

Project Title:

Implementing a group based online mental wellbeing program for breast cancer survivors - a mixed methods pilot study

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Declaration

This dissertation contains no material which has been accepted for the award of any other degree or diploma in any University, and, to the best of my knowledge, contains no materials previously published except where due reference is made. I give permission for the digital version of my dissertation to be made available on the web, via the University's institutional digital repository, the Library Search and also through web search engines, unless permission has been granted by the School to restrict access for a period of time.

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June 2023

Statement of Contribution

In writing this thesis, my primary and secondary supervisors collaborated with me to discuss the design of the study and appropriate methodology. I conducted the literature search, the quantitative analysis, coded all the interview transcripts and created the qualitative categories. I identified the relevancy of this research and wrote up all aspects of the manuscript. My secondary supervisor overlooked the project.

Title page for the Journal of Supportive Cancer Care

Implementing a group based online mental wellbeing program for breast cancer survivors - a mixed methods pilot study

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Author Note: This article is intended for submission to Journal of Supportive Care in Cancer which requires the article to be no more than 3500 words, with 45 references or less and all in-text references to be numbered consecutively in order of appearance using the specified referencing format. At present, the article has been written according to the Master of Psychology (Health) thesis requirement of 6,000-8,000 words and contains more than 45 references but will be edited prior to submission to meet the above requirements.

Abstract

Purpose: There is a gap in the mental wellbeing services in Australia available to breast cancer survivors, which can reduce distress and help to navigate a new sense of normality beyond a cancer diagnosis. This mixed-methods uncontrolled pilot study aimed to explore the effectiveness of an online mental wellbeing intervention, the Be Well Plan (*BWP*), and explore the experiences of women with breast cancer.

Methods: Women diagnosed with stages 1-IV breast cancer were recruited to participate in the *BWP*, a 5-week group-based mental health program designed to help people develop a personalised wellbeing strategy. Multivariate analysis of variance (MANOVA) and effect sizes were calculated on pre- and post-psychological measures. Following completion, interviews were conducted and qualitative content analysis was undertaken to address research aims.

Results: Nineteen women (mean age 45.7, $SD=7.74$) were included in the study. Large effect sizes were reported for mental wellbeing, self-compassion, depressive symptoms and anxiety. Resilience and quality of life results were not statistically significant. Qualitative content analysis resulted in six categories: *Program Delivery Experience*, *Application of the BWP*, *Mental Health Improvements*, *Supporter Involvement*, *Adopted Interventions* and *Recruitment*, and 44 subcategories. Participants reported benefits in mindfulness, grounding techniques and physical activities. Improved social connectivity and post program follow up were recommended for future groups.

Conclusion: This study supports the potential of the *BWP* as an effective intervention to support people living with breast cancer to improve mental wellbeing and alleviate distress. This study supports the need for flexible interventions that accommodate the diverse needs of consumers.

Key words: mental wellbeing, breast cancer, survivorship

1. Introduction

1.1 Breast cancer survivors

With over 2.3 million women diagnosed in 2020 internationally, breast cancer is the most prevalent cancer for women [1]. Breast cancer survival rates have significantly improved due to early diagnosis and treatment options, with 92% of women surviving five years post-diagnosis equating to over 7.8 million women worldwide [1,2]. This increases the need for breast cancer survivorship care; that is care, that facilitates the transition from focusing on disease treatment to health maintenance and managing issues following the initial cancer treatment [3]. Research has shown that survivors of breast cancer are at an increased risk of experiencing psychological distress (symptoms of depression and anxiety) and reduced mental wellbeing during diagnosis and active treatment. However, the needs of the breast cancer survivor persist well beyond initial treatment leading to significant levels of psychological distress for the survivor and their families [4,5]. When applying the biopsychosocial model, the mental health of people living with or beyond breast cancer is influenced by their unique physical, social and psychological considerations [6]. Unique to every cancer survivor is an arduous experience influenced by physical side effects, social implications and subsequent psychological impact that affect quality of life (QoL) [7].

Firstly, the person's physical functioning is impacted by the cancer as well as the adverse effects and persistent symptoms of treatment, which can result in chronic pain, fatigue, decreased strength, lymphoedema, as well as hormone-induced symptoms [8]. These physical side effects can have a negative impact on sleep quality for people with cancer, with a recent study showing significant sleep disturbance, including insomnia were common, with medication, physical distress, emotional distress, economic distress, and fear of recurrence being contributing factors [9]. Furthermore, studies have shown that cancer-related cognitive decline, often referred to as *chemobrain* [10], may lead to cognitive deficits in memory, language and processing speed which is reported to affect the person's sense of identity and ability to engage socially, thus requiring a significant adjustment to a new sense of normality in survivorship [11].

Secondly, survivors have reported changes in their identity or altered body image when losing one or both breasts from mastectomy, also being viewed as a loss of femininity [12]. Body image, as well as the side effects of treatment, may result in loss of sexuality and sexual pleasure which may lead to difficulties with intimate relationships [13]. Additional social factors reported to have impacted survivors' QoL include the financial burden of treatment, medical procedures and scans with studies showing that individuals are at risk of ongoing out of pocket costs [14]. The ability for physical self-care and maintaining lifestyle factors such as hobbies and spending time with children and grandchildren can also be compromised [15]. Conversely, social support is a protective factor for cancer

survivors, with studies showing that partnership status and support from family and friends is associated with adaptive coping strategies and can improve long term QoL during survivorship [16,17]. Involving the person in decision-making regarding treatment options is also argued to be a predictor of mental health outcomes in survivorship [18].

Lastly, studies have also shown that breast cancer survivors are at a higher risk of a wide range of adverse mental health outcomes, including depression, anxiety, neurocognitive and sexual dysfunctions, and suicide [19] for up to ten years post-diagnosis [20], demonstrating that psychological distress is a concern when coping with the long-term impacts of breast cancer survivorship [21]. A study of 300 female breast cancer survivors found that over 40% were depressed and were four times more likely to experience work productivity loss and lower work ability, having implications for long-term financial security, and social support for women experiencing depression as a result of their diagnosis [22]. A systematic review of the unmet needs of people who have had cancer in Australia found that up to 42% fear cancer recurrence and progression caused by feeling uncertain about the future and worrying about partners, family and friends [23].

Consistent with continual reports of women experiencing distress during survivorship, more care is required to support the increasing number of breast cancer survivors following the completion of initial cancer treatment [24]. This care is recommended to include a greater focus on recovery, health and wellbeing after cancer treatment as well as a shift towards self-management to empower individuals to take on more responsibility for their condition [25]. This has been further supported with models advocating for self-management through proactive support and education, as well as a shift away from an acute care medical model [26].

1.2 Challenges with current health care services for breast cancer survivors

Due to the increasing number of breast cancer survivors and the duration of survivorship, it is argued by Vardy et al [27] that a more sustainable model of health care services is needed, with a stronger emphasis on (emotional) support [27]. At present, breast care clinicians and family and friends are reported to be the most utilised support during survivorship in Australia, with minimal uptake of other multidisciplinary services, argued to be because survivors are unaware of the services and are not commonly referred to them [25]. A recent study by Keesing, Rosenwax and McNamara [28] in Australia examined the adequacy of healthcare services for breast cancer survivors who had received a breast cancer diagnosis and completed active treatment within the last five years. The study reported a variety of physical, psychological and emotional unmet needs of women and their partners as they transitioned into survivorship with ongoing difficulties returning to previous roles, employment, hobbies and intimacy with their partner, ultimately affecting their wellbeing. The authors argued that whilst there are a range of

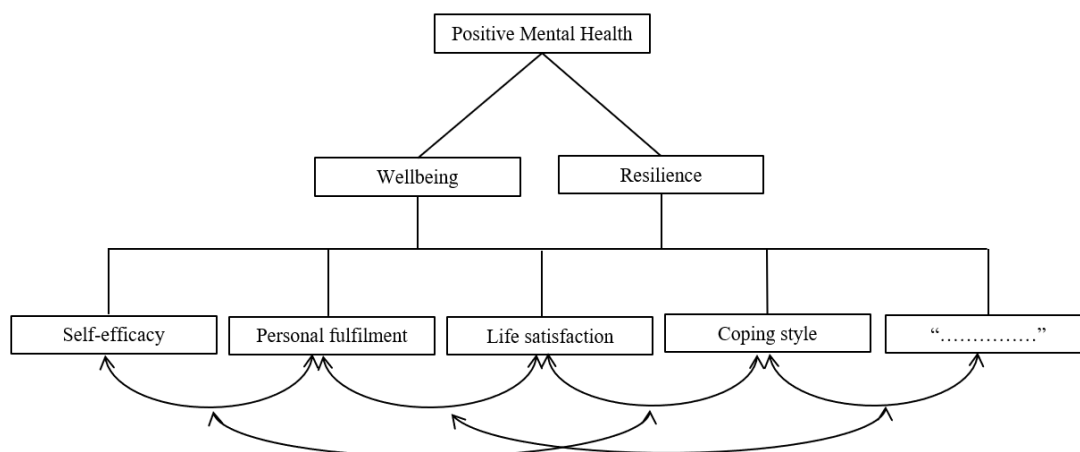
services available to cancer survivors, the barriers to accessing those supports extended to poor identification of the needs of the survivor and referrals by treating health professionals, unclear referral pathways and limited awareness of the services [28]. Furthermore, a recent systematic review of cancer survivorship found efforts are still required to support the health and mental wellbeing of cancer survivors [29]. It is argued that increased efforts are fast-needed to promote the wellbeing for survivors and their caregivers to support them in transitioning into mainstream life and enjoying a better QoL [30].

The above mentioned problems are compounded for people who live outside of metropolitan areas. Due to high demand, it is often difficult for individuals with psychological distress to access psychological services in rural and regional Australia [31]. Psychosocial support in rural and remote settings in Australia is limited throughout survivorship care with a large burden continuing to be placed on the person and their families to travel for services despite an increase in internet reliance for information and services [32]. The lack of post-treatment pathways is argued to be a contributing factor to the poor QoL of rural cancer survivors in rural Australia with recommendations for more digital healthcare services [33].

1.3 The role of positive mental health in breast cancer survivorship

The mental health of cancer survivors is a growing field of interest due to the increased demand from consumers for different types of support throughout their cancer survivorship [34]. Most cancer research focuses on indicators of psychological distress and QoL [35,36], with less attention being paid to indicators of *positive* mental health, despite the fact that it offers a different approach to building someone's psychological health, which may be particularly suited to breast cancer survivors. Positive mental health is an umbrella term that refers to various psychological constructs that are associated with positive functioning, including eudaimonic wellbeing (which includes areas such as personal fulfillment, meaning and purpose, and mastery [37] and hedonic wellbeing (which includes areas such as life satisfaction and positive emotions [38] as well as resilience (which captures an individual's ability to draw upon resources to overcome adversity [39], see Figure 1 for an illustration of the constructs of positive mental health. Whilst outcomes of positive mental health are interrelated with outcomes of mental illness and psychological distress, positive mental health is argued to be a distinct domain of mental health (40), and a protective factor for developing a future mental illness [41].

Figure 1: Illustration of the constructs of positive mental health



Mental wellbeing development could be targeted through a variety of methods, such as psychological functioning, meaning in life and personal growth [42] to improve the QoL of individuals beyond diagnosis. The literature on the benefits of mental wellbeing in cancer survivors is growing, with improvements of mental wellbeing associated with mitigating depressive symptoms, anxiety and fatigue as well as lowering perceived stress [43]. Studies have shown that breast cancer survivors can experience psychological and physical benefits from interventions focused on meaning making through creating adaptive meaning from their cancer experience [44], as well as to manage emotions by focusing on positive copying styles and the emotional impact [45].

Mindfulness has been shown to significantly improve mental wellbeing and lower distress, with a recent systematic review of breast cancer survivors showing improvements in depression, fatigue and stress [46], with supporting evidence showing benefits in cognitive functioning [47]. A further meta-analysis of mindfulness-base stress reduction found moderate-to-large effect sizes in reducing perceived stress, depression and anxiety in breast cancer [48].

Additionally, resilience is a protective factor in breast cancer survivors and can facilitate adapting to a life beyond a cancer diagnosis, an important factor in wellbeing [49]. Resilience in breast cancer survivors has been found to mitigate distress associated with negative body image, better self-esteem and body image satisfaction after mastectomy [50]. Family and individual resilience is also argued to ease caregiver burden amongst families of breast cancer survivors [51]. A systematic review exploring what aids QoL and resilience of breast cancer survivors found that psychological interventions such as self-management training, involvement of social support, assessment of resilient qualities and planning can improve QoL, mental wellbeing and resilience, which enables women to navigate their new sense of normality [52].

One particular concept of interest to researchers for breast cancer survivors that is linked to positive mental health is self-compassion. Self-compassion has been found to be a protective mental health factor, as reported in a systematic review and meta-analysis, to significantly improve psychosocial outcomes including rumination, stress, depression and self-criticism [53]. As described by Neff and Knox [54] self-compassion consists of three central components: self-kindness versus self-judgment, common humanity versus isolation, and mindfulness versus overidentification. Self-compassion in breast cancer survivors has been found to be effective in body image disturbance, perceived stress and self-care [55,56].

1.4 Online psychological interventions

When designing mental health solutions for breast cancer survivors, a number of formats can be considered. One particular format is online psychological interventions, as these have been shown to have a growing evidence base. For example, a meta-review by Leslie et al [57] showed that internet-delivered interventions can have merit in ameliorating symptoms of psychological distress associated with cancer survivorship as well as increasing mental wellbeing. Individuals living with a breast cancer diagnosis are reported to be open to online interventions for addressing their psychological and emotional needs [57,58]. A recent study found a significant effect on depression and anxiety when delivering internet-based mindfulness cognitive therapy, with sustained decreased anxiety at six months [59]. Furthermore, a study exploring a mobile meditation app argued that forming regular meditation habits delivered significant mental health benefits, which increased with more considerable improvements for those who practiced meditation more frequently [60]. The formation of implementation intentions has been argued to support individuals achieve their goals in a mental health setting [61] and enabled women with breast cancer to achieve sustainable behavioural changes [62].

A particularly interesting angle may be to combine online interventions with elements from other effect intervention formats. For example, group-based interventions have been demonstrated to create a network of connections between the participants and facilitator due to the reciprocity of sharing knowledge and information [63]. Other studies have demonstrated that peer groups facilitate the understanding and application of psychological interventions, as well as promote social support in breast cancer survivors [64]. The quick rise of teleconferencing software and the ability to host group sessions has made it technologically feasible to deliver online group-based mental health interventions.

Caregivers also experience distress associated with the family member's illness with the role of a caregiver extending to physical, emotional and tangible support as well as coping with their own feelings of anxiety and distress associated with the unknown [65]. Family and caregiver participation in psychological interventions has

been demonstrated to benefit the individual and the caregivers [66]. Family-based interventions which involve both the individual and caregivers can enhance communication and overcome barriers to sensitive topics such as fear about the future, support and reinforcement of treatment and address maladaptive coping responses [67]. Studies have also shown that caregivers benefit from psychological interventions, including increased emotional wellbeing [68].

1.5 Purpose of this study

With increased numbers of individuals living with a breast cancer diagnosis there is a need to explore alternate evidence-based mental health solutions. Despite growing research showing the benefits of mental wellbeing, there remains a gap in how mental wellbeing interventions can be used to complement traditional models of support. This mixed-method study had two aims: the first aim was to test the effectiveness of an online group-based mental health program (the Be Well Plan (*BWP*)) in improving the mental health outcomes of those living with and beyond breast cancer. The second aim was to explore the qualitative experiences of breast cancer survivors to explore the integration of mental wellbeing solutions into existing services.

2. Method

2.1 Ethics approval

Ethics approval was granted (Flinders University HREC Sub-committee #4866, and noted by the University of Adelaide HREC sub-committee #36368). Participants were informed about the nature and content of the study prior to providing their consent to participate, including a warning of the potential risk of emotional stress and their right to withdraw from the study at any time. Participant confidentiality was ensured, and all collected data were coded and stored in a protected database. Written informed consent was obtained from each participant.

2.2 Participants and recruitment

Women diagnosed with stages I-IV breast cancer were invited to take part in the *BWP* across Australia. Inclusion criteria were as follows: women diagnosed with breast cancer in the last 3 years, age 18 years and older, internet access and fluent in English. Recruitment of participants was via social media, as well as through Cancer Voices South Australia and South Australian Health and Medical Research Institute (SAHMRI), which included a webpage containing a video introducing the study and information on the project.

2.3 *BWP* intervention

The SAHMRI Be Well Co team has developed the *BWP*: a mental health program designed to help people develop their own wellbeing strategy, made up of evidence-based activities that participants choose to best suit them and

their current situation [69]. The program is delivered in a group-based setting and can be delivered online or face to face, meaning that it can be delivered cost-effectively to large numbers of people in need, and in remote and hard to reach settings.

The *BWP* is a weekly, 5-session internet-based, group-facilitated intervention that aims to improve mental health and wellbeing, as previously described by van Agteren et al [70]. The program, delivered by an accredited *BWP* facilitator, enables participants to develop an individualised wellbeing plan tailored to their unique circumstances and needs. Participants are introduced to 30 evidence-based activities and skills [71] to improve their mental health and wellbeing, which are drawn from a number of therapeutic approaches including CBT, ACT, mindfulness, and positive psychology. The weekly sessions follow a format consisting of psychoeducation, self-reflection, and sharing between participants. As part of the *BWP*, participants are invited to complete a brief survey to receive insights on their mental health and wellbeing via a platform called the *Be Well Tracker*. After completing the survey, participants received a detailed report about their levels of wellbeing, resilience, and distress, which provided them with psychological insights they could use within the program. Outcomes from the *Be Well Tracker* were used within the intervention only, not for examining the efficacy of this study.

2.4 Procedure

A consultation process was undertaken prior to the commencement of this study to ensure all study materials and training content were adapted in a way that would be appropriate for breast cancer survivors. Meetings were held with five individuals with lived experience (survivors and caregivers) via the Health Translation SA Consumer Engagement Group as well as clinicians, researchers and lived experience representatives from the Primary Care Collaborative Cancer Clinical Trials Group (PC4) Consumer Group. They provided critical insight into the way the program recruited participants and inclusion criteria in the study. No changes to the *BWP* intervention were necessary for this pilot study.

Participants completed an online EOI including general demographic questions (age, gender, employment status, breast cancer diagnosis, treatment history, mental health support), preferences of the *BWP* (online or face to face, time of attendance), interest in bringing a support person and the mental health continuum short form (MHC-SF) (70). Once participants provided their written informed consent they completed an online baseline assessment on measures including mental wellbeing using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) (71), resilience using the Brief Resilience Scale (BRS) [72], self-compassion using the Self Compassion Short Form (SCS-SF) [73], depression using the 9 item Patient Health Questionnaire (PHQ-9) (74), anxiety using the 7-item

General Anxiety Disorder scale (GAD-7) [75], and health related QoL (EORC-QLQ-C30) [76]; see a detailed description for outcome measures below. The baseline survey included 78 questions.

Participants received a welcome email the week prior to the intervention, inviting them to participate in the weekly 5-session, group-based program. A hardcopy workbook was posted out to them and they were invited to download the *Be Well App*; a wellbeing scheduling tool used to complement the *BWP*. Both groups were delivered online via Zoom to make it accessible for participants across Australia and to be considerate of local COVID-19 and Influenza outbreaks. Two individual groups were delivered by accredited *BWP* facilitators between June 2022 and October 2022. *BWP* facilitators go through a rigorous training and accreditation process to ensure that the program adheres to the intervention protocol and follow the weekly content as described by van Agteren et al. [77]. Prior clinical skills or education is not required for accreditation. Group 1 contained 2 facilitators, one with lived experience as a breast cancer survivor, and Groups 2-4 were delivered by 1 facilitator and supported by a lived experience participant who had previously participated in the *BWP*.

Following the completion of the *BWP* (post-Session 5), participants were asked to complete the baseline assessment to capture a post-intervention result. Up to three email reminders were sent to participants to complete the assessment. Participants were also invited to attend a follow up interview via Zoom to obtain qualitative feedback on the program, in which 8 participants and 2 supports took part. The 1-hour semi-structured interview involved questions about the participant's overall experience, outcomes from the program, facilitation, format, and the involvement of a support person.

2.5 Outcome measures

The following outcome measures were used to evaluate the *BWP* and assess participants' level of wellbeing, resilience, self-compassion, depressive symptoms, anxiety and QoL.

2.5.1 Positive mental health outcomes

Mental Wellbeing

The Warwick-Edinburgh Mental Well-being Scale (WEMWBS) was used to assess mental wellbeing, including eudaimonic and hedonic aspects of wellbeing [71]. The 14-item scale asks participants to indicate how often, over the past 2 weeks, from 0 (none of the time) to 5 (all of the time) they have experienced different thoughts and feelings (e.g., "I've been feeling optimistic about the future"). Total scores range from 0 to 70, with higher scores indicating greater levels of mental wellbeing. The WEMWBS demonstrates good content and construct validity in diverse populations with adequate test-retest reliability, and good internal consistency (Cronbach $\alpha=.89$) [71].

Resilience

The Brief Resilience Scale (BRS) contains 6 questions and used to assess the ability to bounce back and recover from stress [72] (i.e., “I tend to bounce back quickly after hard times”). It is scored on a five-point Likert scale (1=strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree), with some reverse coded items. A recent study by Sánchez et al [80] found the internal reliability and construct validity to be sound in a clinical population (Cronbach’s alpha coefficient of 0.87).

Self-compassion

Containing 12 questions, the Self Compassion Short Form (SCS-SF) was used to measure self-compassion [73]. Participants respond on a five-point Likert scale from 1 (almost never) to 5 (almost always), indicating how often they behaved in the stated manner (e.g., “When I fail at something important to me I become consumed by feelings of inadequacy”). The SCS-SF has reported adequate internal consistency (Cronbach's alpha \geq 0.86 in all samples) and a reliable and valid alternative to the long-form Self Compassion Scale [73].

2.5.2 Depression and Anxiety

Depressive symptoms

Symptoms of depression was assessed using the 9 item Patient Health Questionnaire (PHQ-9) [74]. A 4-point Likert scale from 0 (not at all) to 3 (nearly every day) allows participants to report how often, over the past 2 weeks, they have experienced depressive symptoms (e.g., “Feeling negative about yourself or that you are a failure or have let yourself or your family down”). Total scores range from 0 to 27, with higher scores indicating greater levels of depressive symptoms. Good construct validity and internal consistency (Cronbach α =.86-.89) has been demonstrated, and the internal consistency is good (Cronbach α =.85) [74]. The PHQ-9 detects depression with a sensitivity of 88% and a specificity of 88% when using the cut off scores of 0-9 = no-to-mild depressive symptoms and \geq 10 = moderate-to-severe depressive symptoms [74].

Anxiety

Anxiety was assessed using the 7-item General Anxiety Disorder scale (GAD-7) [75]. Participants respond on a 4-point Likert scale from 0 (not at all) to 3 (nearly every day) on how often they have experienced symptoms of anxiety (e.g., “3. Worrying too much about different things”) over the past 2 weeks. Total scores range from 0 to 21, with higher scores indicating greater levels of anxiety. Good construct validity and internal consistency has been

demonstrated (Cronbach $\alpha=.91$), with a good internal consistency reported in this sample (Cronbach $\alpha=.85$) [77]. The GAD-7 has a sensitivity of 89% and specificity of 82% using the cut-offs scores of 0-9 = minimal-to-mild anxiety and ≥ 10 = moderate-to-severe anxiety [75].

2.5.3. Health related QoL

Quality of Life (QoL)

Health-Related QoL of participants was measured using the health related QoL questionnaire (EORTC QLQ-C30), consisting of 30 items [76]. The EORTC QLQ-C30 has five functioning scales (physical, role, cognitive, emotional, and social), three symptom scales (fatigue, nausea/vomiting, and pain), and single symptom items (dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties). A Likert scale of 1 – 4 (1 = not at all, 2 = a little bit, 3 = quite a bit, 4 = very much) is used to rate each item. Two global questions are also included that use a 7-point scale scoring (1=very poor, 7=excellent) to generate a global health status/QoL score. The summary score was calculated by calculating the mean of questions 29 (How would you rate your overall health during the past week?) and question 30 (How would you rate your overall QoL during the past week?), according to the EORTC scoring manual. Higher functioning and global health status/QoL scores indicate better health related QoL, while higher symptom scores indicate more severe symptoms [76]. Good validity and reliability has been demonstrated (Cronbach $\alpha=.85$) in breast cancer survivors [81].

2.6 Data analysis

2.6.1 Statistical analysis

Qualtrics software was used to collect survey responses [82], while IBM SPSS Statistics v27 [83] was used to conduct the statistics analysis. Multivariate analysis of variance (MANOVA) was used to analyse pre- and post-intervention differences on outcome measures rather than an individual analysis of variance (ANOVA), as there were multiple grouping and outcome variables [83].

Participants who participated in at least three sessions of the *BWP* and complete the pre and post measures were included in the analysis. The significance level was set at $p < 0.05$. Partial eta squared effect size was used to indicate magnitudes of effect. Cohen [84] has provided benchmarks to define small ($\eta^2 = 0.01$), medium ($\eta^2 = 0.06$), and large ($\eta^2 = 0.14$) effects.

2.6.2 Qualitative analysis

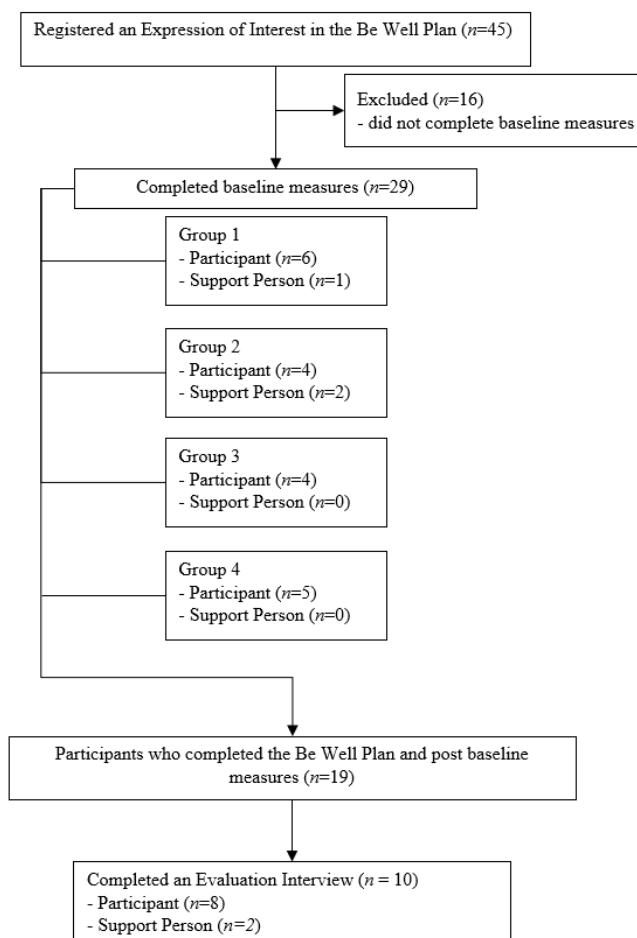
Qualitative content analysis was used to categorise the data from the interviews (see Appendix A for the interview questions), which is a systematic process to review the content of the text data, then process into codes using subjective interpretation of the content, followed by frequency counts [85]. Ten interviews (8 participants, 2 supporters) were undertaken, by the researchers, lasting between 15-45 minutes. The first author transcribed the interviews verbatim, including any grammatical errors and then NVivo© was used to organise the data. Using an inductive approach, the first step was to code the transcripts by segmenting the text into verbatim short phrases and words, which were then assigned to a code. For example, the short phrase “*It was going back and just re-focusing on my goals.*” was assigned to the code name ‘*goals and habit statements*’. This process was repeated until all text was coded. In step two, the process of examining and interpreting the data was conducted to identify similarities between categories and to identify overlaps resulting in codes being sorted according to similarities and differences resulting in 6 categories and 48 subcategories to reflect the first research aim of evaluating the *BWP*, and 5 subcategories to reflect the second research aim of exploring the experiences of breast cancer survivors. The third step involved calculating the frequencies and percentage of codes within the sub-categories, to highlight divergent ideas among participants and further sort the data. Strategies to ensure credibility and trustworthiness included the maintenance of an audit trail, regular peer review, and cross examination of 10% of codes against the raw data (by second author) for trustworthiness.

3. Results

3.1 Participants

A total of 19 women diagnosed with breast cancer were included in the study. Figure 1 outlines the participant flow in the study, with 45 women with breast cancer expressing an initial interest in the study. A wellbeing screening tool was used at this time with the intention to exclude participants who already had the highest levels of mental wellbeing, to avoid ceiling effects, however no participants were excluded from the study due to difficulties with recruitment. Of the 29 women who completed the baseline measures 10 did not commence the program. A total of 19 women participated in the *BWP* and completed the post-intervention measures. An average of 4 out of 5 sessions of the *BWP* were attended by the participants. Participants were provided with a pre-recorded video to watch in their own time if they were absent.

Figure 2: Participant flow diagram



Participants were aged between 32 and 57, with a mean age of 45.7 (SD=7.74). All of the participants were women with 37% ($n=7$) employed in paid work. See Table 2 for the timepoint of being diagnosed relative to participating in the *BWP* and the stage of breast cancer diagnosis. Treatment across the participants included radiotherapy ($n=13$, 68%), chemotherapy ($n=12$, 63%), hormone therapy ($n=12$, 63%), mastectomy ($n=11$, 58%), and lumpectomy ($n=7$, 37%). Those reporting to have seen a psychologist or psychiatrist since diagnosis was 42% ($n=8$). Those interested in bringing a supporter to the *BWP* was 5% ($n=1$), with 42% ($n=8$) reporting no interest in bringing a supporter and 37% ($n=7$) reporting “maybe”. When asked about their preference of delivery 58% ($n=11$) of participants were open to either online or face to face, 21% ($n=4$) preferring online delivery with only 1 person preferring to attend in person.

Table 1. Participant's time of diagnosis and stage of breast cancer

Characteristics	Participants (<i>n</i> =19) (%)
Diagnosed with breast cancer	
Within the past 3 months	2 (10.5)
3-6 months ago	4 (21.1)
Between 6 and 12 months ago	1 (5.3)
Between 1 and 2 years ago	4 (21.1)
Between 2 and 3 years ago	2 (10.5)
Between 3 and 4 years ago	1 (5.3)
Between 4 and 5 years ago	0 (0.0)
5 years ago and longer	3 (15.8)
Missing	2 (10.5)
Stage of breast cancer diagnosis	
Stage I	2 (10.5)
Stage II	7 (36.8)
Stage III	6 (31.6)
Stage IV	2 (10.5)
Missing	2 (10.5)

3.2 Evaluating the impact of the *BWP*

3.2.1 MANOVA on pre- and post-intervention measures

A detailed outline of the scores for outcomes measures in the *BWP* can be found in Table 2. There were significant improvements in mental wellbeing ($F_{1,18}=26.560, P=.000$), self-compassion ($F_{1,18}=7.335, P=.014$), depressive symptoms ($F_{1,18}=12.149, P=.003$) and anxiety ($F_{1,18}=14.816, P=.001$). The effect sizes were large for mental wellbeing, self-compassion, depressive symptoms, and anxiety. Resilience ($F_{1,18}=0.004, P=.948$) and QoL ($F_{1,18}=1.374, P=.256$) changes were not statistically significant.

Table 2. Pre and Post intervention measures from participants of the BWP (n=19)

Scale	Baseline	Post-Intervention	MANOVA
	Mean (SD)	Mean (SD)	
Mental wellbeing	44.6 (9.0)	53.4 (5.2)	F(1,18) = 26.560; p = .000, partial η^2 = .596
Resilience	17.7 (1.6)	17.7 (1.2)	F(1,18) = 0.004; p = .948, partial η^2 = .000
Self-compassion	3.3 (0.8)	3.6 (0.6)	F(1,18) = 7.335; p = .014, partial η^2 = .290
Depressive symptoms	18.3 (6.0)	13.6 (3.1)	F(1,18) = 12.149; p = .003, partial η^2 = .403
Anxiety	13.4 (5.0)	9.7 (2.0)	F(1,18) = 14.816; p = .001, partial η^2 = .451
Quality of life	8.5 (2.8)	9.3 (2.6)	F(1,18) = 1.374; p = .256, partial η^2 = .071

3.2.2 Evaluating the effectiveness of the BWP using qualitative content analysis

In addressing the first research aim of evaluating the effectiveness of the BWP, the qualitative feedback captured in the participant interviews was coded and arranged into six categories: *Program Delivery Experience*, *Application of the BWP*, *Mental Health Improvements*, *Supporter Involvement*, *Adopted Interventions* and *Recruitment*, as shown in Table 3. From those categories, forty-four subcategories were identified, with overlap between categories reflected in Figure 2. *Program Delivery Experience* contained the most codes representing 24% of total codes, followed by *Application of the BWP* (15%) and *Mental Health Improvements* (9%) (see Supplementary Information for count and illustrative quotes for each of the subcategories).

Figure 3. Summary of categories and themes in evaluating the BWP using qualitative content analysis

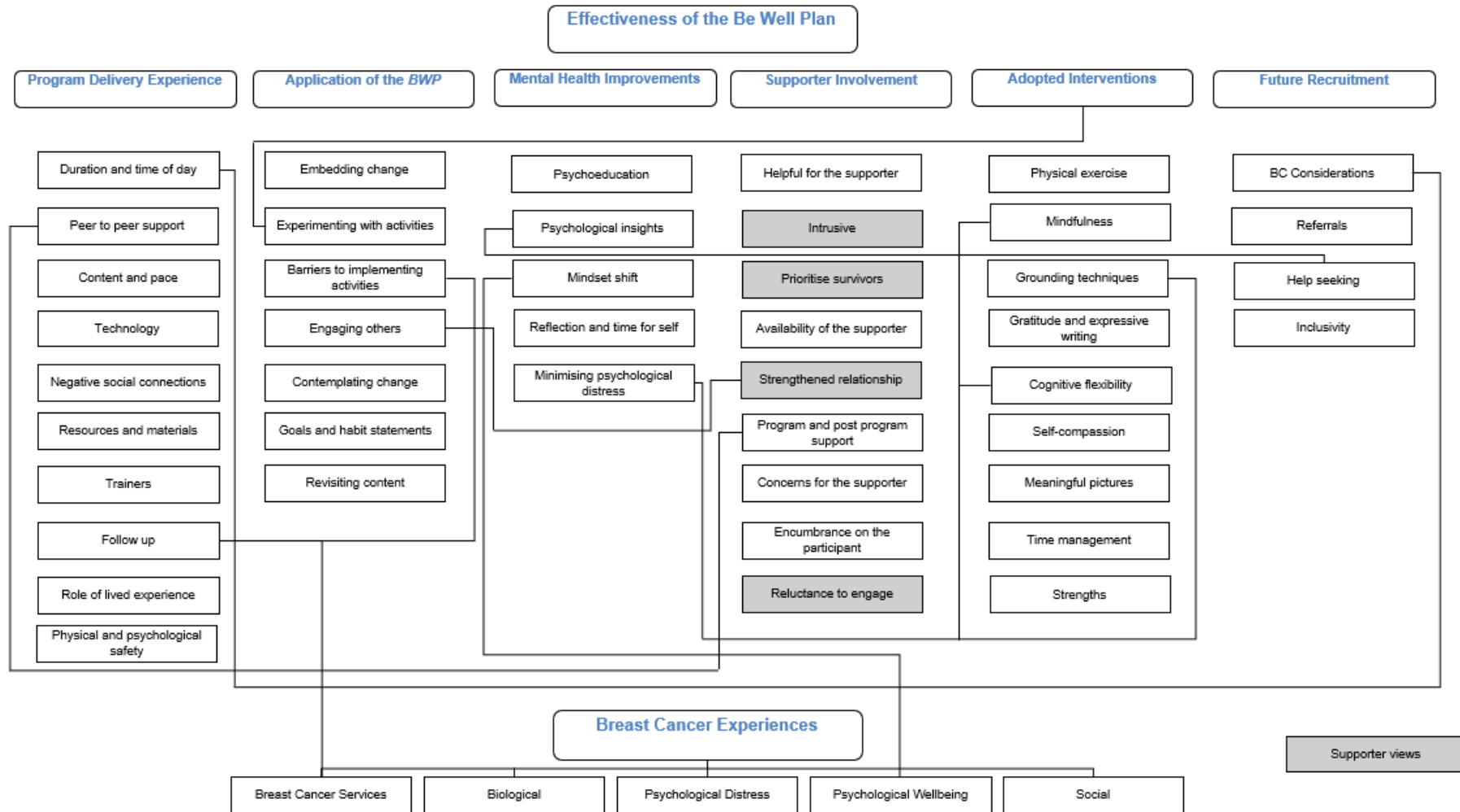


Table 3: Category description with illustrative quotes

Category	Description	Illustrative Quote
Program delivery experience	Comments about the program as a whole as well as on the format and structure	“Made some great connections in a safe space where we could explore mental health and wellbeing.” <i>(Participant#8)</i>
Mental health improvements	Cognitive and emotional changes and reflections observed by the participant	“I was in a real victim mode, I was dying, and I was, I don't know, everything hurt, and I just focused on the negatives and now I'm focusing on the positives.” <i>(Participant#6)</i>
Application of the BWP	How participants are implementing the evidence-based activities	“I found that doing it again, that they became more an integral part of me, that I would just stop and do deep breathing during the day and I would incorporate that.” <i>(Participant#7)</i>
Supporter involvement	Participants and supporter experiences of including supporters	“Perhaps that the program may have shifted focus at times to incorporate the person with you. Yeah for me it would have been an encumbrance.” <i>(Participant#2)</i> “I think the course got us very tight with each other. And got us very supportive of each other as well. Not just me.” <i>(Supporter#2)</i>
Adopted interventions	Activities participants used from the BWP	“We practice while we walked, we went to aqua aerobics and then we walk barefoot around the footy oval just to do the mindful walking.” <i>(Participant#6)</i>
Future recruitment	Recommendations on how to recruit future participants.	“You spend a bit of time with the breast care nurses there, and I think it would be really good in those conversations if they mention have you heard about the BWP.” <i>(Participant#3)</i>

Category 1: Program Delivery Experiences

Comments relating to how the *BWP* was organised, facilitated, structured and delivered made up 24% of total codes. Participants shared their thoughts on the social interactions with other participants as well as their engagement with the program resources. Positive sentiments about the overall program and experience were captured, with participants reporting strengths of the *BWP* to be the variety of interventions, the ability to individualise the program and the psychological safety in the group. Participants also highlighted the strength in engaging the *BWP* with other breast cancer survivors who could relate to their experiences and alleviate feelings of being alone and isolated. Participants highlighted the benefit of having a hard copy workbook and how they had been able review the booklet post the program.

Comments about the pace of the program and the 2-hour duration differed between participants with some suggesting it was too slow, and others preferring a faster pace, with recommendations to schedule sessions earlier in the day. Technology challenges were captured with some apprehension in participating online and the need for longer break out times. Whilst participants enjoyed the comfort of being in their own environment, many participants commented on the challenges of online engagement and not feeling as they could connect as well as they could compared with an in person setting. Participants appreciated the weekly accountability in a group format, with participants requesting a follow up in the future to maintain momentum and engagement.

Participants commented on the value of the facilitators demonstrating the application of activities through personal stories and relatability. Thoughts about involving lived experience facilitators or using breast cancer related examples to demonstrate the concepts were captured with some participants rating this as critical to the program with others highlighting the diversity of cancer survivorship and feeling indifferent to using breast cancer specific examples.

Category 2: Application of the BWP

Participants commented on the change process they were adopting when applying the wellbeing strategies from the *BWP* (15% of total codes). Participants commented on experimenting with the evidence-based activities during and post the program, adopting an explorative approach. The language of using goals, habit statements and celebrations, as taught in the *BWP* was reflected in the statements. Participants commented on engaging friends and family in the activities to maintain engagement, and how the *BWP* had reinvigorated their desire for activities which had ceased over time, such as yoga and meditation. During the interview, participants set intentions to incorporate an activity in their lives at a later stage using statements such as “try”, “should” “might”, expressing

desires to maintain their progress. Participants commented on the barriers of implementing the wellbeing activities post completion such as the change in weather, busy lifestyle and lack of weekly accountability post- program. Participants had been sharing the concepts from the program with family, friends and in breast cancer survivorship support groups, with suggestions that the program is relevant to others not limited to survivors of cancer.

Category 3: Mental Health Improvements

Participants reflected on the improvements to their mental health since completing the program (9% of total codes). Cognitive and emotional changes were observed by the participant, as a result of attending the program, including a mindset shift from having a negative outlook in life and responding to challenges with more optimism. Participants demonstrated insight into their mental health by noticing the difference in their coping style prior to the program, compared the present application of the recently learnt wellbeing strategies. Reflections were also made on the reduction in psychological distress and duration of the distress when faced with medical appointments and waiting for results. Grounding activities, such as mindful breathing, were found to be the most useful in those scenarios. Participants commented on the new psychoeducation they had learnt in the program whereas others commented on hearing familiar messages pertaining to other mental wellbeing programs they had attended. Participants shared how the program came at the 'right time' for them personally and the importance of having the time to reflect and break away from their personal routine.

Category 4: Supporter Involvement

The experience of involving a supporter in the *BWP* were captured from both separate interviews of participants and supporters involved in the program (8% of total codes). Participants highlighted the support they received both during the 5-week duration as well as post- to maintain engagement and regularity of activities. Supporters helped the participants to reinforce learnings and concepts from the program, particularly when experiencing cognitive challenges from treatment. Participants commented on the concerns they had for the supporter with regards to technology and helping them to overcome feelings or irrelevancy in the group. Conversely, some participants reflected that a support person could be an encumbrance on their experience and the importance of the program was to maintain a focus on breast cancer survivors.

Of the interviewed supporters, comments were made about the positive engagement between the supporter and participant undertaking the activities and how, as a pair, they were evolving the activities and embedding them in their lives post completion of the program. Supporters shared both positive and negative sentiments about being involved, with one supporter feeling like an intruder and irrelevant to participating. Supporters commented on

feeling the need to remain quiet to give space for the survivor to speak and limit diverting attention to the supporter.

Category 5: Adopted Interventions

Wellbeing activities that were adopted by participants varied (7% of total codes). Mindfulness was the most frequently reported, as a result of the activities being enjoyable and easily adopted by participants. Mindfulness techniques were used to maintain focus on the present situation, rather than focus on the unknown in the breast cancer journey. Physical exercise such as walking and yoga were favoured as post-program interventions, particularly with their support network. Grounding techniques such as breathing techniques and using sensory strategies were also commonly adopted when attending medical appointments, and easily embedded into the participant's weekly routines. Other wellbeing activities mentioned included cognitive flexibility techniques, gratitude practices, self-compassion, strengths and time management strategies. Participants spoke of how they used the activities in different circumstances both during the 5-week program and beyond.

Category 6: Future Recruitment

Participants' ideas on how to recruit future participants to the *BWP* (8% of total codes). Suggestions reflected the unique physical symptoms associated with survivorship with fatigue being a contributing factor. Avoiding attendance soon after diagnosis was highlighted due to information overload and to be cognisant of some treatments making it difficult to concentrate. Comments were made about their interest of help seeking at the time of enrolment, as well as having a prior interest in mental health, which made the program appealing. When discussing how to be referred to the program, participants commented on receiving an abundance of brochures as part of their diagnosis, so the focus should be on the quality of the referrer, not the pamphlet. Participants shared how medical specialists and breast cancer nurses would be a reputable source of referral. It was also noted that the program may need to be modified to suit the broader population, with reference to low literacy and culturally disadvantaged women.

3.3 Experiences of breast cancer survivors

As per the second research aim, personal sentiments and circumstances relating to the participant's survivorship experience was captured in the qualitative interviews, reflected in 4 subcategories: Breast cancer services, Biological, Psychological and Social.

Biological

Comments relating to the physiological impact of breast cancer survivorship reflected 5% of codes which included experiences with medical treatment and physical side effects and from breast cancer. Fatigue was a major factor as well as the need to improve physical exercise and nutrition. Statements reflected the immense change that takes place when being treated for breast cancer, particularly the physical side effects such as lethargy and cognitive challenges with chemotherapy. Participants commented on the focus on the medical model and the difficulties navigating treatment options.

“I have completely changed my diet. So, once you’ve got the food organised the next thing is to get fitter. It doesn’t matter which doctor you’re talking to they say you need to be the leanest, fitter version of you.”

(Participant#3)

Psychological

Comments relating to the psychological impact from breast cancer diagnosis and survivorship represented 11% of total codes, including the anxiety, stress and depressive symptoms experienced. The feeling of being overwhelmed at the time of diagnosis was reflected as well as the anxiety of future scans and recurrence of cancer. Participants’ expectations about the lack of control during the survivorship journey was reflected as well as the need to invent a “new self” beyond diagnosis. Comments about self-doubt and self-criticism were also included.

“I know when I had a PICC line inserted, which was the bane of my life while I had that in. I hated it. I was so anxious. I was just so anxious. And it was before I’d done the program and you know, and I cried, it was just so traumatic for me.” (Participant#4)

Participants also commented on positive mental health symptoms including a sense of determination and motivation throughout their cancer journey. Comments about being optimistic about the survivorship experience and feeling resilient were also included. Participants projected empathy towards other survivors, obtaining perspective and acceptance of their circumstances.

“I don’t see stage 4 as a death sentence. With the treatment I’m getting, my cancer is under control. But because of the original site it’s just one of those things and there’s so many of us out there.” (Participant#7)

Social

The participants’ social aspects on breast cancer survivorship represented 7% of total codes. Statements pertaining to participant lifestyle changes and circumstances were captured including the impact of treatment on lifestyle,

family and work commitments. Social support was an important factor including specific support groups for breast cancer survivors, supportive medical staff and family and friends. Some participants were involved in advocacy for other survivors.

“I’m actually in a breast cancer survivor dragon boat team. I had breast cancer 16 years ago recovered that was all great I joined this team now of course I got it again, so most of my friends are breast cancer survivors actually.” (Participant#1)

Breast Cancer Services

Participants’ experience with breast cancer services represented 6% of codes which extended to mental and physical health and their interactions with medical professionals. Statements were made how alternate or complementary therapies to support their holistic health, such as naturopathy, massage, fitness and spirituality were up to them to navigate and research. Comments from participants were made about the lack of contact and support they have received beyond their initial medical treatment.

“It’s a real shock because they stop seeing people every week, you’re going to see someone and they’re giving you treatmentand then there’s no one. You turn around and they’re all gone.” (Participant#6)

Participants commented on how services which had individual follow up such as weekly phone calls, stood out from other programs, with a recommendation for the BWP to adopt the same strategy. Statements were also captured about the lack of resources available in regional Australia.

“The McGrath foundation is just cutting back our nurse’s time. She can only come to under four meetings a year or something and we meet monthly but they’re just cutting her funding all the time. So, she’s got to spread herself between the bottom end meetings and the Clare meetings and our meetings.” (Participant#6)

4. Discussion

The present mixed methods pilot study aimed to evaluate a group based online mental wellbeing intervention for women living with and beyond breast cancer. The study found large effect sizes in analysing pre- and post-intervention outcome measures for mental wellbeing, self-compassion, depressive symptoms and anxiety supported by qualitative experiences from participants. Resilience and QoL measures did not report significant changes. The qualitative content analysis adds context of how participants applied the outcomes in the study.

Additionally, the qualitative experiences of participants living with breast cancer provided valuable insights of how to navigate breast cancer services and the biopsychosocial impacts of living beyond a breast cancer diagnosis. The results produced novel findings but also contributed to a growing body of research demonstrating the benefits of mental wellbeing interventions.

4.1 Evaluating the effectiveness of the *BWP*

The study demonstrated significant improvements in mental wellbeing and self-compassion, confirming the positive effects previously identified in prior evaluations of the *BWP* [69]. This study reported large effect sizes, particularly for mental wellbeing where the effect size is above average in reported literature in mental wellbeing interventions [86]. Qualitative analysis found participants had a positive experience in participating in the program and reports of a positive mindset shift, increased psychological insights and psychoeducation about mental wellbeing. Participants expressed the benefit of the variety of wellbeing strategies to choose from and the use of habit formation to enable behavioural activation [60]. Individuals enjoyed experimenting with different positive mental health activities with friends, the facilitator and other program participants [55].

Large effect sizes were also reported in reducing depressive symptoms and anxiety, which is consistent with prior studies of the *BWP* [69], and studies on mindfulness-based stress interventions [48]. High levels of depressive symptoms and anxiety at baseline by included participants, may be a contributing factor to the results. It is inconclusive whether participant demographics, such as stage of breast cancer, impacted the results due the variation in participants. Qualitative analysis found that the time of diagnosis was the most overwhelming and stressful, consistent with the literature [87], however anxiety and depressive symptoms persisted when attending current medical appointments, waiting for scan results and maintaining a reduction in lifestyle activities, due the physical symptoms of their survivorship. Qualitative statements from participants demonstrated heightened psychological insight by reflecting on coping styles before and after the program. Participants highlighted that prior to attending the program they focused on negative thoughts, catastrophising and depressive symptoms. Others highlighted that learning the techniques and practices such as mindfulness, breathing and self-compassion to be fundamental to improving their wellbeing and ability to manage psychological distress.

In comparison with the *BWP* outcomes previously studied in the RCT by Fassnacht et al [69], no meaningful statistical change was found with resilience post intervention. Interestingly, the participants of this study reported high levels of resilience pre-intervention, contributing to results being insignificant. Research has found that cancer survivors can demonstrate high levels of resilience [88] in gaining skill, knowledge and confidence in

overcoming their disease [89] with post-traumatic growth and associated with both positive and negative life changes [90]. This is reinforced by the qualitative statements from participants who are practicing positive thinking, perspective and optimism about their future.

QoL scales also did not report meaningful improvements, which was expected as the items in the measure are on a variety of physical symptoms and capabilities, which is not the primary outcome of the 5-week *BWP*. Qualitative analysis found participants did report an increase in behavioural activation as a result of the program by introducing regular physical exercise such as walking and yoga. As research has showed that positive mental health does improve physical illness in the longer term [91], further research on the long-term physical health outcomes of the *BWP* is recommended.

A novel finding in this study was the differing perspectives to involve support people in the *BWP*, with only 3 participants (5%) in the sample inviting a support person to the program. Participants highlighted the desire to build their own network outside of family and friends and avoid the perceived burden of the supporter's experience. Other participants welcomed the support, which aided their participation and reinforced wellbeing activities during the program and post intervention, which is reinforced with prior studies [66]. Those that brought a supporter reported better engagement with the activities through the program and beyond the 5 weeks to embed the changes in their routines. There was also the ability to reinforce the content through weekly discussions between the participant and supporter. Supporters themselves also had differing views, including feeling like an intruder and an interference to the discussions. Supporters felt hesitant to speak up and discuss their own goals, perceiving by them to be irrelevant. Despite these experiences, supporters felt it strengthened the relationship with their partner and is enabling lasting change to their wellbeing habits.

4.2. Experiences of breast cancer survivors

Qualitative analysis found participants felt both positive mental health outcomes such as resilience, perspective and social connection with others, whilst also feeling psychological distress when rediscovering their self-post cancer diagnosis. This is consistent with emerging research that mental illness and positive mental health can co-exist [40]. Participants reported the need to reduce social interactions as a result of the perceived risk of contracting COVID-19, and a reduction in hobbies and helping with children and grandchildren from experiencing fatigue and being immune compromised [15]. Additionally, participants commented on the desire for more comprehensive treatment options, not just medical intervention, leaving the burden of exploring complementary therapies on the individual [92]. Participants also noted the lack of support beyond the initial active treatment with

a sense of feeling dropped from services. This supports the literature on the demand for better services and support throughout survivorship [27,28]. Consistent with this theme, participants also reported a desire for more follow up post completion of the *BWP*, finding that other programs offering this personalised service to be a strength. As well researched, symptoms and side effects of breast cancer treatment differs for each individual [8] with participants recommending enrolment of the *BWP* should be based on the needs and ability of the participant, with a common view to avoid enrolling immediately after being diagnosed or when experiencing fatigue related side effects from treatment.

4.3 Study strengths and limitations

This study had a number of strengths. Firstly, the study has reported above average effect sizes in several measures, positive sentiments from participant feedback and high attendance once participants commenced the program. Participants also reported feeling psychologically safe in the group, and felt physically safe to participate virtually. The strengths can be attributed to a number of factors including that the *BWP* has been tested previously under RCT conditions [69] which provided for a solid foundation to deliver and administer this study. Furthermore, the *BWP* has been delivered to over 5000 participants across both clinical and community settings, which has seen the content refined and improved through end user feedback [69]. Additional strengths of this study include that the pilot consisted of 4 groups of participants across the calendar year, alleviated cyclical mental wellbeing effects (such as holiday periods, weather changes). Furthermore, as this study employed a mixed-method design, quantitative and qualitative data has provided a level of depth that a may be absent using a single method [93]. Also, the mental wellbeing program, the *BWP*, is delivered by accredited facilitators that are not required to be clinically trained, allowing for a scalable mental health solution to supplement the shortage of mental health professionals [94].

Limitations of this study include that pre- and post- questionnaires may have been influenced by women undergoing active treatment due to the known fluctuations in physical, and mental side effects [10]. Participants highlighted prior interest and knowledge in mental wellbeing, which may have attracted participants with an ardour for mental wellbeing, thus the *BWP* reinforced mental wellbeing practices and those already focused on self-management. Additionally, interviews and evaluation were undertaken by the designers of the study which may have led to bias in the interpretation of responses [95]. It is recommended that additional studies in clinical populations are conducted to test the *BWP* to eliminate any research biases, with the researchers blind to participants and data collection.

4.4 Future directions of the BWP

A number of recommendations are provided to enable the *BWP* to be implemented beyond a research setting. Firstly, consistent with prior studies, recruitment and uptake of participation was a recruitment challenge [95], with only 42%, of those who expressed an interest, enrolled in the study. The *BWP* was only delivered online with set time points, which may have been a barrier to those with differing personal commitments. Qualitative statements from participants reported technology challenges, and some apprehension in engaging in the chat rooms and as a group. It is recommended that multiple time points are offered to provide choice to the consumer, as well as an introductory session to explain the program, and attend to any technology barriers. Recruitment may have been influenced by the relying on social media and flyers, as participants highlighted in the qualitative interviews they were inundated with brochures when visiting practitioners. Participants demonstrated a desire for follow up beyond the program for both social engagement with the other participants and tracking of wellbeing progress, hence a follow-up session is recommended.

Participants commented on the desire for more connectivity with group participants, thus it is recommended that future interventions add a welcome session before the program commences to formally introduce participants to the study. Furthermore, with regards to involving supporters in the program, it is recommended consistency be applied across the group to have balanced numbers and expectations set up front or offer improved incentives.

4.5 Implications for clinicians

The group-based intervention can be offered as a complementary tool to support individuals with their breast cancer diagnosis, in a scalable way to reach those in need. Facilitation can be delivered online to include rural and hard to reach survivors or those concerned about the physical challenges with a face-to-face environment. The *BWP* can also be delivered as an in person offering. Clinicians could add additional sessions pre- or post- the intervention to accommodate participants' desire for ongoing interaction and more social connectivity. Regardless of the format, considerations should be given whether to include support people or not in the intervention, and how to integrate program into existing services. Health professionals should also consider the time to deliver the program and provide support between sessions.

4.6 Conclusion

In conclusion, this study has found that the online mental wellbeing program, the *BWP* is an effective and accessible way to improve the mental wellbeing in women living with breast cancer, with significant improvements in wellbeing and self-compassion and alleviating symptoms of depression and anxiety. The *BWP*

was well received by participants, with highlights included the diversity and individual tailoring of wellbeing activities as well as the weekly accountability. This study highlighted the desire from participants to enhance social interactions and post intervention follow up. Involving a support person had benefits to embedding change and reinforcing learnings of the *BWP*, however, was perceived differently across participants. Future research to explore the long-term impact of online mental wellbeing interventions is recommended.

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Statements & Declarations

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Competing Interests

There are no direct financial interests for this study. Several authors are employed by SAHMRI, in which the *BWP* is a revenue source.

Author Contributions

All authors contributed to the study conception and design. The first draft of the manuscript was written by the student and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Ethics approval

Ethics approval was granted (Flinders University HREC Sub-committee #4866, and noted by the University of Adelaide HREC sub-committee #36368).

Consent to participate

Participants were informed about the nature and content of the study prior to providing their consent to participate, including a warning of the potential risk of emotional stress and their right to withdraw from the study at any time.

Supplementary Table 1:

Qualitative interview questions

<i>Category</i>	<i>Question</i>
<i>Program Impact</i>	<ul style="list-style-type: none"> • What were your thoughts on the Be Well Plan program? • How have you applied the Be Well Plan in your life? • How have you used any activities that you learnt in the program? • What was the main learning that you took from the program? • Will you continue to use the activities? • What would help you to continue to use the activities?
<i>Breast Cancer-specific</i>	<ul style="list-style-type: none"> • Why did you register for the Be Well Plan? • How did you find the facilitator of the program? • Is there point care that this program would have been better suited e.g., in-care treatment or after • Would you recommend this program for other cancer survivors? Why, why not? • Would you have liked for the program to be recommended to you by your medical team? • What support did you receive about your treatment? Have they supported you after treatment?
<i>Support Person</i>	<ul style="list-style-type: none"> • You had a choice to bring someone with you to participate in the program. <ul style="list-style-type: none"> ○ You didn't bring anyone with you, can you tell me why? OR <ul style="list-style-type: none"> ○ What were the benefits of attending the program with your supporter? • How do you think the program would have been different if you did / did not? • Would you have preferred for a support person to go through a different group to you?
<i>Format-specific</i>	<ul style="list-style-type: none"> • How did you find attending the program over 5 consecutive weeks? • Would you change the program format/content in any way to suit you? • How was the pace of the program? Could you follow along or was it too fast?

- Was the use of language in the program appropriate and understandable?
 - Did you find the hard copy booklet useful?
-

Supplementary Table 2

Subcategory count of codes and illustrative quotes

Research Aim	Category	Theme	Code Count	Illustrative Quote
Effectiveness of the BWP	Program Delivery Experience	Duration and time of day	33	"I'd had enough. By five weeks I needed that to stop." <i>(Participant#4)</i>
		Peer to peer support	31	"It was a highlight to speak with people who 'get' cancer, and make some great connections." <i>(Participant#8)</i>
		Content and pace	25	"Week 4 was full of really important information, but I wonder if it is too much for one session - I know I came out of it with information overload. It felt a bit rushed as understandably we had a timetable to keep to." <i>(Participant#8)</i>
		Technology	21	"It's hard to know when to talk and when not to talk." <i>(Participant#6)</i>
		Negative social connections	20	"If I'd done it with this person face to face and I was there to support her and we could have a conversation afterwards." <i>(Participant#7)</i>
		Resources and materials	20	"There are easy guides in how to use the activity section that link it back to the assessments we complete, and what areas we choose to work on." <i>(Participant#8)</i>
		Trainers	16	"The presenters were so warm and empathetic and knowledgeable. It was fantastic." <i>(Participant#2)</i>

	Follow up	12	"It would also be great to have the option to repeat the course to consolidate learnings." <i>(Participant#8)</i>
	The role of lived experience	11	"It's always encouraging to see people who have come through it and looking good and energetic and engaged and so on." <i>(Participant#1)</i>
	Physical and psychological safety	8	"Make some great connections in a safe space where we could explore mental health and wellbeing." <i>(Participant#8)</i>
Application of the <i>BWP</i>	Embedding change	27	"What it did do was cemented in me things that I need to put in place in my own life." <i>(Participant#7)</i>
	Experimenting with activities	22	"I keep trying to do mindful eating but I don't seem to be able to eat for more than a couple of minutes at a time." <i>(Participant#1)</i>
	Barriers to implementing activities	22	"It's winter and you know I've got a lot of responsibilities." <i>(Participant#3)</i>
	Engaging others	21	"I've been sharing bits and pieces with the group every time I go." <i>(Participant#6)</i>
	Contemplating change	19	"Maybe in summer I might be able to pick it up again." <i>(Participant#3)</i>
	Goals and habit statements	12	"I take some tablets. So, after I do that, bathroom, you know and I do some, what do you call it, some moisturising and whatever and then I do a little bit of this breathing yoga." <i>(Participant#4)</i>

	Revisiting content	5	"I might go back over some of the earlier weeks." (<i>Participant#1</i>)
Mental Health Improvements	Psychoeducation	22	"Physical, medical reasons for the way that I was feeling." (<i>Participant#2</i>)
	Psychological Insights	18	"It makes you think and it makes you step back and focus more on your wellbeing." (<i>Participant#5</i>)
	Mindset shift	14	"It's changed my whole outlook." (<i>Participant#6</i>)
	Reflection and time for self	13	"Also, I think just as things happen you sort of reflect back on what we went through in the Be Well Plan." (<i>Participant#5</i>)
	Minimising psychological Distress	11	"It's been more when I come with a negative thought, probably re-examining it. All negative thoughts have effects on you personally. So really looking at that and in some ways putting it out there so I can examine it more rather than letting it affect me emotionally." (<i>Participant#7</i>)
Supporter Involvement	Helpful for the supporter	10	"Like she's got nerve problems and stuff with her arms and things so we're sort of supporting each other." (<i>Participant#6</i>)
	Intrusive	9	"I felt that I was intruding." (<i>Supporter#1</i>)
	Prioritise survivors	8	"I probably would encourage them to sort of have more airtime." (<i>Supporter#1</i>)

	Availability of supporter	7	"Wasn't really anybody I would demand that time commitment from." <i>(Participant#1)</i>
	Strengthened relationship	6	"Helped with that it's made me more aware of her and you know just to show more compassion." <i>(Supporter#1)</i>
	Program and post program support	5	"Sometimes we'd actually ring each other after the session straight after and have a chat for about an hour." <i>(Participant#6)</i>
	Concerns for the Supporter	5	"It sort of made me doubt whether it. I think I thought that one week was this a good idea." <i>(Participant#5)</i>
	Encumbrance on participant	5	"Worrying about if they're OK if they're bored or yeah whatever." <i>(Participant#2)</i>
	Reluctance to engage	4	"And even when I was doing it. I thought I didn't want to say too much." <i>(Supporter#2)</i>
Adopted Interventions	Physical exercise	14	"So, there are some morning stretches I do that have stayed." <i>(Participant#3)</i>
	Mindfulness	14	"It's great to be able to use some mindful strategies." <i>(Participant#2)</i>
	Grounding techniques	14	"I would just stop and do deep breathing during the day and I would incorporate that." <i>(Participant#7)</i>

	Gratitude and expressive writing	5	"The whole gratefulness thing as well, you know, getting people every day despite what they're going to write down things that they're grateful for all of these can give me and others a more positive lifestyle." <i>(Participant#7)</i>
	Cognitive flexibility	4	"I particularly found the thought distortions good, useful. Yeah. Some I hadn't really recognised until we did this." <i>(Participant#1)</i>
	Self-Compassion	4	"Easier on myself I'm giving myself space to say OK you're." <i>(Participant#1)</i>
	Meaningful pictures	3	"I think the photos one was a great opportunity." <i>(Participant#4)</i>
	Strengths	1	"I liked the character strengths." <i>(Participant#1)</i>
	Time management	1	"So, from my perspective it was, I'm not very good at organizing my day and that was one of the things that came across and it was really hard to start that out." <i>(Participant#7)</i>
Recruitment	Breast Cancer Considerations	33	"I'm glad I was towards the end of my first lot of chemo." <i>(Participant#5)</i>
	Referrals	19	"Promote it more through the wellness centre because it's in those conversations that we have with people when they're diagnosed, that you can let them know." <i>(Participant#7)</i>
	Help seeking	11	"I was at a point where I really wanted to, reach, to discuss what was going on." <i>(Participant#2)</i>
	Inclusivity	2	"Breast cancer doesn't just attract middle class women." <i>(Participant#4)</i>

Breast Cancer Experiences	Psychological	92	"You know cancer doesn't define who we are, you know and so it's just something that sort of attacked us. And so, we need to have an open mind to all these things that can help us and the treatment on its own mind help us." <i>(Participant#7)</i>
			"I lost purpose and was very depressed." <i>(Participant#7)</i>
	Social	55	"I've got some very good friends who keep in touch." <i>(Participant#5)</i>
	Breast Cancer Services	47	"If you want to look at alternative therapies to support your treatment that's really on you, you know, and you don't get the same support unless you go to a naturopath who also happens to be a GP because you know it's very difficult to navigate." <i>(Participant#3)</i>
	Biological	40	"So damn useless to anybody or anything that you're able to do that." <i>(Participant#5)</i>
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Appendix A: Journal of Supportive Cancer Care Instructions to Authors

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Instructions for Authors

Peer Review Taxonomy

Supportive Care in Cancer and Springer Nature are participating in a pilot of STM's Working Group on Peer Review Taxonomy.

STM, the International Association of Scientific, Technical and Medical Publishers, has recognized a need to identify and standardize definitions and terminology in peer review practices in order to help align nomenclature as more publishers use open peer review models.

A [peer review taxonomy](#) that is used across publishers will help make the peer review process for articles and journals more transparent, and will enable the community to better assess and compare peer review practices between different journals.

Taxonomy:

1. Identity transparency: Single anonymized
2. Reviewer interacts with: Editor
3. Review information published: None

We would welcome your feedback on the Peer Review Taxonomy Pilot - please can you take the time to fill this short survey [Survey](#)

Scope

Supportive Care in Cancer publishes papers devoted to medical, technical and surgical topics as they relate to supportive therapy and care that supplements or substitutes basic cancer treatment at all stages of the disease. The journal focuses on papers and reviews that report on intervention studies and policy-related issues to manage treatment-related toxicities and other supportive care endpoints.

Papers devoted to nursing, rehabilitative, psychosocial and spiritual issues of support are also considered for publication.

The journal's Editorial Board has placed a low priority on pilot research of interventions or instrument development studies. Due to the large, existing base of literature concerning cancer patients' needs for supportive care, papers reporting on these issues will no longer be considered. The journal is dedicated to publishing supportive care intervention studies that address patients' needs. The journal does not publish papers that focus on tumor outcomes.

Ethical Responsibilities of Authors

This journal is committed to upholding the integrity of the scientific record. As a member of the Committee on Publication Ethics ([COPE](#)) the journal will follow the [COPE](#) guidelines on how to deal with potential acts of misconduct.

Authors should refrain from misrepresenting research results which could damage the trust in the journal, the professionalism of scientific authorship, and ultimately the entire scientific endeavour. Maintaining integrity of the research and its presentation is helped by following the rules of good scientific practice, which include*:

The manuscript should not be submitted to more than one journal for simultaneous consideration.

The submitted work should be original and should not have been published elsewhere in any form or language (partially or in full), unless the new work concerns an expansion of previous work. (Please provide transparency on the re-use of material to avoid the concerns about text-recycling ('self-plagiarism').

A single study should not be split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (i.e. 'salami-slicing/publishing').

Concurrent or secondary publication is sometimes justifiable, provided certain conditions are met. Examples include: translations or a manuscript that is intended for a different group of readers.

Results should be presented clearly, honestly, and without fabrication, falsification or inappropriate data manipulation (including image based manipulation). Authors should adhere to discipline-specific rules for acquiring, selecting and processing data.

No data, text, or theories by others are presented as if they were the author's own ('plagiarism'). Proper acknowledgements to other works must be given (this includes material that is closely copied (near verbatim), summarized and/or paraphrased), quotation marks (to indicate words taken from another source) are used for verbatim copying of material, and permissions secured for material that is copyrighted.

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Authors should make sure they have permissions for the use of software, questionnaires/(web) surveys and scales in their studies (if appropriate).

Research articles and non-research articles (e.g. Opinion, Review, and Commentary articles) must cite appropriate and relevant literature in support of the claims made. Excessive and inappropriate self-citation or coordinated efforts among several authors to collectively self-cite is strongly discouraged.

Authors should avoid untrue statements about an entity (who can be an individual person or a company) or descriptions of their behavior or actions that could potentially be seen as personal attacks or allegations about that person.

Research that may be misapplied to pose a threat to public health or national security should be clearly identified in the manuscript (e.g. dual use of research). Examples include creation of harmful consequences of biological agents or toxins, disruption of immunity of vaccines, unusual hazards in the use of chemicals, weaponization of research/technology (amongst others).

Authors are strongly advised to ensure the author group, the Corresponding Author, and the order of authors are all correct at submission. Adding and/or deleting authors during the revision stages is generally not permitted, but in some cases may be warranted. Reasons for changes in authorship should be explained in detail. Please note that changes to authorship cannot be made after acceptance of a manuscript.

*All of the above are guidelines and authors need to make sure to respect third parties rights such as copyright and/or moral rights.

Upon request authors should be prepared to send relevant documentation or data in order to verify the validity of the results presented. This could be in the form of raw data, samples, records, etc. Sensitive information in the form of confidential or proprietary data is excluded.

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The reason will be given in the published erratum/correction, expression of concern or retraction note. Please note that retraction means that the article is **maintained on the platform**, watermarked "retracted" and the explanation for the retraction is provided in a note linked to the watermarked article.

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Fundamental errors

Authors have an obligation to correct mistakes once they discover a significant error or inaccuracy in their published article. The author(s) is/are requested to contact the journal and explain in what sense the error is impacting the article. A decision on how to correct the literature will depend on the nature of the error. This may be a correction or retraction. The retraction note should provide transparency which parts of the article are impacted by the error.

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Authors are welcome to suggest suitable reviewers and/or request the exclusion of certain individuals when they submit their manuscripts. When suggesting reviewers, authors should make sure they are totally independent and not connected to the work in any way. It is strongly recommended to suggest a mix of reviewers from different countries and different institutions. When suggesting reviewers, the Corresponding Author must provide an institutional email address for each suggested reviewer, or, if this is not possible to include other means of verifying the identity such as a link to a personal homepage, a link to the publication record or a

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Authorship principles

These guidelines describe authorship principles and good authorship practices to which prospective authors should adhere to.

Authorship clarified

The Journal and Publisher assume all authors agreed with the content and that all gave explicit consent to submit and that they obtained consent from the responsible authorities at the institute/organization where the work has been carried out, **before** the work is submitted.

The Publisher does not prescribe the kinds of contributions that warrant authorship. It is recommended that authors adhere to the guidelines for authorship that are applicable in their specific research field. In absence of specific guidelines it is recommended to adhere to the following guidelines*:

All authors whose names appear on the submission

- 1) made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; or the creation of new software used in the work;
- 2) drafted the work or revised it critically for important intellectual content;
- 3) approved the version to be published; and
- 4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

* Based on/adapted from:

[ICMJE, Defining the Role of Authors and Contributors,](#)

[Transparency in authors' contributions and responsibilities to promote integrity in scientific publication, McNutt at all, PNAS February 27, 2018](#)

Disclosures and declarations

All authors are requested to include information regarding sources of funding, financial or non-financial interests, study-specific approval by the appropriate ethics committee for research involving humans and/or animals, informed consent if the research involved human participants, and a statement on welfare of animals if the research involved animals (as appropriate).

The decision whether such information should be included is not only dependent on the scope of the journal, but also the scope of the article. Work submitted for publication may have implications for public health or general welfare and in those cases it is the responsibility of all authors to include the appropriate disclosures and declarations.

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All authors are requested to make sure that all data and materials as well as software application or custom code support their published claims and comply with field standards. Please note that journals may have individual policies on (sharing) research data in concordance with disciplinary norms and expectations.

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One author is assigned as Corresponding Author and acts on behalf of all co-authors and ensures that questions related to the accuracy or integrity of any part of the work are appropriately addressed.

The Corresponding Author is responsible for the following requirements:

ensuring that all listed authors have approved the manuscript before submission, including the names and order of authors;

managing all communication between the Journal and all co-authors, before and after publication;*

providing transparency on re-use of material and mention any unpublished material (for example manuscripts in press) included in the manuscript in a cover letter to the Editor;

making sure disclosures, declarations and transparency on data statements from all authors are included in the manuscript as appropriate (see above).

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Author contributions

In absence of specific instructions and in research fields where it is possible to describe discrete efforts, the Publisher recommends authors to include contribution statements in the work that specifies the contribution of every author in order to promote transparency. These contributions should be listed at the separate title page.

Examples of such statement(s) are shown below:

- Free text:

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by [full name], [full name] and [full name]. The first draft of the manuscript was written by [full name] and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Example: CRediT taxonomy:

- Conceptualization: [full name], ...; Methodology: [full name], ...; Formal analysis and investigation: [full name], ...; Writing - original draft preparation: [full name, ...]; Writing - review and editing: [full name], ...; Funding acquisition: [full name], ...; Resources: [full name], ...; Supervision: [full name],....

For **review articles** where discrete statements are less applicable a statement should be included who had the idea for the article, who performed the literature search and data analysis, and who drafted and/or critically revised the work.

For articles that are based primarily on the **student's dissertation or thesis**, it is recommended that the student is usually listed as principal author:

[A Graduate Student's Guide to Determining Authorship Credit and Authorship Order, APA Science Student Council 2006](#)

Affiliation

The primary affiliation for each author should be the institution where the majority of their work was done. If an author has subsequently moved, the current address may additionally be stated. Addresses will not be updated or changed after publication of the article.

Changes to authorship

Authors are strongly advised to ensure the correct author group, the Corresponding Author, and the order of authors at submission. Changes of authorship by adding or deleting authors, and/or changes in Corresponding Author, and/or changes in the sequence of authors are **not accepted after acceptance** of a manuscript.

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Adding and/or deleting authors at revision stage are generally not permitted, but in some cases it may be warranted. Reasons for these changes in authorship should be explained. Approval of the change during revision is at the discretion of the Editor-in-Chief. Please note that journals may have individual policies on adding and/or deleting authors during revision stage.

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For cases in which a co-author dies or is incapacitated during the writing, submission, or peer-review process, and the co-authors feel it is appropriate to include the author, co-authors should obtain approval from a (legal) representative which could be a direct relative.

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To ensure objectivity and transparency in research and to ensure that accepted principles of ethical and professional conduct have been followed, authors should include information regarding sources of funding, potential conflicts of interest (financial or non-financial), informed consent if the research involved human participants, and a statement on welfare of animals if the research involved animals.

Authors should include the following statements (if applicable) in a separate section entitled "Compliance with Ethical Standards" when submitting a paper:

Disclosure of potential conflicts of interest

Research involving Human Participants and/or Animals

Informed consent

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The corresponding author should be prepared to collect documentation of compliance with ethical standards and send if requested during peer review or after publication.

The Editors reserve the right to reject manuscripts that do not comply with the above-mentioned guidelines. The author will be held responsible for false statements or failure to fulfill the above-mentioned guidelines.

Competing Interests

Authors are requested to disclose interests that are directly or indirectly related to the work submitted for publication. Interests within the last 3 years of beginning the work (conducting the research and preparing the work for submission) should be reported. Interests outside the 3-year time frame must be disclosed if they could reasonably be perceived as influencing the submitted work. Disclosure of interests provides a complete and transparent process and helps readers form their own judgments of potential bias. This is not meant to imply that a financial relationship with an organization that sponsored the research or compensation received for consultancy work is inappropriate.

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Financial interests: Stocks or shares in companies (including holdings of spouse and/or children) that may gain or lose financially through publication of this manuscript; consultation fees or other forms of remuneration from organizations that may gain or lose financially; patents or patent applications whose value may be affected by publication of this manuscript.

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Summary of requirements

The above should be summarized in a statement and placed in a 'Declarations' section before the reference list under a heading of 'Funding' and/or 'Competing interests'. Other declarations include Ethics approval, Consent, Data, Material and/or Code availability and Authors' contribution statements.

Please see the various examples of wording below and revise/customize the sample statements according to your own needs.

When all authors have the same (or no) conflicts and/or funding it is sufficient to use one blanket statement.

Examples of statements to be used when funding has been received:

Partial financial support was received from [...]

The research leading to these results received funding from [...] under Grant Agreement No[...].

This study was funded by [...]

This work was supported by [...] (Grant numbers [...] and [...])

Examples of statements to be used when there is no funding:

The authors did not receive support from any organization for the submitted work.

No funding was received to assist with the preparation of this manuscript.

No funding was received for conducting this study.

No funds, grants, or other support was received.

Examples of statements to be used when there are interests to declare:

Financial interests: Author A has received research support from Company A. Author B has received a speaker honorarium from Company Wand owns stock in Company X. Author C is consultant to company Y.

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Financial interests: Author A received a speaking fee from Y for Z. Author B receives a salary from association X. X where s/he is the Executive Director.

Non-financial interests: none.

Financial interests: Author A and B declare they have no financial interests. Author C has received speaker and consultant honoraria from Company M and Company N. Dr. C has received speaker honorarium and research funding from Company M and Company O. Author D has received travel support from Company O.

Non-financial interests: Author D has served on advisory boards for Company M, Company N and Company O.

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Research involving human participants, their data or biological material

Ethics approval

When reporting a study that involved human participants, their data or biological material, authors should include a statement that confirms that the study was approved (or granted exemption) by the appropriate institutional and/or national research ethics committee (including the name of the ethics committee) and certify that the study was performed in accordance with the ethical standards as laid down in the [1964 Declaration of Helsinki](#) and its later amendments or comparable ethical standards. If doubt exists whether the research was conducted in accordance with the 1964 Helsinki Declaration or comparable standards, the authors must explain the reasons for their approach, and demonstrate that an independent ethics committee or institutional review board explicitly approved the doubtful aspects of the study. If a study was granted exemption from requiring ethics approval, this should also be detailed in the manuscript (including the reasons for the exemption).

Retrospective ethics approval

If a study has not been granted ethics committee approval prior to commencing, retrospective ethics approval usually cannot be obtained and it may not be possible to consider the manuscript for peer review. The decision on whether to proceed to peer review in such cases is at the Editor's discretion.

Ethics approval for retrospective studies

Although retrospective studies are conducted on already available data or biological material (for which formal consent may not be needed or is difficult to obtain) ethics approval may be required dependent on the law and the national ethical guidelines of a country. Authors should check with their institution to make sure they are complying with the specific requirements of their country.

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Case reports require ethics approval. Most institutions will have specific policies on this subject. Authors should check with their institution to make sure they are complying with the specific requirements of their institution and seek ethics approval where needed. Authors should be aware to secure informed consent from the individual (or parent or guardian if the participant is a minor or incapable) See also section on **Informed Consent**.

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If human cells are used, authors must declare in the manuscript: what cell lines were used by describing the source of the cell line, including when and from where it was obtained, whether the cell line has recently been authenticated and by what method. If cells were bought from a life science company the following need to be given in the manuscript: name of company (that provided the cells), cell type, number of cell line, and batch of cells.

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Further information is available from the [International Cell Line Authentication Committee](#) (ICLAC).

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Research Resource Identifiers (RRID) are persistent unique identifiers (effectively similar to a DOI) for research resources. This journal encourages authors to adopt RRIDs when reporting key biological resources (antibodies, cell lines, model organisms and tools) in their manuscripts.

Examples:

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Cell Line: RST307 cell line **RRID:CVCL_C321**

Antibody: Luciferase antibody DSHB Cat# LUC-3, **RRID:AB_2722109**

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Software: ImageJ Version 1.2.4 **RRID:SCR_003070**

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Clinical Trial Registration

The World Health Organization (WHO) definition of a clinical trial is "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the

effects on health outcomes". The WHO defines health interventions as "A health intervention is an act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions" and a health-related outcome is generally defined as a change in the health of a person or population as a result of an intervention.

To ensure the integrity of the reporting of patient-centered trials, authors must register prospective clinical trials (phase II to IV trials) in suitable publicly available repositories. For example www.clinicaltrials.gov or any of the primary registries that participate in the [WHO International Clinical Trials Registry Platform](#).

The trial registration number (TRN) and date of registration should be included as the last line of the manuscript abstract.

For clinical trials that have not been registered prospectively, authors are encouraged to register retrospectively to ensure the complete publication of all results. The trial registration number (TRN), date of registration and the words 'retrospectively registered' should be included as the last line of the manuscript abstract.

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Checklists are available for a number of study designs, including:

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Systematic reviews and meta-analyses ([PRISMA](#)) and protocols ([Prisma-P](#))

Diagnostic/prognostic studies ([STARD](#)) and ([TRIPOD](#))

Case reports ([CARE](#))

Clinical practice guidelines ([AGREE](#)) and ([RIGHT](#))

Qualitative research ([SRQR](#)) and ([COREQ](#))

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Summary of requirements

The above should be summarized in a statement and placed in a 'Declarations' section before the reference list under a heading of 'Ethics approval'.

Examples of statements to be used when ethics approval has been obtained:

- All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Bioethics Committee of the Medical University of A (No. ...).
- This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of University B (Date.../No. ...).
- Approval was obtained from the ethics committee of University C. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.
- The questionnaire and methodology for this study was approved by the Human Research Ethics committee of the University of D (Ethics approval number: ...).

Examples of statements to be used for a retrospective study:

- Ethical approval was waived by the local Ethics Committee of University A in view of the retrospective nature of the study and all the procedures being performed were part of the routine care.
- This research study was conducted retrospectively from data obtained for clinical purposes. We consulted extensively with the IRB of XYZ who determined that our study did not need ethical approval. An IRB official waiver of ethical approval was granted from the IRB of XYZ.
- This retrospective chart review study involving human participants was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The Human Investigation Committee (IRB) of University B approved this study.

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- This is an observational study. The XYZ Research Ethics Committee has confirmed that no ethical approval is required.
- The data reproduced from Article X utilized human tissue that was procured via our Biobank AB, which provides de-identified samples. This study was reviewed and deemed exempt by our XYZ Institutional Review Board. The BioBank protocols are in accordance with the ethical standards of our institution and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Authors are responsible for correctness of the statements provided in the manuscript. See also Authorship Principles. The Editor-in-Chief reserves the right to reject submissions that do not meet the guidelines described in this section.

Informed consent

All individuals have individual rights that are not to be infringed. Individual participants in studies have, for example, the right to decide what happens to the (identifiable) personal data gathered, to what they have said

during a study or an interview, as well as to any photograph that was taken. This is especially true concerning images of vulnerable people (e.g. minors, patients, refugees, etc) or the use of images in sensitive contexts. In many instances authors will need to secure written consent before including images.

Identifying details (names, dates of birth, identity numbers, biometrical characteristics (such as facial features, fingerprint, writing style, voice pattern, DNA or other distinguishing characteristic) and other information) of the participants that were studied should not be published in written descriptions, photographs, and genetic profiles unless the information is essential for scholarly purposes and the participant (or parent/guardian if the participant is a minor or incapable or legal representative) gave written informed consent for publication. Complete anonymity is difficult to achieve in some cases. Detailed descriptions of individual participants, whether of their whole bodies or of body sections, may lead to disclosure of their identity. Under certain circumstances consent is not required as long as information is anonymized and the submission does not include images that may identify the person.

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When biological material is donated for or data is generated as part of a research project authors should ensure, as part of the informed consent procedure, that the participants are made aware what kind of (personal) data will be processed, how it will be used and for what purpose. In case of data acquired via a biobank/biorepository, it is possible they apply a broad consent which allows research participants to consent to a broad range of uses of their data and samples which is regarded by research ethics committees as specific enough to be considered “informed”. However, authors should always check the specific biobank/biorepository policies or any other type of data provider policies (in case of non-bio research) to be sure that this is the case.

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For all research involving human subjects, freely-given, informed consent to participate in the study must be obtained from participants (or their parent or legal guardian in the case of children under 16) and a statement to this effect should appear in the manuscript. In the case of articles describing human transplantation studies, authors must include a statement declaring that no organs/tissues were obtained from prisoners and must also name the institution(s)/clinic(s)/department(s) via which organs/tissues were obtained. For manuscripts reporting studies involving vulnerable groups where there is the potential for coercion or where consent may not have been fully informed, extra care will be taken by the editor and may be referred to the Springer Nature Research Integrity Group.

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Individuals may consent to participate in a study, but object to having their data published in a journal article. Authors should make sure to also seek consent from individuals to publish their data prior to submitting their paper to a journal. This is in particular applicable to case studies. A consent to publish form can be found

[here. \(Download docx, 36 kB\)](#)

Summary of requirements

The above should be summarized in a statement and placed in a ‘Declarations’ section before the reference list under a heading of ‘Consent to participate’ and/or ‘Consent to publish’. Other declarations include Funding, Competing interests, Ethics approval, Consent, Data and/or Code availability and Authors’ contribution statements.

Please see the various examples of wording below and revise/customize the sample statements according to your own needs.

Sample statements for "**Consent to participate**":

Informed consent was obtained from all individual participants included in the study.

Informed consent was obtained from legal guardians.

Written informed consent was obtained from the parents.

Verbal informed consent was obtained prior to the interview.

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The authors affirm that human research participants provided informed consent for publication of the images in Figure(s) 1a, 1b and 1c.

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Authors are responsible for correctness of the statements provided in the manuscript. See also Authorship Principles. The Editor-in-Chief reserves the right to reject submissions that do not meet the guidelines described in this section.

Images will be removed from publication if authors have not obtained informed consent or the paper may be removed and replaced with a notice explaining the reason for removal.

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Please make sure your title page contains the following information.

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Please provide a structured abstract of 150 to 250 words which should be divided into the following sections:

Purpose (stating the main purposes and research question)

Methods

Results

Conclusion

For life science journals only (when applicable)

Trial registration number and date of registration for prospectively registered trials

Trial registration number and date of registration followed by “retrospectively registered”, for retrospectively registered trials

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Please provide 4 to 6 keywords which can be used for indexing purposes.

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Authors are asked to state the relevance of their manuscript to inform research, policies and/or programs.

Review procedure

All manuscripts undergo strict peer review. Manuscripts are initially considered by the Editor-in-Chief. Any manuscript that does not meet the general certain criteria of the journal, e.g.

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All listed authors should have seen and approved the final version of the manuscript.

All authors of accepted articles must sign an authorship form affirming that they have met all three of the following criteria for authorship, thereby accepting public responsibility for appropriate portions of the content:

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