The impact of COVID-19 on cognitive and emotional health amongst women living with breast cancer

Protocol Version 1.1 /20th April 2020

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Ethical approval
The study has received approval from the Research Ethics Committee of the Department of Psychological Sciences and the College Research Ethics Committee at Birkbeck College, University of London (reference number: 192078) as well Economic and Social Research Council (Grant number: ES/P000592/1).

Project Summary
As a result of the Coronavirus Disease (2019) outbreak (COVID-19), many oncology services and appointments such as scans have been postponed or cancelled. In addition to the disruption to oncology services, the UK Government and health care officials have also executed a 12-week social restriction and isolation plan for any individual over the age of 70 or anyone with known underlying
health conditions including, women living with breast cancer. The current study, therefore, aims to examine the effects of the COVID-19 outbreak on women living with breast cancer in the UK. Women recruited through online support centres will be asked to complete a short session of online questionnaires assessing their current cognitive and emotional vulnerability.

**Rationale**
Given that the body of existing research has shown that women living with breast cancer are at a greater risk of developing clinical affective disorders such as anxiety and depression as well as suicidal behaviours it is of great importance that we examine the impact of the COVID-19 outbreak on emotional and psychological health. By understanding the level of vulnerability generated by this outbreak we will be able to make more informed suggestions about ways to promote emotional resilience.

**Objective**
This cross-sectional study aims to explore the impact of the COVID-19 outbreak is having on the cognitive and emotional health of women living with a diagnosis of breast cancer. In particular, the study will explore the effects of the disruption to oncology services and the UK Government shielding letter.

**Methodology**
The study will employ a cross-sectional design. For this study, participants will be instructed to complete a battery of online questionnaires designed to measure their perceived cognitive and emotional health as well as their COVID-19 generated emotional vulnerability (COVID-EMV). On completion, each participant will be asked to provide a preferred email address for their £5 e-gift voucher to be sent.

**Questionnaires**
1. **Demographic questionnaire (DQ)** – Collects demographic information regarding the participant's breast cancer history, sociodemographic (i.e. education) as well as their work.
2. **Modified Self-Report-Generated Charlson Comorbidity Index** (Charlson et al., 1987) – Short self-report questionnaire used to assess and identify the comorbidities experienced by an individual.

3. **Functional Assessment of Cancer Therapy-Cognitive Scale** (FACT-Cog, version 3; Wagner et al, 2009) – Self-report questionnaire composed of 37-items that measure the perceived cognitive ability of cancer patients and the impact that these difficulties/changes have had on their quality of life in the last week.


5. **Hospital Anxiety and Depression Scale** (HADS) (Zigmond and Snaith, 1983) – Standardised self-report questionnaire used in clinical and research settings to assess the severity of anxiety and/or depression symptoms experienced in the last 7 days.

6. **Health Anxiety Inventory** (HAI; Salkovskis et al., 2002) – Self-report inventory used in clinical and research settings to assess the symptoms of health anxiety experienced as well as an individual’s attitude towards developing a particular illness.

7. **Penn State Worry Questionnaire** (PSWQ; Meyer et al., 1990) - Self-report questionnaire composed of 16-items measuring trait worry on a Likert scale from one (‘not at all typical of me’) to five (‘very typical of me’).

8. **Work Limitations Questionnaire** (WLQ; Lerner et al, 2001; 2003) – Self-report instrument composed of 25-items that examine the work limitations experienced by individuals with health-related problems and health-related productivity impairment over the last 2 weeks.

9. **COVID-19 Impact Questionnaire** – Self-report questionnaire assessing the impact of the COVID-19 outbreak on women with a diagnosis of breast cancer including, the impact on treatment, work ability and emotional wellbeing.

**Participants**

Women diagnosed with breast cancer (N = 300) over the age of 18 will be recruited through voluntary sampling using advertisements placed on social media support groups including, the BRiC Centre, Breast Cancer Now and Macmillan.

**Inclusion Criteria**
• Women living with a diagnosis of breast cancer.
• At any stage of treatment or diagnosis
• Aged 18 or over.
• Employed, self-employed, volunteering or currently not undertaking any form of work

Exclusion Criteria

• Women under the age of 18.
• Women not diagnosed with breast cancer.

Data Management

Only the four researchers involved with the study will have access to the data collected. All data will be anonymised - participants will be provided with a randomly generated number which will be referenced in place of their name in all stored data files. In addition, participants will be asked to refrain from providing any identifiable information such as their name or the name of their employer. The data will be stored in an encrypted file to ensure that the confidentiality of the participants is maintained. All data from this study will be kept only for a duration of three years. Emails sent between the researcher and the participants will also be sent from and stored in an encrypted account (as approved by the college).

Ethical Consideration

Informed consent will be collected from all participants at the start of their online session and participants will not be able to access any of the questionnaires before consent has been provided.

There is a minimal risk associated with this study as the online questionnaires are designed to ask non-distressing questions regarding various aspects of the participants cognitive and emotional health. To alleviate any stress created at the end of the study participants will be asked to write three things they feel positive about despite the outbreak. This is an alleviating method that is currently being employed by Professor Derakshan at the BRiC centre.

All of our participants will be provided with the contact details of the four researchers as well as sources of support available. Professor Derakshan is founder and director of the BRiC centre at
Birkbeck University of London and Professor Beth Grunfeld is an internationally renowned expert in the field of psycho-oncology.

**Analysis plan**

Statistical analyses will be performed using the Statistical Package for the Social Sciences (SPSS, version 25). Descriptive statistics will be conducted for the sociodemographic and clinical characteristics. Demographics will then be considered using Chi-square tests.

ANOVA’s will be utilised to examine the impact of the disruption to oncology services and the UK Government shielding letter on cognitive and emotional health as well as COVID-19 generated emotional vulnerability (COVID-EMV). Follow-up independent t-test will be performed to explore the disruption to oncology services on women’s level of general anxiety, depression, perceived cognitive function and COVID-EMV.

Finally, three-stage hierarchical regression analyses will be conducted to examine the relationships between COVID-EMV and three dependent variables: anxiety, depression and perceived cognitive function after allowing for the effects of a series of sociodemographic and clinical predictors.