Background

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study.

Patients facing surgery for cancer, or possible cancer, often experience increased stress or distress. This distress can be due to a wide variety of things. However, regardless of the cause, increased distress can affect people's quality of life before and after surgery. Because of this, programs that provide strategies to manage stress and distress before surgery can be useful.

Purpose

The purpose of this research study is to find out if a very brief program of support is appreciated by, and helpful to patients who are scheduled to have surgery for cancer or possible cancer, and are experiencing distress for any reason. As part of this program you will have the opportunity to learn different ways to cope with stress, as well as some strategies for managing your health and your mood before and after surgery. The Be-WEL program stands for Behavioral intervention for Wellness and Engaged Living, and the goal of the program is to provide strategies to help reduce distress before surgery and improve quality of life after surgery.

Because we know that patients being seen at Baylor College of Medicine often have to travel long distances to reach the facility, this program will be telephone-based, which means that this study does not involve any additional trips to the hospital.

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine.

We will invite patients who receive care at the Baylor Surgical Oncology Clinic to participate in this study.

If you participate in this study, you and a study clinician will talk over the telephone 2 to 3 times during the weeks leading up to your surgery. Because each person's situation is different, the study clinician will work with you to tailor these telephone sessions to match your unique concerns and preferences. The sessions are structured, but ultimately you choose the program focus with the clinician serving as a consultant or guide. Depending on your preference, the sessions could focus on strategies to manage stress, mood, or health concerns. Most of the telephone sessions will last about 45 minutes. The study clinician will also give you a call 2 times during the week after your surgery. These phone calls will last about 30 minutes, and will focus on how the strategies for managing stress, mood, or health may work for you after the surgery.

We are looking for patients who are scheduled for a cancer- or possible cancer-related surgery (except non-melanoma skin cancer) at least 13 days in advance who are experiencing distress. Patients with severe mental illness (psychotic or bipolar disorder for example) are not eligible for this project. It is also important that you don't have significant problems with your thinking or memory (for example, patients

with dementia or Alzheimer's disease). Patients must also be able to read and understand English. This is because, at the current time, we do not have resources that can accommodate patients that have a severe mental health issue or are cognitively impaired or cannot read or speak English.

If you agree to be in the study, someone on the research team will ask you a series of questions about your emotional and physical health today if your schedule allows, or over the telephone within the next 2 business days. These questions take about 30 minutes to complete, and will help us determine if you are eligible to participate. If you are eligible, you will then be scheduled for your first telephone session with a study clinician. Additionally, you will be called by a research team member 1 day before surgery to ask about your distress (this call will last approximately 5 minutes), 1-week after surgery to ask about your emotional and physical health (this call will last approximately 30 minutes), and 1-month after surgery to ask about your emotional and physical health and your feedback on the program (this call will last approximately 45 minutes). If you are not eligible for the study, the research team member may provide you with some information on other resources in the community. All eligible people will have an equal opportunity to participate in the program; there is no “control” group or wait-list.

While participating in this study, you may continue to receive your usual medical treatments. You may continue taking prescribed medications. The study staff will also review your medical record to keep track of relevant medical information and other treatment you are currently receiving or have received in the past. All sessions will be audio taped so that a licensed psychologist can make sure you receive quality and safe treatment. These audio recordings will not be disclosed outside of Baylor College of Medicine, and will not be shared with anyone who is not directly involved in this study.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Photographs, videotapes, and/or audiotapes of you

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine is required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research does not involve treatment. Baylor College of Medicine may not condition (withhold or refuse) treating you on whether you sign this Authorization.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Dr. Chelsea Ratcliff, Baylor College of Medicine One Baylor Plaza, Office N1317 Houston, TX 77030

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts
This study has minimal risks and discomforts. However, it is important to recognize that talking about physical and mental health concerns while answering questionnaires or participating in the telephone sessions can be uncomfortable for some people (which is completely understandable). The risks, however, are considered low.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

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Potential Benefits

The benefits of participating in this study may be: Participating in this study may include decreases in distress, worry, sadness, and associated symptoms (e.g., fatigue, pain). You may also experience improved ability to perform activities of daily life. However, this will always be unique to the person, it is possible that you may not receive any benefit from your participation in this study. Just as importantly, you will have an opportunity to teach us about how we can better help the patient population at large and understand what is important to them before and shortly after surgery. You should know that your participation will help the researchers of this study learn more about how effective this program is , and how well patients accept it. . However, you may receive no benefit from participating.

Alternatives

You may choose to not participate in this study.

Subject Costs and Payments

You will not be asked to pay any costs related to this research.

Depending on the number of assessments that you complete, you may receive Amazon gift cards up to $45. You will receive a $10 gift card for the beginning assessment, $15 gift card for a 1-week post-surgery assessment, and $20 gift card for a 1-month post-surgery assessment. These incentives will be mailed to you once you complete each step.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, CHELSEA RATCLIFF, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: Chelsea Ratcliff at 713-798-4872 and/or 936-294-4662 during the day.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date