ABC Neuroscience Virtual Summer School
New Advances in Online Research Methods
17th – 18th of August 2021

The effects of internet-supported mindfulness-based cognitive therapy on brain-derived extracellular vesicles and psychological distress in cancer: A study protocol

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Introduction

- Distress, an unpleasant affective and common experience in people with cancer since the diagnosis to the point beyond illness remission, is recognized to have a detrimental effect on quality of life (Muzzati, Bomben, Flaiban, Piccinin, & Annunziata, 2020; Ravindran, Shankar, & Murthy, 2019).
- Mindfulness-based interventions (MBIs) have been showing promising results in people diagnosed with cancer, fostering improvements in multiple health-related and psychosocial variables, including reductions in distress, depression, anxiety, fatigue, and improvements in quality of life, sleep quality, post-traumatic growth, and mindfulness abilities (e.g., Cillessen et al., 2019). Thus, MBIs can be an important tool in the management of cancer distress.
- Most of the beneficial evidence have been obtained in the context of face-to-face MBIs, but technology-mediated MBIs are receiving increased attention, especially considering that not all cancer patients and survivors have access to face-to-face MBIs (Tate, Newbury-Birch, & McGeechan, 2018) and the challenges imposed by the current pandemic situation (Kubo et al., 2020).
- Nonetheless, few randomized controlled studies have tested online MBIs, their effects on biological parameters, and related long-term effects.
- **Objective:** To probe the effects of internet-supported mindfulness-based cognitive therapy (MBCT) vs. treatment as usual (TAU) on brain-derived extracellular vesicles (EVs) and psychological distress in people with history of breast, colorectal or prostate cancer (ClinicalTrials.gov Identifier: NCT04727593).

Methodology

Participants

At least 111 participants complying with the following criteria:

- Diagnosis of breast, prostate, or colorectal cancer (cancer stage I to III);
- Primary cancer treatments completed between 3 months to 5 years previously (ongoing hormonal therapy will be included);
- Experience of significant distress at the time of inclusion (Distress Thermometer - DT ≥ 4);
- Willingness to accept randomization to one of the two study conditions and participation in the intervention and data collection for the duration of the study;
- Ability to speak, read, and write in Portuguese and literacy to autonomously complete the self-report measure;
- Sufficient digital literacy and access to a device (e.g., smartphone; tablet; computer) with a camera, microphone, and internet.

Study design

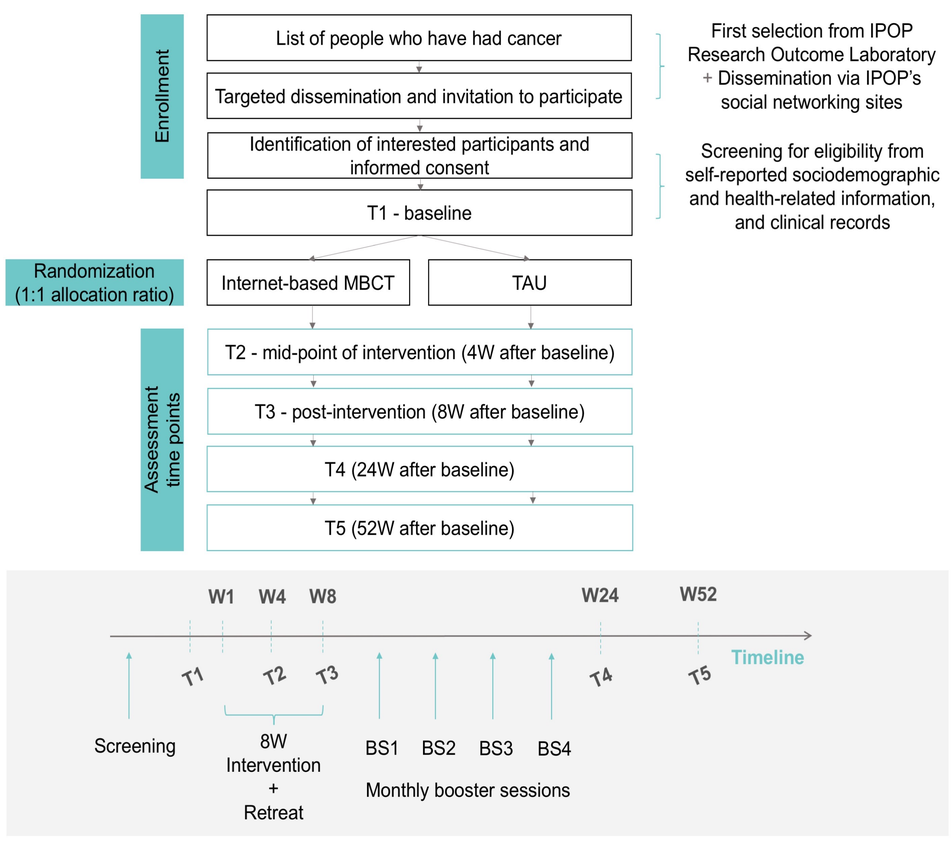


Figure 1. Study design and participant flow diagram (BS: Booster Session; IPOP: Instituto Português de Oncologia do Porto; MBCT: Mindfulness-Based Cognitive Therapy; TAU: Treatment as Usual; W: Week).

Outcome measures

Primary

Subjective
- Psychological distress

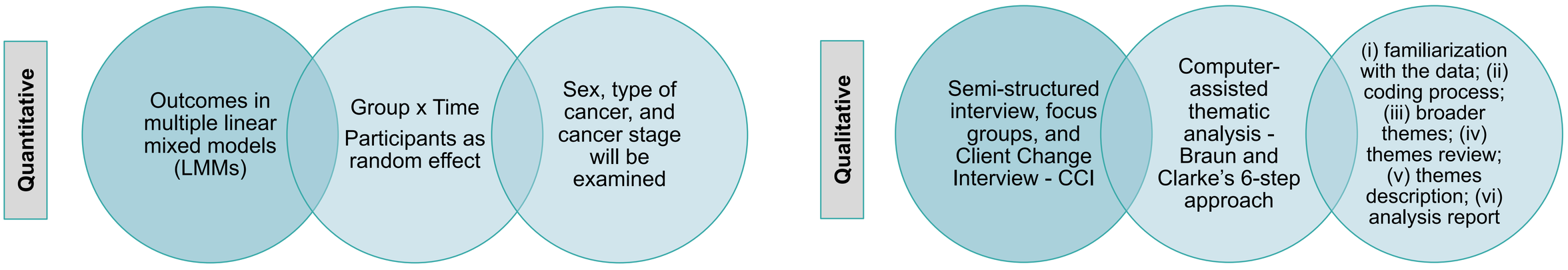
Objective
- EVs cargo

Secondary

Subjective
- Quality of life
- Fear of cancer recurrence
- Emotion suppression
- Mindfulness abilities
- Sleep quality
- Posttraumatic growth
- Health-related behaviors
- Perceived social support

Objective
- Immunological response (interleukins IL-1, IL-6, IL-8, IL-10, IFN-γ, and TNF, and C-reactive protein)

Analysis plan



Final considerations

- This study will allow to better characterize the effects of internet-based MBCT on psychosocial and biological indicators in the context of cancer. This contribution is relevant given the paucity of randomized controlled studies testing online MBIs.
- Remarkably, the effects of MBCT on the cargo of brain-derived EVs will be studied for the first time, allowing to explore a novel neurobiological mechanism supporting mind-body interactions.

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This study is funded by the European Commission, Horizon 2020, H2020-FETOPEN-2018-2020, programme Novel ideas for radically new Technologies RIA. Research and Innovation, Action proposal number 829040.

GA 829040
European Commission
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