POEM (Practice Of Embracing Each Moment) STUDY
NCT03078608

04/19/2019

Methods

Setting

The POEM (Practice Of Embracing each Moment) study was conducted within Kaiser Permanente Northern California (KPNC), an integrated health care delivery system that provides comprehensive health care to a large, diverse community-based population of over 4.1 million individuals. KPNC provides coverage for approximately 31% of the northern California population, and its membership is similar demographically, ethnically, and socioeconomically to the area's overall population. The only exception is with regard to income; KPNC members underrepresent the very poor and the very wealthy. Participants for the POEM study were recruited from 7 KPNC oncology clinics in the San Francisco Bay Area.

Participants

We included patients with a diagnosis of cancer who were currently receiving or had received chemotherapy, targeted therapies, or immunotherapy in the prior 6 months. The inclusion criteria for both patients and caregivers included age ≥18 years; owning a smartphone, tablet, or computer with internet access; and understanding English. Primary informal caregivers of the patients were also eligible and invited to participate. We excluded persons who regularly meditated or prayed at least 3 times per week, were currently participating in another type of stress reduction program, were severely hearing impaired, or had severe mental illness.

Procedures

This 2-arm randomized controlled pilot trial was conducted between October 2017 and November 2018. Participants completed an online informed consent form, and study protocols and procedures were approved by the KPNC Institutional Review Board. The study was registered on ClinicalTrials.gov (NCT03078608).

Recruitment. Patients were recruited using several strategies, including clinic referrals from oncologists, oncology social workers, and nurses; brochures at each clinic; and invitation emails, followed up with phone calls. Eligible patients were identified using the KPNC electronic health record. Caregivers were recruited by patient participant referral. Patients could participate with or without caregiver participation, and caregivers could also participate without an enrolled patient. Participants who completed the study received a $40 gift card and a year's subscription to the mindfulness program used for this trial.

Randomization. Participants were allocated to the 2 study groups using simple balanced blocked randomization, stratified by facility. Randomization was implemented by use of allocation assignment concealed in a set of sequentially numbered opaque envelopes filled by research personnel not affiliated with the trial. Caregivers who enrolled with a patient participant were assigned to the same arm as the patient.

Intervention. Participants in the intervention arm received free access to a commercially available mindfulness program, Headspace™ (www.headspace.com), for 8 weeks. Headspace is a self-paced program that provides guided mindfulness meditation instructions via a website or mobile application (iOS and Android). Research staff emailed participants randomized to the intervention arm device-specific instructions for downloading the Headspace app and information about the program. Research staff checked in with participants over the phone a few days after emailing the instructions and provided support for setting up Headspace over the phone, if needed.

Participants were asked to complete Headspace sessions on a daily basis during the 8-week intervention. They were encouraged to first complete the 30-day Foundation Course, which teaches users the basics of mindfulness meditation, then the cancer pack, which was designed specifically for individuals affected by cancer. They also had the option to choose other 10- to 30-day courses that are more condition- or situation-specific, such as "Anxiety," "Stress," "Acceptance," "Relationships," or "Sleep," or single meditation sessions. All Headspace courses teach mindfulness using various basic techniques, including breathing exercises, body scan (to mindfully pay attention to different parts of one's body—one of the most basic exercises in the MBSR program), noting (being aware of any emotions that may be arising at the moment), and visualization (visualizing images such as sun shining on the entire body). The length of the sessions can be set from 10 to 20 minutes. The length was initially set to 10 minutes for all participants. In addition to the daily, progressive audio instruction, there are short (1-2 minutes) lecture videos every several days designed to increase the understanding of mindfulness and to encourage its integration into daily life. Headspace can be set up to send reminders using push notifications, and study staff made phone calls if an intervention participant completed fewer than 3 Headspace sessions in a week.

Wait-list Control Arm. Participants randomized to the waitlist control arm received usual care and were asked not to start any stress reduction programs during the study period. On completion of the 8-week survey, the control participants were provided with a year's subscription to Headspace and instructions on downloading the app.

Outcome Measures

Retention. The retention rate was measured as the proportion of enrolled participants who completed the 8-week survey (the primary outcome time point).

Adherence. The Headspace program automatically collects adherence data, including date, time, length, and name of each session to which participants listened, identified by a study ID. Headspace transferred these adherence data to the researchers monthly during the study. Using these data, we calculated the proportion of days during the 8-week intervention period that each participant used the program for any amount of time.

Participant-Reported Measures. We collected outcome data using self-administered online surveys using DatStat software (DatStat Ilume, version 6.1.18.19, Seattle, WA) at the time of consent (baseline survey) and immediately post-intervention (8-week survey) using validated questionnaires as follows.

Distress. The NCCN Distress Thermometer was used to assess current distress level. Respondents were asked to rate their level of distress during the past week by choosing a number, with 0 indicating no distress and 10 extreme distress.

Anxiety and depression. We used the 14-item Hospital Anxiety and Depression Scale (HADS) to assess anxiety and depression. Higher scores indicate greater anxiety and depression.

Pain. The PROMIS Pain Intensity numeric rating scale asks participants to rate average pain level in the past 7 days on a scale of 0 ("no pain") to 10 ("worst imaginable pain"). The 8-item PROMIS Pain Interference scale assesses extent to which pain interfered with functional activities during the past 7 days. Higher scores indicate more interference due to pain.

Sleep quality. The 8-item PROMIS Sleep Disturbance scale assesses sleep disturbance during the past 7 days. A higher summary score indicates worse sleep disturbance.

Quality of life. We used the 27-item Functional Assessment of Cancer Therapy General Scale (FACT-G) to assess QoL in patients. FACT-G asks respondents to rate their QoL in 4 domains (physical, social/family, emotional, and functional well-being). Caregiver QoL was determined using the Caregiver Quality of Life Index–Cancer (CQOLC) scale. The CQOLC gauges the daily and overall impact caregiving has on respondents' QoL. Higher scores indicate better QoL on both scales.

Fatigue. The 9-item Brief Fatigue Inventory assesses the severity and impact of fatigue on various aspects of life in the past 24 hours. Higher scores indicate greater fatigue.

Posttraumatic growth. The 21-item Posttraumatic Growth Inventory (PTGI) assesses 5 factors of posttraumatic growth, positive change experienced because of a traumatic event or crisis—relating to others, new possibilities, personal strength, spiritual change, and appreciation of life. Respondents are asked to rate to what extent they have seen the listed changes as a result as a crisis in their lives. We modified the wording to ask about changes as a result of their (patients) or their loved one's (caregivers) cancer diagnosis. Higher scores indicate greater post-traumatic growth.

Mindfulness. The 24-item Five Facet Mindfulness Questionnaire–Short Form (FFMQ-SF) measures 5 factors representing elements of mindfulness: observing, describing, acting with awareness, nonjudging of inner experience, and nonreactivity to inner experience. Higher scores indicate greater mindfulness.

Post-Intervention Interview. We conducted phone interviews with participants after they completed the 8-week intervention period to obtain qualitative feedback regarding the study. Question topics included benefits of using Headspace, things they liked about Headspace or thought could be improved, suggestions for improving the experience of study participants, and experience being in the wait-list control arm.

Data Analyses

Data from patient participants and caregiver participants were analyzed separately. We described baseline distributions between arms. Retention rates were calculated by dividing the number of participants who completed the 8-week surveys by the number of randomized participants. We used the program usage data collected by Headspace to calculate intervention adherence rates—the percent of days within the 8-week intervention period that participants engaged in at least one Headspace session of any length.

To obtain preliminary efficacy results, we performed repeated measures analysis of variance tests comparing change in outcome measures between baseline and 8-week follow-up survey between intervention and control arms using all participants who completed both surveys. Cohen's *d* effect size was calculated by taking the difference between group mean change scores and dividing by the pooled standard deviation. All analyses were intent-to-treat. As a pilot study, this randomized clinical trial was not adequately powered to detect statistically significant differences between groups. As such, standardized effect sizes were calculated to demonstrate effects and trends. Effect sizes of approximately 0.2, 0.5,

and 0.8 are generally considered small, medium, and large effects, respectively.

As a supplementary analysis, we conducted dose-response per-protocol analyses, repeating the analysis but stratifying intervention participants by level of adherence to the mindfulness intervention protocol (percent of days during intervention period used Headspace: <50% and ≥50%) and comparing with the control participants.

Interviews were transcribed and uploaded into Nvivo 12 software. Inductive thematic analysis was employed to identify and develop codes on themes related to mindfulness benefits, the interface experience, the cancer patients'/caregivers, perspective of mindfulness. One primary coder (MM) initially coded each interview and met with a secondary coder (AA) to discuss the coding, identify disagreements, and ensure accuracy of codes. This article focuses on the feasibility component of the qualitative interviews.