates in the urine are in the bladder, the longer the bladder will be exposed to the anti-cancer activities. Many people urinate several times throughout the day, and less often at night. If you eat power vegetables later at night, there is a greater chance that the isothiocyanates from the power vegetables will stay in your bladder longer.

Correct

No **Yes**

CORRECT: Yes, that's right- good job!

INCORRECT: Isothiocyanates/ITCs from power vegetables goes to your urine. The urine then goes to your bladder. The isothiocyanates in your urine will work to kill any cancer cells in your bladder. The longer the bladder is exposed to the isothiocyanates in your urine, the longer it will be exposed to anti-cancer activities. Many people urinate several times a day a less often at night. So there is a greater chance that the isothiocyanates from the power vegetables will stay in your bladder longer if you eat power vegetables at night.

Scoring Circle all questions that were answered <u>incorrectly</u> .	none	TB1	TB2	# Incorrect
	TB3	TB4	TB5	
	TB6	TB7		

ALL CORRECT: Excellent job! You're an expert now on the POW-R Health Magazine and you got all of those questions correct. Now let's move on and put together an Action Plan! *[Go to Part F]*

ANY INCORRECT: We'll go over these questions one more time before we end our call today. *[GO TO PART F]*

Part F: Complete Action Plan with Participant

Now let's go to the Action plan, which is on page 12 of the POW-R Health Magazine. Please fill out this page with me.

Reasons for joining POW-R Health

What are the most important reasons you have for joining the POW-R Health Program. Write this/these down in your action plan.

Participant reason(s):

Power vegetable eating goals

Let's set some short- and long-term goals. Let's start with a long-term goal. In 6 months, which is by the end of this program, how many power vegetable cups do you pledge to eat each day.

Long term goal

Now let's set your short-term goal. For this week, how many cups of power vegetables will you try to eat this week?

Short-term goal

Who can help me

Who can help you eat more power vegetables? Who can support you?

Support person

Power vegetable obstacles and strategies

Let's now talk about some obstacles that could make it harder for you to complete your plan. What are one or two obstacles that could make it harder for you to eat your power vegetables every day?

Obstacle 1

Obstacle 2

What are some strategies you could use to help overcome the obstacles you listed?

Obstacle 1, Strategies (2-4)

Obstacle 2, Strategies (2-4)

My plan this week to eat more power vegetables

Now let's make a plan to eat more power vegetables this week. The next time you or someone else goes to the grocery store, which power vegetables will you buy with medium to high isothiocyanates (page 7)?

Power vegetables to buy

The next time you eat power vegetables, how will you make them? Remember that when you cook the power vegetable, to cook it for less than 10 minutes.

Raw, microwave, sauté/stir-fry, steam

 Part G: Go over POW-R Track Book

One of the things you received in the packet we mailed to you is a POW-R Book. Please have your POW-R Book ready to review. In this book, I am asking that you keep track of how many power vegetables you eat every day, and each week. Science shows that keeping track of what you eat is a powerful way to change your habits. Keeping track of how many power vegetables you eat will help you eat more power vegetables. Let's go over all of the parts of the POW-R Book.

<i>Check box when section is covered</i>			
1. 1 POW-R book for each week; 24 sent to you—1 is for practice to use now. We are asking you to keep track of how many power vegetables you eat every week for the entire program.	3. 7 days in one POW-R book	5. Each day you say whether you ate at least 1 power vegetable cup where you prepared it in a POW-R Health Preferred way (explain what this is)	7. On the back is the phone number of the person from our team that you can call if you have any questions.
2. Cover page—write down dates of the week you are keeping track	4. Each day you write down how many cups of power vegetables you had at dinner or after dinner . Only write down those power vegetables you ate at dinner or after dinner (have them open book)	6. On the first page, is where you will write down the total number of power vegetables you ate at dinner or after dinner for that week. After our phone call, you will receive automated messages and will be asked to enter the number of cups of power vegetables you ate for the week.	8. Any questions?

Let's practice using the POW-R Track Book.

 Practice using POW-R Track Book

Take a POW-R Track Book. Can you think back this past week of any power vegetables you ate at dinner or after dinner? If you did not eat any power vegetables, how about any type of vegetable? Let's go through each day.

Monday	Tuesday	Wed
Thursday	Friday	Sat
		Sunday

Not let's add how many cups you ate that week

Total	Correct
No	Yes

CORRECT: Yes, that's right- good job!

INCORRECT: Ok, so the correct total is X. Let's try that again to make sure you can use the POW-R Book correctly.

Feel free to use a calculator if that would make things easier.

□ Part H: Going over magazine components: Teach Back Opportunity #3

Only ask questions that were answered incorrectly in Part E. SKIP if all questions were answered correctly in Part D or E.

Is this Part applicable?

No Yes

Before we end the call, I just want to re-ask you the questions about the key points from the magazine that you were not able to recall last time

TB1.3 What is a power vegetable?

Correct: A cruciferous vegetable

Correct

No Yes

CORRECT: Yes, that's right! A power vegetable is a certain type of vegetable called cruciferous vegetables.

INCORRECT: Power vegetables are cruciferous vegetables.

TB2.3 Please give me three examples of power vegetables.

Correct Answer: Anything listed in the POW-R Health magazine.

Correct

No Yes

1) _____

2) _____

3) _____

CORRECT: Yes, that's right- good job! There are a lot of vegetables that are considered cruciferous vegetables.

INCORRECT: Ok, no problem, you missed *[state answers that are incorrect and correct]*. If you look at on page X of your POW-R Health Magazine, there is a list of cruciferous vegetables.

TB3.3 How many power vegetable servings do you need to eat each day.

Correct Answer: 1 serving/day

Correct

No Yes

CORRECT: Excellent, you're right. You only need to eat one power vegetable serving a day to help stop bladder cancer from coming back.

INCORRECT: Okay, no problem, the correct answer is 1 serving a day. You only need to eat one power vegetable serving a day to help stop bladder cancer from coming back.

TB4.3 What is the amount of 1 serving of a power vegetable?

Correct Answer: 1 cup at time of eating/consumption.

Correct

No Yes

CORRECT: Excellent, you're right. 1 serving of a power vegetable is 1 cup at the time you eat it. 1 cup is about the size of your fist.

INCORRECT: Okay, no problem, the correct answer is 1 serving of a power vegetable is 1 cup at the time you eat it. 1 cup is about the size of your fist.

TB5.3 QUESTION: What is an isothiocyanate?

Correct

No Yes

Correct Answer: An active compound in power vegetables that has strong anti-cancer properties

CORRECT: Ok great, you really seem to understand what an isothiocyanate is.

INCORRECT: Isothiocyanates are an active compound in power vegetables that has strong anti-cancer properties.

TB6.3 What is the best way to prepare power vegetables so they give you most isothiocyanates?

Correct

No Yes

Correct Answer: It is best to eat power vegetables fresh or raw. You can also lightly cook them too (cook for less than 10 minutes).

CORRECT: Yes, that's right- good job!

INCORRECT: It's best to eat power vegetables fresh or raw. If you want to cook them, it's best to eat them lightly cooked, where you cook them for less than 10 minutes.

TB7.2 Why is it important to eat power vegetables at dinner or as a late night snack before bedtime?

Correct

No Yes

Correct Answer: Isothiocyanates from power vegetables go to the urine. The isothiocyanates in the urine soak the inside of the bladder; the longer the isothiocyanates in the urine are in the bladder, the longer the bladder will be exposed to the anti-cancer activities. Many people urinate several times throughout the day, and less often at night. If you eat power vegetables later at night, there is a greater chance that the isothiocyanates from the power vegetables will stay in your bladder longer.

CORRECT: Yes, that's right- good job!

INCORRECT: Isothiocyanates from power vegetables goes to your urine. The urine then goes to your bladder. The isothiocyanates in your urine will work to kill any cancer cells in your bladder. The longer the bladder is exposed to the isothiocyanates in your urine, the longer it will be exposed to anti-cancer activities. Many people urinate several times a day a less often at night. So, there is a greater chance that the isothiocyanates from the power vegetables will stay in your bladder longer if you eat power vegetables at night.

Scoring Circle all questions that were answered incorrectly.

none	TB1	TB2	# Incorrect
TB3	TB4	TB5	
TB6	TB7		

ALL CORRECT: Excellent job! You know all the important parts of the POW-R Health Magazine and you got all of those questions correct.

ANY INCORRECT: You did a good job remembering information from the magazine. I know there was a lot of information covered. So, let's just briefly recap the ones you missed before ending the call.

PART I: Closing

Thanks for taking the time to complete this call. Next week you will start receiving automated phone calls from our POW-R Health Program. The purpose of the calls will be to support you to eat more power vegetables. The calls will be tailored personally to you. Each call will ask you how many cups of power vegetables you ate for the week, figure out whether you are meeting your action plan goals, and then give you tailored support based on the obstacles and strategies you wrote down in your action plan. So, it will really be important for you to complete your POW-R Book every day, calculate your total power vegetables eaten at dinner or after dinner at the end of every week, and have that available when you receive the phone call.

The system will call you from this number: 716-333-POWR (7697). You can also call this number if you miss the call. This number is on the magnet we mailed to you to remind you that this is not a spam number. Can you please get the magnet we sent you out? Please place this magnet in a place that you'll be able to see it. If you miss a call, you can also call this number too to complete your automated phone call. There will be 11 automated phone call and we ask you to complete all 11 calls.

Each call will start by asking you what your date of birth is, so the system will know it is you. For example, if you were born January 3, 1953, you would enter 01-03-1953. The system will call you from this number: 716-333-POWR. You can also call this number if you miss the call.

Can you tell me how you will enter your date of birth? *[Confirm that the participant can provide their DOB correctly]*

DOB

Correctly read

No

Yes

Each automated phone call will last about 10-15 minutes. Please stay on the phone until the call is complete, otherwise the system will think that you did not complete the call and it will call you again.

(Go over any magazine content questions they missed: Let's go over one last time the question(s) you missed)

What questions do you have for me before we hang up?

Okay, just remember, if you ever have any questions or concerns, you can always get a hold of us by calling one of our team members at 716-845-1300, Ext 7221. This number is on the back of the Track Book and the last page of the magazine.

Record questions

Thank you for completing the call!

Control

Participant ID: _____

Staff Initials: _____

Date: _____

Start Time: _____

End Time: _____

Treatment Control

Materials that should have been sent to participant

Cover Letter/Welcome Letter

POW-R Health Magazine

POW-R Track Book (24 copies)

Refrigerator Magnet

PART A: Getting participant on the phone, call intro, packet receipt

Note: Only make three attempts to reach the participant

Phone Answered

Hello, this is [staff name] from the POW-R Health program calling for [participant name], she/he is expecting my call. Is [participant name] home/available right now?

Yes

Hi [participant name] I'm calling to review the POW-R Health program materials with you. It should take about 60 minutes; do you have time to complete it right now?

No

That's okay, can we schedule a time that would work better for you? Thanks, I will give you a call then.

Time to call back

Leaving Message

1st Attempt

This is [staff name] from the POW-R Health program calling for [participant name]. I'm calling to review the POW-R Health program materials with you, which should take about 1 hour. I'll try calling you again, but if you would like to call me back and let me know a good time for us to chat, I can be reached at 716-697-4615/716-720-2308. Thanks, and I hope I catch up with you soon!

2nd Attempt

Hello again, this is [staff name] from the POW-R Health program calling for [participant name]. I left a message with you on _____ [date] and I am calling you back to review the POW-R Health program materials with you, which should take about 1 hour. I'll try calling you one more time, but if you would like to call me back and let me know a good time for us to chat, I can be reached at 716-697-4615/716-720-2308. Thanks, and I hope I catch up with you soon!

3rd Attempt

Hello again, this is [staff name] from the POW-R Health program calling for [participant name]. I left a message with you on _____ [date], and I am calling you back to review the POW-R Health program materials with you, which should take about 1 hour. If you would like to call me back and let me know a good time for us to chat, I can be reached at 716-697-4615/716-720-2308. Thanks, and I hope I catch up with you soon!

Confirm Intervention Packet Receipt

We are glad you are a part of the program. We put a program packet in the mail for you about the POW-R Health Program. The packet should have included a magazine, booklets, and a magnet.

A1. Did you receive the program packet in the mail?

If YES: (Go to Question A2)

If NO: It's really important that you have your packet before we go over it. Let me make a note to send you the packet again. What is your mailing address? I'll call you again after your packet is sent. Thank you for taking the time to talk with me. I'll talk to you again soon.

END CALL.

A2. If so, did you have time to review the information in this packet?

No	Yes
<i>Mailing Address</i>	
No	Yes

PART B: OVERVIEW

How can you get the best health benefits from fruits and vegetables?

- Vegetables: Fresh, frozen, and canned vegetables can all be a part of healthy eating.
 - Fresh vegetables are best
 - Canned vegetables can be high in salt, so if you buy canned vegetables make sure you look for the 'no salt' ones.
- Fruit: Fresh, frozen, and canned fruit can all be a part of healthy eating
 - Fresh fruit is best
 - Canned fruit can be high in sugar and calories, so buy canned fruit in 100% fruit juice with no sugar added.
 - Be careful of fruit juices! They're high in sugar and calories, and you can miss out on a lot of other vitamins and minerals that eating fruits will give you.
- Eat 2½ to 3 cups of vegetables and 1½ to 2 cups of fruit each day; or a total of 4-5 cups of both fruits and vegetables a day. 1/2 cup is about the size of the **front** of a closed fist. 1 cup is about the size of your entire fist or a baseball.

How to prepare fruits and vegetables?

- You can eat a lot of fruits and vegetables raw. You can also cook them in many different ways too

Tips to Eat More Fruits and Vegetables

- Tips on how to eat more fruits and vegetables are on pages 6-7 of your POW-R Health Magazine.

I'm going to begin by going over the POW-R Magazine. After I go over the magazine's contents, we'll complete your personal action plan. I'll then go over the POW-R Books and the magnet. So let's start with the POW-R Magazine. Please have your POW-R Magazine next to you so you can follow along what I'm going to review.

PART C: MAGAZINE CONTENT

Welcome to the POW-R Health Program (page 2)

- Living a healthy lifestyle is important for bladder cancer survivors
- Eating fruits and vegetables is an important part of health
- Doctors made the **POW-R Health Program** to make sure you live the longest, healthiest life possible

Interesting convo points

What are fruits and vegetables?

- Fruit and vegetables are plants that have lots of minerals, vitamins, and other healthy things that are good for the human body.
- Common fruits and vegetables are listed in the POW-R magazine on page 3.

How are fruits and vegetables good for you? (page 4)

- Research has shown that eating fruits and vegetables can help you live longer. Eating fruits and vegetables reduces the risk of getting some cancers, high blood pressure (hypertension), heart disease, and diabetes.
- Fruits and vegetables have all of these great health benefits because they have a lot of vitamins C and A, electrolytes, and antioxidants. Vitamin C protects cells and molecules from damage that causes many diseases, including cancer.
- Fruits and vegetables are also a great source of fiber. The fiber in fruits and vegetables lowers cholesterol, which reduces heart disease risk. The fiber in fruits and vegetables can also help control the body's blood sugar, which reduces risk of diabetes. Fruits and vegetables can also help you have a healthy weight by giving you lots of fiber and water, which can fill you up without giving too many calories.

If YES: Okay great, I'm glad you got a chance to review the material. Just to make sure that the magazine clearly conveyed the information, I will now ask you some questions to go over the main points of the magazine. We will then work together to create your personal action plan to eat more power vegetables. Before we begin, please pull out the packet we sent. It would really help to have them with you for the later part of the call. Please have a pen handy too (Go to PART D).

If NO: That is okay. We can still go over what is in the packet right now. Before we begin, please pull out the packet we sent. It would really help to have them with you for the later part of the call. Please have a pen handy too. (Go to PART B)

Part D: Going over Magazine Components: Teach Back

Just to make sure that the magazine clearly conveyed the information, I am now going to ask you a few questions to review some of the main points of the magazine. You may feel like I'm testing you, but the purpose of this is to make sure that the magazine communicated the information to you clearly. Are you ready? Let's go!

Note: For a question to be answered correctly, all parts of the question must be answered correctly.

CTB1 How are fruits and vegetables good for you?

Correct: 1) have lots of vitamins that 2) reduces the risk of getting some cancers, high blood pressure (hypertension), heart disease, and diabetes, 3) fiber in fruits and vegetables can also help you have a healthy weight

		<i>Correct</i>
No	Yes	

CORRECT: Yes, that's right!

INCORRECT: Let's go to page X in the POW-R Health magazine. On this page, there is a description of fruits and vegetables are good for you. Fruits and vegetables are good for you because they 1) have lots of vitamins that 2) reduces the risk of getting some cancers, high blood pressure (hypertension), heart disease, and diabetes, 3) fiber in fruits and vegetables can also help you have a healthy weight.

CTB2 How many cups of fruit do you need to eat each day?

Correct Answer: 1 ½ to 2 cups/day

Correct
No Yes

CORRECT: Yes, that's right- good job!

INCORRECT: If you look at on page X of your POW-R Health Magazine, there is the recommendation on how many cups of fruit to each day for best health. For best health, you need to eat 1 ½ to 2 cups of fruit a day. 1 cup of fruit is about the size of your fist.

CTB3 How cups of vegetables do you need to eat each day?

Correct Answer: 2 ½ to 3 cups/day

Correct
No Yes

CORRECT: Excellent, you're right.

INCORRECT: If you look at on page X of your POW-R Health Magazine, there is the recommendation on how many cups of vegetables to each day for best health. For best health, you need to eat 2 ½ to 3 cups of vegetables a day. 1 cup of vegetables is about the size of your fist.

CTB4 What does 1 cup of fruit or vegetable look like?

Correct Answer: 1 cup is about the size of your fist.

Correct
No Yes

CORRECT: Excellent, you're right. 1 cup of vegetables or fruit is about the size of your fist.

INCORRECT: If you look at on page X of your POW-R Health Magazine, there are pictures of what 1 cup looks like. The size of your fist is about 1 cup.

CTB5 Fresh, frozen, and canned fruits can all be a part of healthy eating. Can you please tell me what you need to watch out for when you buy canned fruit?

Correct Answer: Added sugars in canned fruit (buy no added sugar, 100% fruit juice kind)

Correct
No Yes

CORRECT: Ok great, you're right.

INCORRECT: If you look at on page X of your POW-R Health Magazine, there is describes what types of fruit are best to eat. Fresh, frozen, and canned fruits can all be a part of healthy eating. When it comes to canned fruits, you just need to watch out for too much sugar. Buy the no added sugar type.

CTB6 Fresh, frozen, and canned vegetables can all be a part of healthy eating. Can you please tell me what you need to watch out for when you buy canned vegetables

*Correct Answer: Too much salt in canned vegetables
(buy no salt added kind)*

Correct
No Yes

CORRECT: Ok great, you're right.

INCORRECT: If you look at on page X of your POW-R Health Magazine, there is describes what types of vegetables are best to eat. Fresh, frozen, and canned vegetables can all be a part of healthy eating. When it comes to canned vegetables, you just need to watch out for too much salt. Buy the no salt added.

CTB7 Can fruit juices be a part of a healthy diet?

Correct Answer: It's best to choose fruits you can eat instead of drink. Many fruit juices are high in sugar and calories and don't have a lot of minerals that fruit has when you eat them instead.

Correct
No Yes

CORRECT: Yes, that's right- good job!

INCORRECT: If you look at on page X of your POW-R Health Magazine, there it talks about fruit juices. It's best to choose fruits you can eat instead of drink. Many fruit juices are high in sugar and calories and don't have a lot of minerals that fruit has when you eat them instead.

Scoring Circle all questions that were answered incorrectly.

none	TB1	TB2	# Incorrect
TB3	TB4	TB5	
TB6	TB7		

ALL CORRECT: Excellent job! You really read through the POW-R Health Magazine and you got all of those questions correct. Now let's move on and put together an Action Plan! *[Go to Part F]*

ANY INCORRECT: *[GO TO PART E]*

Part E: Going over Magazine Components: Teach Back Opportunity

Only ask questions that were answered incorrectly in Part D. SKIP if all questions were answered correctly in Part D.

Is this part applicable?

No Yes

You did a good job remembering information that I just covered. I know there was a lot of information covered. So, let's just briefly recap the ones you missed.

CTB1.2 How are fruits and vegetables good for you?

Correct: 1) have lots of vitamins that 2) reduces the risk of getting some cancers, high blood pressure (hypertension), heart disease, and diabetes, 3) fiber in fruits and vegetables can also help you have a healthy weight

Correct

No Yes

CORRECT: Yes, that's right!

INCORRECT: Let's go to page X in the POW-R Health magazine. On this page, there is a description of fruits and vegetables are good for you. Fruits and vegetables are good for you because they 1) have lots of vitamins that 2) reduces the risk of getting some cancers, high blood pressure (hypertension), heart disease, and diabetes, 3) fiber in fruits and vegetables can also help you have a healthy weight.

CTB2.2 How many cups of fruit do you need to eat each day?

Correct Answer: 1 1/2 to 2 cups/day

Correct

No Yes

CORRECT: Yes, that's right- good job!

INCORRECT: If you look at on page X of your POW-R Health Magazine, there is the recommendation on how many cups of fruit to each day for best health. For best health, you need to eat 1 1/2 to 2 cups of fruit a day. 1 cup of fruit is about the size of your fist.

CTB3.2 How cups of vegetables do you need to eat each day?

Correct Answer: 2 1/2 to 3 cups/day

Correct

No Yes

CORRECT: Excellent, you're right.

INCORRECT: If you look at on page X of your POW-R Health Magazine, there is the recommendation on how many cups of vegetables to each day for best health. For best health, you need to eat 2 1/2 to 3 cups of vegetables a day. 1 cup of vegetables is about the size of your fist.

CTB4.2 What does 1 cup of fruit or vegetable look like?

Correct Answer: 1 cup is about the size of your fist.

Correct

No

Yes

CORRECT: Excellent, you're right. 1 cup of vegetables or fruit is about the size of your fist.

INCORRECT: If you look at on page X of your POW-R Health Magazine, there are pictures of what 1 cup looks like. The size of your fist is about 1 cup.

CTB5.2 Fresh, frozen, and canned fruits can all be a part of healthy eating. Can you please tell me what you need to watch out for when you buy canned fruit?

Correct Answer: Added sugars in canned fruit (buy no added sugar, 100% fruit juice kind)

Correct

No

Yes

CORRECT: Ok great, you're right.

INCORRECT: If you look at on page X of your POW-R Health Magazine, there is describes what types of fruit are best to eat. Fresh, frozen, and canned fruits can all be a part of healthy eating. When it comes to canned fruits, you just need to watch out for too much sugar. Buy the no added sugar type.

CTB6.2 Fresh, frozen, and canned vegetables can all be a part of healthy eating. Can you please tell me what you need to watch out for when you buy canned vegetables

Correct Answer: Too much salt in canned vegetables (buy no salt added kind)

Correct

No

Yes

CORRECT: Ok great, you're right.

INCORRECT: If you look at on page X of your POW-R Health Magazine, there is describes what types of vegetables are best to eat. Fresh, frozen, and canned vegetables can all be a part of healthy eating. When it comes to canned vegetables, you just need to watch out for too much salt. Buy the no salt added.

CTB7.2 Can fruit juices be a part of a healthy diet?

Correct Answer: It's best to choose fruits you can eat instead of drink. Many fruit juices are high in sugar and calories and don't have a lot of minerals that fruit has when you eat them instead.

Correct

No

Yes

CORRECT: Yes, that's right- good job!

INCORRECT: If you look at on page X of your POW-R Health Magazine, there it talks about fruit juices. It's best to choose fruits you can eat instead of drink. Many fruit juices are high in sugar and calories and don't have a lot of minerals that fruit has when you eat them instead.

Scoring Circle all questions that were answered incorrectly.
g

non	TB1	TB2	# Incorrect
e	TB4	TB5	
TB3	TB7		
TB6			

ALL CORRECT: Excellent job! You really read through the POW-R Health Magazine and you got all of those questions correct. Now let's move on and put together an Action Plan! *[Go to Part F]*

ANY INCORRECT: We'll go over these questions one more time before we end our call today. *[GO TO PART F]*

Part F: Complete Action Plan with Participant

Now let's go to the Action plan, which is on page 9 of the POW-R Health Magazine. Write your answers down in the plan.

Reasons for joining the POW-R Health Program

What are the most important reasons you have for joining the POW-R Health Program? Write this/these down in your action plan.

Participant reason(s):

Power vegetable eating goals

Let's set some short- and long-term goals. Let's start with a long-term goal. In 6 months, which is by the end of this program, how many cups of fruit and vegetables do you pledge to eat each day.

Long term goal

Now let's set your short-term goal. For this week, how many cups of fruit and vegetables will you try to eat this week?

Short-term goal

Who can help me

Who can help you eat more fruit and vegetables?
Who can support you?

Support person

Fruit and vegetable obstacles and strategies

Let's now talk about some obstacles that could make it harder for you to complete your plan. What are one or two obstacles that could make it harder for you to eat more fruit and vegetables every day?

Obstacle 1

Obstacle 2

What are some strategies you could use to help overcome the obstacles you listed?

Obstacle 1, Strategies (2-4)

Obstacle 2, Strategies (2-4)

My plan this week to eat more fruit and vegetables

Now let's make a plan to eat more fruit and vegetables this week. The next time you or someone else goes to the grocery store, which fruit and vegetables will you buy?

Fruit and vegetables to buy

Part G: Go over POW-R Track Book

One of the things you received in the packet we mailed to you is a POW-R Book. Please have your POW-R Book ready to review. In this book, I am asking that you keep track of how many fruit and vegetables you eat every day, and each week. Science shows that keeping track of what you eat is a powerful way to change your habits. Keeping track of how many fruit and vegetables you eat will help you eat more fruit and vegetables. Let's go over all of the parts of the POW-R Book.

Check box when section is covered

1. 1 POW-R book for each week; 24 sent to you—1 is for practice to use now; we are asking you to complete a track book each week for the entire program	3. 7 days in one POW-R book	5. Each day write down how many cups of fruit you had that day. (have them go through pages of book)	7. On the back is the phone number of the person from our team that you can call
---	-----------------------------	--	--

2. Cover page—write down dates of the week you are keeping track

4. Each day write down how many cups of vegetables you had that day. (have them open up book)

6. On the front page, is where you will write down: 1) the total cups of fruit, 2) total cups of vegetables, and 3) total number of fruits AND vegetables you ate that week. Place a check-mark by whether you ate at least 1.5 cups of fruit that week (yes/no). Same with vegetables. After our phone call, you will receive automated messages and will be asked to enter the total number of cups of fruit AND vegetables you ate for the week (refer them to last line). It will also ask you whether you ate at least 1.5 cups of fruit, and 2.5 cups of vegetables and you will use the information here to tell them 'yes' or 'no'

if you have any questions.

8. Any questions?

Let's practice using the POW-R Track Book.

Practice using POW-R Track Book

Take a POW-R Track Book. Can you think back this past week of any fruit you ate? Let's go through each day.

Now let's add how many cups you ate that week

	Monday	Tuesday	Wed	
	Thursday	Friday	Sat	Sunday
	Total			Correct
				No Yes

CORRECT: Yes, that's right- good job!

INCORRECT: Ok, so the correct total is X. Let's try that again to make sure you can use the POW-R Book correctly. Feel free to use a calculator if that would make things easier.

Part H: Going over magazine components: Teach Back Opportunity #3

Only ask questions that were answered incorrectly in Part E. SKIP if all questions were answered correctly in Part D or E.

Is this Part applicable?

No Yes

Before we end the call, I just want to re-ask you the questions about the key points from the magazine that you were not able to recall last time

CTB1.3 How are fruits and vegetables good for you?

Correct: 1) have lots of vitamins that 2) reduces the risk of getting some cancers, high blood pressure (hypertension), heart disease, and

Correct
No Yes

*diabetes, 3) fiber in
fruits and vegetables
can also help you
have a healthy weight*

CORRECT: Yes, that's right!

INCORRECT: Let's go to page X in the POW-R Health magazine. On this page, there is a description of fruits and vegetables are good for you. Fruits and vegetables are good for you because they 1) have lots of vitamins that 2) reduces the risk of getting some cancers, high blood pressure (hypertension), heart disease, and diabetes, 3) fiber in fruits and vegetables can also help you have a healthy weight.

CTB2.3 How many cups of fruit do you need to eat each day?

Correct Answer: 1 ½ to 2 cups/day

Correct

No

Yes

CORRECT: Yes, that's right- good job!

INCORRECT: If you look at on page X of your POW-R Health Magazine, there is the recommendation on how many cups of fruit to each day for best health. For best health, you need to eat 1 ½ to 2 cups of fruit a day. 1 cup of fruit is about the size of your fist.

CTB3.3 How cups of vegetables do you need to eat each day?

Correct Answer: 2 ½ to 3 cups/day

Correct

No

Yes

CORRECT: Excellent, you're right.

INCORRECT: If you look at on page X of your POW-R Health Magazine, there is the recommendation on how many cups of vegetables to each day for best health. For best health, you need to eat 2 ½ to 3 cups of vegetables a day. 1 cup of vegetables is about the size of your fist.

CTB4.3 What does 1 cup of fruit or vegetable look like?

Correct Answer: 1 cup is about the size of your fist.

Correct

No

Yes

CORRECT: Excellent, you're right. 1 cup of vegetables or fruit is about the size of your fist.

INCORRECT: If you look at on page X of your POW-R Health Magazine, there are pictures of what 1 cup looks like. The size of your fist is about 1 cup.

CTB5.3	Fresh, frozen, and canned fruits can all be a part of healthy eating. Can you please tell me what you need to watch out for when you buy canned fruit?	<i>Correct</i>
		No Yes

Correct Answer: Added sugars in canned fruit (buy no added sugar, 100% fruit juice kind)

CORRECT: Ok great, you're right.

INCORRECT: If you look at on page X of your POW-R Health Magazine, there is describes what types of fruit are best to eat. Fresh, frozen, and canned fruits can all be a part of healthy eating. When it comes to canned fruits, you just need to watch out for too much sugar. Buy the no added sugar type.

CTB6.3	Fresh, frozen, and canned vegetables can all be a part of healthy eating. Can you please tell me what you need to watch out for when you buy canned vegetables	<i>Correct</i>
		No Yes

Correct Answer: Too much salt in canned vegetables (buy no salt added kind)

CORRECT: Ok great, you're right.

INCORRECT: If you look at on page X of your POW-R Health Magazine, there is describes what types of vegetables are best to eat. Fresh, frozen, and canned vegetables can all be a part of healthy eating. When it comes to canned vegetables, you just need to watch out for too much salt. Buy the no salt added.

CTB7.3	Can fruit juices be a part of a healthy diet?	<i>Correct</i>
		No Yes

Correct Answer: It's best to choose fruits you can eat instead of drink. Many fruit juices are high in sugar and calories and don't have a lot of minerals that fruit has when you eat them instead.

CORRECT: Yes, that's right- good job!

INCORRECT: If you look at on page X of your POW-R Health Magazine, there it talks about fruit juices. It's best to choose fruits you can eat instead of drink. Many fruit juices are high in sugar and calories and don't have a lot of minerals that fruit has when you eat them instead.

Scoring	Circle all questions that were answered <u>incorrectly</u> .	none	TB1	TB2	# Incorrect
		TB3	TB4	TB5	
		TB6	TB7		

ALL CORRECT: Excellent job! You know all the important parts of the POW-R Health Magazine and you got all of those questions correct.

ANY INCORRECT: You did a good job remembering information from the magazine. I know there was a lot of information covered. So, let's just briefly recap the ones you missed before ending the call.

PART I: Closing

Thanks for taking the time to complete this call. Next week you will start receiving automated phone calls from our POW-R Health Program. The purpose of the calls will be to support you to eat more fruit and vegetables. The calls will be tailored personally to you. Each call will ask you how many fruit and vegetables you ate for the week, figure out whether you are meeting your action plan goals, and then give you tailored support based on the obstacles and strategies you wrote down in your action plan. So, it will really be important for you to complete your POW-R Book every day, calculate your total cups of fruit and vegetables eaten at the end of every week, and have that available when you receive the phone call.

The system will call you from this number: 716-333-POWR (7697). You can also call this number if you miss the call. This number is on the magnet we mailed to you to remind you that this is not a spam number. Can you please get the magnet we sent you out? Please place this magnet in a place that you'll be able to see it. If you miss a call, you can also call this number too to complete your automated phone call. There will be 11 automated phone call and we ask you to complete all 11 calls.

Each call will start by asking you what your date of birth is, so the system will know it is you. For example, if you were born January 3, 1953, you would enter 01-03-1953. The system will call you from this number: 716-333-POWR. You can also call this number if you miss the call.

Can you tell me how you will enter your date of birth? *[Confirm that the participant can provide their DOB correctly]*

DOB	Correctly read
No	Yes

Each automated phone call will last about 10-15 minutes. Please stay on the phone until the call is complete, otherwise the system will think that you did not complete the call and it will call you again.

(Go over any magazine content questions they missed: Let's go over one last time the question(s) you missed)

What questions do you have for me before we hang up?

Record questions

Okay, just remember, if you ever have any questions or concerns, you can always get ahold of us by calling one of our team members at 716-845-1300, Ext 7221. This number is on the back of the Track Book and the last page of the magazine.

Thank you for completing the call!

Appendix R. Participant Track Books

Intervention

SUNDAY

How many cups of vegetables did you eat?

- 0
- 1/2 cup
- 1 cup
- 1 1/2 cups
- 2 cups
- 2 1/2 cups
- 3 cups
- OTHER: _____

How many cups of fruit did you eat?

- 0
- 1/2 cup
- 1 cup
- 1 1/2 cups
- 2 cups
- OTHER: _____

Dates This Week: ____/____ to ____/____



TRACK BOOK

How many fruits and vegetables did you eat this week? _____

Total cups of vegetables eaten this week: _____

Did you eat at least 2.5 cups of vegetables this week? YES NO

Total cups of fruit eaten this week: _____

Did you eat at least 1.5 cups of FRUIT this week? YES NO

If you have any questions,
please call 716-845-1300, Ext 7221.

If you need to access the
POW-R automated phone system,
call 716-333-POWR (7697).

MONDAY

How many cups of vegetables did you eat?

- 0
- $\frac{1}{2}$ cup
- 1 cup
- $1\frac{1}{2}$ cups
- 2 cups
- $2\frac{1}{2}$ cups
- 3 cups
- OTHER: _____

How many cups of fruit did you eat?

- 0
- $\frac{1}{2}$ cup
- 1 cup
- $1\frac{1}{2}$ cups
- 2 cups
- OTHER: _____

SATURDAY

How many cups of vegetables did you eat?

- 0
- $\frac{1}{2}$ cup
- 1 cup
- $1\frac{1}{2}$ cups
- 2 cups
- $2\frac{1}{2}$ cups
- 3 cups
- OTHER: _____

How many cups of fruit did you eat?

- 0
- $\frac{1}{2}$ cup
- 1 cup
- $1\frac{1}{2}$ cups
- 2 cups
- OTHER: _____

FRIDAY

How many cups of vegetables did you eat?

- 0
- $\frac{1}{2}$ cup
- 1 cup
- $1\frac{1}{2}$ cups
- 2 cups
- $2\frac{1}{2}$ cups
- 3 cups
- OTHER: _____

How many cups of fruit did you eat?

- 0
- $\frac{1}{2}$ cup
- 1 cup
- $1\frac{1}{2}$ cups
- 2 cups
- OTHER: _____

TUESDAY

How many cups of vegetables did you eat?

- 0
- $\frac{1}{2}$ cup
- 1 cup
- $1\frac{1}{2}$ cups
- 2 cups
- $2\frac{1}{2}$ cups
- 3 cups
- OTHER: _____

How many cups of fruit did you eat?

- 0
- $\frac{1}{2}$ cup
- 1 cup
- $1\frac{1}{2}$ cups
- 2 cups
- OTHER: _____

WEDNESDAY

How many cups of vegetables did you eat?

- 0
- ½ cup
- 1 cup
- 1 ½ cups
- 2 cups
- 2 ½ cups
- 3 cups
- OTHER: _____

How many cups of fruit did you eat?

- 0
- ½ cup
- 1 cup
- 1 ½ cups
- 2 cups
- OTHER: _____

THURSDAY

How many cups of vegetables did you eat?

- 0
- ½ cup
- 1 cup
- 1 ½ cups
- 2 cups
- 2 ½ cups
- 3 cups
- OTHER: _____

How many cups of fruit did you eat?

- 0
- ½ cup
- 1 cup
- 1 ½ cups
- 2 cups
- OTHER: _____

Control

SUNDAY

How many cups of vegetables did you eat?

- 0
- ½ cup
- 1 cup
- 1 ½ cups
- 2 cups
- 2 ½ cups
- 3 cups
- OTHER: _____

How many cups of fruit did you eat?

- 0
- ½ cup
- 1 cup
- 1 ½ cups
- 2 cups
- OTHER: _____

Dates This Week: ____/____ to ____/____



TRACK BOOK

How many fruits and vegetables did you eat this week? _____

Total cups of vegetables eaten this week: _____

Did you eat at least 2.5 cups of vegetables this week? YES NO

Total cups of fruit eaten this week: _____

Did you eat at least 1.5 cups of FRUIT this week? YES NO

If you have any questions, please call 716-845-1300, Ext 7221.

If you need to access the POW-R automated phone system, call 716-333-POWR (7697).

MONDAY

How many cups of vegetables did you eat?

- 0
- ½ cup
- 1 cup
- 1 ½ cups
- 2 cups
- 2 ½ cups
- 3 cups
- OTHER: _____

How many cups of fruit did you eat?

- 0
- ½ cup
- 1 cup
- 1 ½ cups
- 2 cups
- OTHER: _____

SATURDAY

How many cups of vegetables did you eat?

- 0
- ½ cup
- 1 cup
- 1 ½ cups
- 2 cups
- 2 ½ cups
- 3 cups
- OTHER: _____

How many cups of fruit did you eat?

- 0
- ½ cup
- 1 cup
- 1 ½ cups
- 2 cups
- OTHER: _____

FRIDAY

How many cups of vegetables did you eat?

- 0
- $\frac{1}{2}$ cup
- 1 cup
- $1\frac{1}{2}$ cups
- 2 cups
- $2\frac{1}{2}$ cups
- 3 cups
- OTHER: _____

How many cups of fruit did you eat?

- 0
- $\frac{1}{2}$ cup
- 1 cup
- $1\frac{1}{2}$ cups
- 2 cups
- OTHER: _____

TUESDAY

How many cups of vegetables did you eat?

- 0
- $\frac{1}{2}$ cup
- 1 cup
- $1\frac{1}{2}$ cups
- 2 cups
- $2\frac{1}{2}$ cups
- 3 cups
- OTHER: _____

How many cups of fruit did you eat?

- 0
- $\frac{1}{2}$ cup
- 1 cup
- $1\frac{1}{2}$ cups
- 2 cups
- OTHER: _____

WEDNESDAY

How many cups of vegetables did you eat?

- 0
- ½ cup
- 1 cup
- 1 ½ cups
- 2 cups
- 2 ½ cups
- 3 cups
- OTHER: _____

How many cups of fruit did you eat?

- 0
- ½ cup
- 1 cup
- 1 ½ cups
- 2 cups
- OTHER: _____

THURSDAY

How many cups of vegetables did you eat?

- 0
- ½ cup
- 1 cup
- 1 ½ cups
- 2 cups
- 2 ½ cups
- 3 cups
- OTHER: _____

How many cups of fruit did you eat?

- 0
- ½ cup
- 1 cup
- 1 ½ cups
- 2 cups
- OTHER: _____

Appendix S. Participant Thank You Letter

[DATE]

[FIRST AND LAST NAME OF PARTICIPANT]

[STREET ADDRESS]

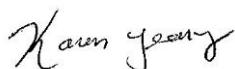
[CITY, STATE ZIP CODE]

Dear [FIRST NAME OF PARTICIPANT],

I am writing to thank you personally for completing the [baseline/follow-up] assessment of the POW-R Health Program. To show our appreciation for your time and effort, we have enclosed Tops gift card for \$X. In 6 months, we will ask you to complete these surveys again and if you do, you will earn another \$X.

On behalf of the POW-R Health team, thank you so much for supporting our research! Please don't hesitate to contact us at: 716-845-1300, Ext 7221.

Sincerely,



Karen Yearly, PhD
Principal Investigator



Li Tang, PhD
Principal Investigator

Appendix T. Recruitment Letter for Roswell Park Cancer Registry

Date

Dear Participant,

We recently received funding from the National Institutes of Health to learn more about how diet may reduce the risk of recurrence in individuals with early-stage bladder cancer. Men and women who were recently diagnosed with early-stage bladder cancer and who live in the counties of Niagara, Orleans, Genesee, Erie, Wyoming, Chautauqua, Cattaraugus, and Allegany may be eligible for the study.

We are asking you to take part in this study because you have been diagnosed and treated for bladder cancer. The goal of this study is to make a healthy eating program to improve cancer outcomes. The purpose of this study is to compare two types of healthy eating programs. This study will allow the researchers to know whether different types of healthy eating programs can improve the bladder cancer outcomes of the patients. The intervention that you will receive as part of this study will be given to you at no cost.

If you agree to take part in this research study, you will receive a \$100 gift card for completion of the baseline surveys and you will receive another \$100 gift card for completion of the 6-month survey.

This study has been reviewed and approved by the Roswell Park Institutional Review Board to assure that the study plans will not put any participants at risk. Your involvement in this study does not involve any physical risk to you. The possible risks might be feeling uncomfortable answering questions, embarrassment, or someone identifying you as a participant in the group, although this would be rare. You will not receive any direct health benefit from participating in this study.

Someone from our office will call you to make sure you received this letter and to discuss the study with you. If you have any questions, please call us at 716-845-XXXX. We hope that you will be able to help us by completing the survey.

We hope to hear from you soon!

Appendix U. Invitation Letter for Physician Interview and Opt-In/Out Card

Date

Dear Dr. X,

Your patient or colleague recently participated in the POW-R Health research study, a National Cancer Institute (NCI)-funded study that is testing different dietary strategies to lower the risk of bladder cancer recurrence. We are excited about this study because it may produce a dietary intervention that helps reduce the risk of bladder cancer recurrence and improve bladder cancer survivorship. To be noted, the funded study is a behavior intervention program that has no relevance to clinical treatment regardless of whether clinical care is provided.

We are contacting you because either your patient or colleague nominated you to be a part of this study. To be part of the study, all we need is to conduct a 15-minute phone interview with you to gain a physician's insight on how our dietary intervention—if proven to be successful—could be incorporated into routine care. Physicians who participate will receive a \$100 gift card from a local store as a small token of our appreciation.

If you can participate in a 15-minute phone interview, please let us know by filling out the card included in this mailing. If you do not want to participate, please let us know on the card so we do not contact you in the future.

For more detailed information about the study, please review the included information sheet.

Thanks so much for our consideration. We hope to hear from you soon.

Sincerely,



Karen Yeary, PhD
Professor
Cancer Prevention and Control
Roswell Park Comprehensive Cancer Center



Li Tang, PhD
Associate Professor
Cancer Prevention and Control
Roswell Park Comprehensive Cancer Center



Yes, I'm interested in participating in the phone interview. Please call me at: _____ during the following days and times:

No, I'm not interested in participating. Please do not contact me again about this study.

Appendix V. POW-R Sympathy Card



Study Number and title: I 661820; POW-R Health: Power to Redefine your Health (Internal Title: A Pragmatic Dietary Intervention to Improve Bladder Cancer Survivorship)

Dear [...],

We wanted to write to extend our deepest sympathy for the loss of your [partner/wife/husband/loved one], [Participant's name].

No one should ever have to experience such pain and loss - we are sorry that you are.

Please know that we are thinking of you and your loved ones. We send our heartfelt condolences and strength your way.

Sincerely,
[Names of research staff]
The POW-R Study Research Team
Roswell Park Comprehensive Cancer Center

Appendix W. Participant Information Sheet for Cruciferous Arm Feedback Questions (For Participants that Completed the 6-Month Follow-up Assessment)



[DATE]

Dear POW-R Health Participant,

Thank you for participating in the POW-R Health Program! Your participation will make a difference in understanding how to improve the health of bladder cancer survivors like you. To make the program better, a Roswell Park team member will call you to ask a few questions about what you liked and didn't like about the program. The phone call will take about 10-15 minutes.

Your participation is voluntary. All responses will remain confidential and anonymous and will be shared with only the Roswell Park POW-R Health Program team. If you don't want to talk with us, please tell us when we call you.

We believe that your valuable feedback will help make the POW-R Health program better, so it can be more useful to more bladder cancer survivors like you. Please be on the lookout for a phone call from our POW-R Health team. If you have any questions regarding the upcoming phone call please don't hesitate to contact us at: 716-845-1300, Ext 4236.

Sincerely,

A handwritten signature in blue ink that appears to read "Karen Yeary".

Karen Yeary, PhD
Principal Investigator

A handwritten signature in blue ink that appears to read "Li Tang".

Li Tang, PhD
Principal Investigator