A supportive care clinical trial

An app-based mindfulness intervention for accessible delivery of post-treatment psychosocial care SC28 | NCT 05470010

What is the purpose of this study?

The purpose of this study is to test if a mindfulness program (Mindfulness Based Cancer Survivorship (MBCS) Journey) delivered through a mobile smartphone application (Am Mindfulness) can reduce ongoing psychosocial symptoms such as stress, anxiety, depression, fatigue, and fear of cancer recurrence or progression that are often experienced by survivors.

Why is this study important?

People who had cancer may have multiple unmet psychosocial needs after completion of primary treatment, and during the first 5 years of surveillance and follow-up. Survivors often report feeling "lost in transition" as they shift back to their previous lives at home and in the workplace.

There is a need for more accessible approaches to delivering psychosocial care after completion of primary treatment to ensure the growing population of survivors experience a better quality of life and improved health outcomes.

Who can participate in this study?

This trial is for:

- Adults over 18 years of age, diagnosed with any type of cancer
- People who have completed primary treatment (i.e. surgery, chemotherapy, radiation therapy) at least 2 weeks prior to enrollment

This trial is not for:

- People with major communication difficulties at the time of recruitment, such as severe hearing or cognitive difficulties
- People suffering from untreated serious depression or other psychiatric disorders that would interfere with participation
- People who have previous experience practicing in-person or app-based mindfulness once a week or more within the last year



What are the risks?

If you choose to take part in this study, there is a risk that the app-based mindfulness sessions may not be as effective as the other approaches for managing psychosocial symptoms associated with cancer survival.

You will find details of all the risks in the consent document that you review with your health care team.

What can I expect?

As part of the study, you will get access to the *Am Mindfulness* app and are expected to complete daily *MBCS Journey* sessions over the course of 4 weeks (20-30 minutes per day). You will complete a number of questionnaires about your mental and physical well-being before, during and after the study period.

How can I find out more or join the study?

Talk to your cancer doctor if you are considering joining this study. You can share summaries like this with them and ask if they think joining the trial may be a good option for you.

Before you join this study, you will be asked to review an Informed Consent document which will tell you more about why the research is being done and your role as a participant. You will have an opportunity to discuss anything that is not clear and ask any questions you may have.

Joining this study is entirely up to you, and you can decide to leave at any time without giving a reason. Your decision to join or leave the trial will not affect your standard medical care.

The SC.28 study is currently enrolling participants at cancer centres in Canada. For a full list of participating cancer centres please visit www.clinicaltrials.gov and search using (NCT05470010). https://clinicaltrials.gov/ct2/show/NCT05470010

