

Effectiveness of Mobile-based and Individual Wellness Coaching on Psychosocial Adjustment and Well-being Among Newly Diagnosed Women With Breast Cancer: A Randomized Controlled Trial Protocol

Eylül Yeşilyurt¹, Şeyma Zehra Altunkürek²

¹Gülhane Health Sciences, Health Sciences University, Ankara, Türkiye

²Gülhane Faculty of Nursing, Health Sciences University, Ankara, Türkiye

Correspondence: Eylül Yeşilyurt, Gülhane Health Sciences, Health Sciences University, Türkiye, Etlik 06010, Ankara. Tel: +905061108000

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Abstract

Background and Aim: Breast cancer is one of the most common cancers among women worldwide, and newly diagnosed patients often experience significant psychosocial distress and challenges in adapting to the disease process. Mobile and individual wellness coaching interventions have emerged as promising approaches to support psychosocial adjustment and enhance overall well-being in this population. This study aims to evaluate the effects of individual wellness coaching and mobile wellness coaching on psychosocial adaptation to illness and well-being in women newly diagnosed with breast cancer.

Methods and Materials: This study is designed as a single-center randomized controlled pilot trial. The study sample will consist of women newly diagnosed with breast cancer attending a hospital in Turkey. The study will be conducted in an oncology outpatient clinic and outpatient chemotherapy unit between June 2026 and April 2027. Participants will be allocated into four groups: Experimental Group 1 (Mobile Application Wellness Coaching Program, n=31), Experimental Group 2 (Individual Wellness Coaching Program, n=31), Experimental Group 3 (Mobile Application + Individual Wellness Coaching Program, n=31), and a control group (n=31). Structured individual wellness coaching and mobile wellness coaching interventions will be applied to the experimental groups. A baseline assessment will be conducted prior to the intervention, a post-test will be administered at 8 weeks, and follow-up assessments will be conducted at 1 and 3 months. Data will be collected using a researcher-developed data collection form.

Conclusion: This study presents a comprehensive intervention model that integrates both individualized coaching and the accessibility and sustainability features of digital health applications. The findings are expected to contribute to the development of a novel supportive

intervention approach in post-diagnosis breast cancer care and to provide guidance for healthcare professionals, particularly nurses, in delivering holistic care.

Trial Registration: This protocol has been registered at ClinicalTrials.gov (NCT07364760) on January 23, 2026.

Keywords: breast cancer; digital health; mobile application; psychosocial adjustment; wellness; wellness coaching

1. Introduction

Breast cancer is among the most common types of cancer worldwide. While it is more common in women, it can also occur in men. According to World Health Organization (WHO) data, in 2022, 2.3 million women worldwide were diagnosed with breast cancer, and 670,000 deaths occurred. The International Agency for Research on Cancer (IARC) predicts that 1 in 20 women worldwide will be diagnosed with breast cancer, and that by 2050 there will be approximately 3.2 million new cases and 1.1 million deaths due to breast cancer (1,2). According to the Turkish Ministry of Health cancer statistics, breast cancer is the most common type of cancer in women, with approximately 1 in 4 female cancer cases being breast cancer. In 2020, 22,805 women in Turkey were diagnosed with breast cancer, corresponding to 43.4 cases per 100,000 women (3). According to GLOBOCAN Turkey data, in 2022, 25,249 new cases (23.5%) of breast cancer were reported among women, while 7,360 deaths (5.7%) occurred due to breast cancer (3,4).

Despite increased survival rates due to early diagnosis and advances in treatment, breast cancer represents a multifaceted crisis for women following diagnosis. The period between diagnosis and initiation of treatment is one of the most stressful phases of the disease trajectory. It significantly affects physical, psychological, social, and sexual domains of life (5,6). Effective management of stress in women newly diagnosed with breast cancer is important for improving disease outcomes, enhancing treatment adherence, and supporting adaptation and overall well-being. Qualitative and descriptive studies have shown that women diagnosed with breast cancer experience complex emotional and psychological responses such as pain, anger, anxiety, and difficulty coping with daily life (6–9). During this complex process, it is crucial for patients to feel supported and not alone, and to benefit from shared experiences of individuals who have undergone similar conditions. At this point, the presence of a coach who accompanies the patient and family, helps them make sense of the process, supports healthy behavioral change, increases active participation in treatment, and strengthens motivation and hope may be beneficial (10).

In addition to physical symptoms, women diagnosed with breast cancer experience intense psychological stress, uncertainty, anxiety, and reduced quality of life from the time of diagnosis. Therefore, in recent years, the importance of psychosocial support and lifestyle-based interventions in addition to conventional medical treatments has increasingly been emphasized (11). Mobile health applications and individual counseling approaches are among the notable supportive interventions in this field. For example, Çınar et al. reported that women with breast cancer who received a 12-week mobile application-based education and individual counseling

program focusing on disease education, symptom tracking, nutrition, physical activity, and stress management experienced improvements in quality of life and reductions in stress levels (11). Another study demonstrated that a spiritual nursing care model improved spiritual well-being and quality of care in cancer patients (12). In clinical practice, healthcare professionals, particularly oncology nurses, often function as informal life coaches throughout the care process. Wellness coaching approaches consider individuals holistically, addressing physical, psychological, and spiritual dimensions. The aim of wellness coaching programs is to enhance well-being by focusing on stress, illness perception, life challenges, acceptance of disease, social relationships, and body image concerns (13).

Today, mobile technologies represent an important tool for engaging with individuals in healthcare. Globally, healthcare professionals increasingly use mobile technologies to reach larger populations and support health improvement (14). Evidence suggests that mobile applications have the potential to facilitate health behavior change (15–17). Therefore, integrating mobile health applications into nursing practice is considered important. Currently, no mobile applications offering structured wellness coaching programs are available in major application stores (Android or iOS). This thesis aims to provide wellness coaching support to women newly diagnosed with breast cancer both through a mobile application and individual sessions. The proposed study, which develops and implements a structured wellness coaching program via both mobile and face-to-face delivery, is expected to contribute an innovative approach to the existing literature.

Existing evidence indicates that psychosocial challenges following a breast cancer diagnosis significantly affect treatment processes, quality of life, and adaptation; however, studies examining structured wellness coaching interventions during this period remain limited. The lack of studies specifically evaluating the effects of wellness coaching on psychosocial adjustment, emotional resilience, stress management, quality of life, and well-being in newly diagnosed breast cancer patients highlights the originality and importance of this research. In this regard, the study offers a comprehensive intervention model that integrates individualized coaching with the accessibility and sustainability advantages of digital health technologies. The findings are expected to identify a novel supportive care approach for post-diagnosis breast cancer management, contribute to clinical practice, and guide healthcare professionals, particularly nurses, in delivering holistic care. Overall, this study is anticipated to make a meaningful scientific contribution and inform future intervention-based research.

The aim of this study is to determine the effects of individual wellness coaching programs and mobile wellness coaching applications on psychosocial adjustment to illness and well-being in women newly diagnosed with breast cancer.

Hypotheses

Hypothesis 1

H0: There is no difference in the mean scores on the Psychosocial Adjustment to Illness-Self-Report Scale between patients who received the mobile application wellness coaching program and those in the control group.

H1: Patients who receive the mobile application wellness coaching program will demonstrate higher psychosocial adjustment compared to those in the control group.

Hypothesis 2

H0: There is no difference in the self-assessments of wellness between patients who received the mobile application wellness coaching program and those in the control group.

H1: Patients who receive the mobile application wellness coaching program will report higher levels of wellness self-assessment compared to those in the control group.

Hypothesis 3

H0: There is no difference in the mean scores on the Psychosocial Adjustment to Illness-Self-Report Scale between patients who received the individual wellness coaching program and those in the control group.

H1: Patients who receive the individual wellness coaching program will demonstrate higher psychosocial adjustment compared to those in the control group.

Hypothesis 4

H0: There is no difference in the self-assessments of wellness between patients who received the individual wellness coaching program and those in the control group.

H1: Patients who receive the individual wellness coaching program will report higher levels of wellness self-assessment compared to those in the control group.

Hypothesis 5

H0: There is no difference in the mean scores on the Psychosocial Adjustment to Illness-Self-Report Scale between patients who received both the mobile application wellness coaching and individual wellness coaching programs and those in the control group.

H1: Patients who receive the combined (mobile application and individual) wellness coaching program will demonstrate higher psychosocial adjustment compared to those in the control group.

Hypothesis 6

H0: There is no difference in wellness self-assessments between patients who received mobile app wellness coaching and individual wellness coaching programs and those in the control group.

H1: Patients who receive the combined (mobile application and individual) wellness coaching program will report higher levels of wellness self-assessment compared to those in the control group.

Hypothesis 7

H0: There is no difference in the mean scores on the Psychosocial Adjustment to Illness-Self-Report Scale between patients who received mobile wellness coaching and those who received individual wellness coaching programs.

H1: There is a difference in psychosocial adjustment between patients receiving mobile wellness coaching and those receiving individual wellness coaching programs.

Hypothesis 8

H0: There is no difference in wellness self-assessments between patients who received mobile wellness coaching and those who received individual wellness coaching programs.

H1: There is a difference in wellness self-assessment between patients receiving mobile wellness coaching and those receiving individual wellness coaching programs.

2. Method

2.1. Study design

The study was planned as a single-center randomized controlled experimental pilot study. (Clinical Trials.gov. ID: NCT07364760). The pilot will help determine the intervention's feasibility, acceptability, fidelity and quality of the programme components.

2.2. Ethical considerations

Ethical approval for the study was obtained from the Ethics Committee for Non-Drug and Non-Medical Device Interventional Research at Gülhane University of Health Sciences. Before the commencement of the study, patients will be informed about the purpose of the research, the study plan, and the expected benefits of the research, and participants who agree to participate will provide their written informed consent form as well as verbal consent.

2.3. The Population and Sample of the Study

The study population will consist of newly diagnosed breast cancer patients who present to the oncology outpatient clinic and outpatient chemotherapy unit in Turkey between Jun 2026 and April 2027. A power analysis was performed to determine the number of participants in the study. The power of the test was calculated using the G*Power 3.1 program. In a similar study in the relevant literature, Sherman et al. (2012) calculated the effect size for change in well-being as 0.891 (8). To exceed 99% power, 104 participants (26 people in each group) were required at a 5% significance level and an effect size of 0.518 (df=25; t=2.060). Considering the high power

of the test and potential losses, the study aimed to reach a total of 124 participants (31 people in each group).

2.4. Participants

Inclusion Criteria for the Study: being 18 years of age or older, being female, having recently been diagnosed with breast cancer, not having participated in any coaching training after receiving a breast cancer diagnosis, knowing turkish, being literate patients and owning a smartphone, having active internet access (mobile data or Wi-Fi), having sufficient digital literacy to use mobile applications,

Exclusion Criteria from the Study: being under 18 years of age, refusing to participate in the study, having a visual or hearing impairment and having a smartphone usage restriction.

Criteria for Withdrawal from the Study During the Study: not wanting to use or not using the mobile wellness coaching application regularly at any stage of the study, wanting to withdraw from the study, passing away and not participating in wellness coaching training.

2.5. Randomization and Blinding

The study sample will be determined according to inclusion and exclusion criteria. The study groups will consist of 124 individuals who meet the inclusion criteria and have signed the consent form. Patients accepted to participate in the study will be assigned to a total of 4 groups: Experimental Group-1 Mobile Application Wellness Coaching Program group, Experimental Group-2 Individual Wellness Coaching Program group, Experimental Group-3 Mobile Application + Individual Wellness Coaching Program group, and a control group (Table 1). To avoid bias, participants will be randomized in the order of arrival. The randomization table was created using the website <https://www.calculatorsoup.com> (18). The CONSORT diagram of the study is given in Figure 1. Individuals included in the study will be randomly assigned to groups according to their order of arrival using a randomization table.

Blinding: Due to the behavioral nature of the intervention, the study was designed as an open-label study. Blinding of participants, intervention providers, and researchers conducting the intervention was not possible. The researcher was actively involved in the process and explained the method to the participants. Therefore, participant and researcher blinding could not be implemented in this study. Outcome measures will be collected through self-report scales and data obtained via a mobile application. Therefore, blinding will not be applied in the outcome assessment. However, data analysis will be performed using standardized and objective statistical methods as far as possible.

2.6. Data Collection Tools

Data will be collected using a data collection form created by the researchers; “Descriptive Information”, “Information Regarding Illness”, “Psychosocial Adaptation to Illness-Self-Report

Scale (PAIS-SR)", "Wellness Wheel" and "Wellness Self-Assessment Form". Final test data will be collected using the "Psychosocial Adaptation to Illness-Self-Report Scale (PAIS-SR)", "Wellness Wheel" and "Wellness Self-Assessment Form". Completing the data collection form is planned to take approximately 20 minutes.

2.7. Descriptive Information

This section consists of 10 questions covering the sociodemographic characteristics of patients, such as age, education, occupation, marital status, etc. It also includes questions about menopausal status, number of children, social security status, and smartphone use.

2.8. Disease-Related Information

This section, prepared in line with the literature, includes questions that describe the patient's diagnosis, family processes, and psychosocial aspects. It consists of a total of 12 questions, including open-ended questions.

2.9. Psychosocial Adjustment to Illness-Self-Report Scale (PAIS-SR)

Developed by Derogatis (1986) to assess the quality of a patient's psychosocial adjustment to a current medical condition or the sequelae of a previous illness (19). The Turkish validity and reliability study of the PAIS-SR was conducted by Adaylar in 1995. The scale, which has sub-dimensions of healthcare adjustment, professional environment, family environment, sexual relations, extended family relations, social environment, and psychological pressure, consists of 46 items. The reliability coefficients of the sub-dimensions of the scale were found to be 0.87, 0.85, 0.80, 0.95, 0.89, 0.93, 0.83, respectively, and 0.94 for the entire scale. The lowest possible score on the scale is 0, and the highest is 138. On the scale, scores below 35 indicate "good psychosocial adjustment," scores between 35 and 51 indicate "moderate psychosocial adjustment," and scores above 51 indicate "poor psychosocial adjustment" (20).

2.10. Wellness Wheel

The theoretical basis of this approach is the "Wellness Wheel" model developed by Myers et al. (2000). This model is considered one of the first holistic wellness approaches that addresses an individual's life through various task and sub-task areas. In the model, the spiritual dimension is at the center, and around it, areas of life such as self-regulation, work, play, love, and friendship are positioned in a circular structure. This approach emphasizes that health is not limited to the physical dimension alone but should be considered as a multifaceted whole (21). The Wellness Wheel (also known as the Wheel of Life) is a circular diagram that visualizes the level of satisfaction in different areas of an individual's life. It aims to evaluate the multidimensional structure of personal well-being holistically. It is generally divided into segments consisting of physical, emotional, mental, social, spiritual/mental, occupational, financial, and environmental areas. The client evaluates each area of life on a scale of 1–10; 1 point indicates significant difficulty and low satisfaction in that area; 10 points indicates high satisfaction and adequate

satisfaction. The resulting visual representation reflects the individual's life balance, clearly revealing their strengths and areas needing improvement. In the literature, this model is used, particularly in university-based health programs, nursing interventions, and wellness coaching practices, to increase individual awareness and support the goal-setting process (22, 23, 24). In this approach, the wellness wheel serves not as a psychometric measurement tool, but rather as a visual model that helps individuals develop insight into their life balance. Following completion of the wheel, the assessment process is supported by five open-ended questions designed to increase the client's awareness and strengthen areas of low satisfaction. Thus, the Wellness Wheel serves as an effective tool for quickly and visually assessing the holistic balance of life.

2.11. Wellness Self-Assessment Form

Developed by researchers in line with the literature, this form aims to help individuals determine their level of well-being in various areas of life (physical, emotional, social, mental, occupational, financial, spiritual, and environmental) through self-assessment (21). The form is based on the eight-dimensional model of the wellness approach and contains a total of 8 questions. It reflects the participant's general perception of life balance. Participants are asked to rate their current situation for each area on a scale of 0 to 10 (0 = not well at all / unbalanced, 10 = I feel perfectly balanced and satisfied). The scores obtained help to identify the individual's strengths and areas for improvement. This form is not used for diagnostic purposes; it is only intended to collect data during the research process and support the individual's self-awareness. A wellness self-assessment form was also developed to integrate the Wellness Wheel into the mobile application. In this context, psychometric validation was not performed at the pre-test level for the form used in the study; Instead, expert opinions (academics, wellness coaches/trainers) were sought during the development process to ensure content suitability, and improvements are planned based on user feedback during the implementation phase.

2.12. Intervention Tools

Mobile Wellness Coaching Application

The researcher who will conduct the application has participated in and completed the Wellness Coaching training provided by “Zenith Well Health Academy.” The mobile application content was developed by the researchers and implemented by expert software developers. Patients who log into the application with their username will first complete the Wellness Wheel. They will then be directed to the relevant areas according to their needs and will be able to access eight sub-dimensions of wellness. Participants will be required to complete the educational content, activities, and assignments within each dimension. They will be monitored by the researcher, and feedback will be provided through the application. Users will receive weekly reflective questions and will be asked to respond to them. In addition, participants will be able to communicate actively with the researchers through the “Ask the Coach a Question” section.

Individual Wellness Coaching Program

Prior to the program, priority areas of participants who complete the Wellness Wheel will be identified. In line with participant preferences, the coaching process will be initiated from the most relevant area based on individual needs. In this study, one session per week over a total of eight weeks (eight sessions in total) is planned. The wellness coaching process consists of structured sessions tailored to individual needs. Sessions will be conducted by the researcher and will aim to facilitate deep reflection and enhance personal insight through the use of powerful questioning techniques. Each session is planned to last approximately 40–45 minutes.

2.13. Implementation of the Research

Patients meeting the inclusion criteria will be informed about the study and invited to participate. Written and verbal informed consent will be obtained from those who agree to participate. Participants will be randomly assigned to groups using a randomization table. The flow diagram of the study, including group allocation and follow-up assessments, is presented in Figure 2.

Experimental Group 1 – Mobile Wellness Coaching Application

Participants assigned to Experimental Group 1 will receive the mobile wellness coaching application intervention. Prior to the intervention, they will complete a data collection form and undergo a baseline assessment. The mobile wellness application will be introduced to participants, and they will be guided to download it to their mobile devices. After installation, participants will create a username and password. Account registration will be completed in the presence of the researcher. The “secret question/secret answer” feature will be explained to ensure account recovery in case of forgotten credentials. Participants will receive training on how to use the application. Participants will be encouraged to begin using the mobile wellness application from the first session. Reminder notifications will be sent to support engagement with training content and activities. Participants’ usage and activities within the application will be monitored via an administrative control panel. Participants will be able to ask questions through the “Ask the Coach” section, and these questions will be reviewed and answered daily by the researchers. Participants will have 24/7 access to the application. A post-test will be administered after 8 weeks. Follow-up assessments will be conducted at the end of the 1st and 3rd months. Post-test and follow-up data will be collected via Google Forms.

Experimental Group 2 – Individual Wellness Coaching Program

Participants assigned to Experimental Group 2 will receive an individual wellness coaching program. They will complete a data collection form in an appropriate clinical setting. Participants who agree to take part in the wellness coaching program will receive one coaching session per week for eight weeks, totaling eight sessions. At the end of the 8-week intervention period, a post-test will be administered via a Google Forms link. Follow-up assessments will be conducted at the end of the 1st and 3rd months.

Experimental Group 3-Mobile Application and Individual Wellness Coaching Program

Patients assigned to experimental group 3 will be approached using a mobile application and an individual wellness coaching program. Patients who agree to participate in the study will be asked to complete a data collection form. The mobile application will be explained to the patients, and they will be asked to download it to their mobile phones. Then, the planned individual wellness coaching program will be implemented over 8 weeks, with one session per week. Patients will also have access to the mobile wellness coaching program throughout the intervention period. Wellness coaching sessions will be conducted both through the mobile application and through individual meetings. At the end of the 8th week, patients will be sent a survey link via Google Forms, and a post-test will be administered. Follow-up assessments will then be conducted at the end of the 1st and 3rd months

Control Group

Participants in the control group will not receive any intervention. They will complete a data collection form. After 8 weeks, participants will be sent a survey link via Google Forms. Follow-up assessments will be conducted at the end of the 1st and 3rd months. At the end of the study, a presentation and information session on the mobile wellness coaching application will be provided. Participants who wish to access the mobile application will be able to do so.

2.14. Pilot Study

The pilot study was conducted at the Medical Oncology Outpatient Clinic of SBÜ Gülhane Training and Research Hospital to evaluate the data collection forms and the user experience of the developed mobile application. In this context, a pilot implementation was carried out with 12 patients who met the inclusion criteria and agreed to participate, representing approximately 10% of the intended sample. The pilot study was designed both to identify potential technical issues related to the mobile health application and to standardize the delivery process of wellness coaching sessions. Accordingly, the developed mobile wellness coaching application underwent a pilot evaluation prior to the main study to assess its technical functionality and usability. During this evaluation, the application was reviewed by an experienced software specialist with expertise in software development, user experience, and mobile health applications. The evaluation focused on functional adequacy, interface usability, data processing performance, notification and tracking mechanisms, system stability, and overall functionality. Based on the feedback obtained, technical errors, usability issues, and areas requiring improvement were identified and necessary modifications were implemented. In this context, the updated version of the mobile wellness coaching application (version 1.0.8) was uploaded and made ready for use. In addition, during the pilot phase, simultaneous usage scenarios across different devices and internet connections were tested. Core user processes such as login and logout operations, access to content, communication with the coach, interaction features, and notification delivery were evaluated. Another objective of the pilot study was to standardize the coaching sessions. In this regard, the implementation of coaching techniques by the principal investigator, the structuring of individual goal-setting processes, and the planning of weekly mini-tasks were standardized.

Following the pilot study, necessary technical and content-related revisions were made based on the feedback obtained. Participants included in the pilot study were not included in the main study sample. Participants included in the pilot study will not be included in the main study sample. Data from these participants will not be included in the analyses.

2.15. Research Variables

Dependent Variables

The dependent variables of the research consist of the total mean score of the Psychosocial Adjustment to Illness-Self-Report Scale and the mean scores of the subscales, the Wellness Wheel, and the Wellness self-assessment form.

Independent Variables

The mobile application and individual wellness coaching training constitute the independent variables of the research.

Control Variables

The control variables of the research consist of the data in the "Descriptive Information" and "Illness-Related Information" sections of the survey form.

2.16. Data Analysis

The data obtained in the study will be analyzed using the SPSS (Statistical Package for Social Sciences) for Windows 22.0 software package. The Kolmogorov–Smirnov test will be used to assess whether the data are normally distributed. According to this test, if $p > 0.05$, the distribution will be considered normal; if $p < 0.05$, the distribution will be considered non-normal. In addition, skewness and kurtosis values will be examined, and values between +2 and -2 will be considered indicative of an approximately normal distribution (25). The homogeneity of descriptive characteristics among groups will be assessed using the chi-square test. For comparisons between independent groups, one-way analysis of variance (ANOVA) will be used for normally distributed data, while the Kruskal–Wallis H test will be applied for non-normally distributed data. Within-group changes over time will be analyzed using repeated measures ANOVA for normally distributed data, and the Friedman test will be used when normality assumptions are not met. Missing data will be assessed in terms of extent and pattern. The mechanism of missingness will be evaluated (missing completely at random, missing at random, or not at random). Appropriate statistical methods, such as multiple imputation, will be used when necessary to reduce potential bias. Sensitivity analyses will be performed to evaluate the robustness of the findings under different missing data assumptions. The primary analysis will be conducted based on the intention-to-treat (ITT) principle, including all randomized participants in the groups to which they were originally assigned, regardless of adherence to the intervention. This approach is expected to preserve the benefits of randomization and minimize selection bias. In addition, a per-protocol analysis will be performed as a secondary analysis, including only participants who complete the intervention according to the study protocol with adequate

adherence. This dual approach is expected to provide a more comprehensive understanding of the robustness and potential effectiveness of the intervention. A p-value of < 0.05 will be considered statistically significant.

3. Discussion

This study is designed to develop and evaluate a mobile app-supported wellness coaching intervention for women newly diagnosed with breast cancer, with a focus on psychosocial adjustment and well-being. The increasing integration of mobile health (mHealth) technologies and coaching-based approaches in oncology care has provided a strong rationale for designing structured, user-centered digital interventions that extend psychosocial support beyond traditional clinical settings. Within this context, the present protocol is grounded in the assumption that combining coaching principles with mobile health delivery may offer a structured framework for supporting patient engagement in self-management and adaptive coping processes.

The design of this intervention is informed by existing literature on digital psychoeducational tools and mobile-based support systems in cancer care. Previous studies have reported that mobile applications incorporating psychoeducation and interactive components such as guided discussions or structured self-monitoring features are frequently used as supportive elements in symptom management and psychological adjustment frameworks (12, 26-30). These studies provide supportive evidence in the literature for the integration of educational and reflective components into app-based wellness interventions. In addition, prior research on mobile health interventions incorporating individualized coaching strategies suggests that tailoring content to user needs and providing structured guidance may enhance engagement with health-related behaviors. This protocol builds on the assumption that personalization and structured feedback mechanisms may be critical design features for sustaining user interaction within digital health platforms.

The current protocol is also informed by evidence indicating that mobile health interventions in oncology settings are commonly designed to extend informational and supportive care beyond hospital environments. Such systems are conceptually positioned to address not only informational needs but also psychosocial support requirements throughout the cancer trajectory (28-32). Accordingly, the present study adopts a design-oriented approach that situates the mobile application as a supportive infrastructure for wellness-oriented self-reflection and coaching delivery.

Furthermore, patient engagement is a central consideration in the design of digital health interventions. Existing studies highlight that usability, personalization, and coaching-based interaction structures are key determinants of sustained engagement in mobile health applications (33). This evidence provides justification for incorporating adaptive and user-centered design principles in the development of the intervention.

The psychosocial burden associated with breast cancer diagnosis is well documented in the literature, particularly in relation to anxiety, depression, and the role of social support in adaptation processes (34). Within this protocol, these findings are used to justify the development of a structured wellness coaching framework aimed at supporting adaptive coping processes rather than to infer expected clinical outcomes. Overall, this study contributes to the growing field of digital oncology care by proposing a theoretically grounded, mobile-supported wellness coaching design that integrates behavioral coaching principles with structured self-assessment components.

4. Conclusion

This randomized controlled trial is expected to reveal the effects of wellness coaching and mobile app-supported intervention on psychosocial adjustment and well-being in women newly diagnosed with breast cancer. Participants in the intervention group are projected to show a significant increase in psychosocial adjustment levels compared to the control group.

The study expects the intervention to have particularly positive effects on emotional well-being, psychological resilience, stress management, and overall well-being. The coaching process is thought to support individuals in participating more actively and adaptively in the disease process by increasing their self-awareness.

In terms of secondary outcomes, a decrease in anxiety and emotional distress levels, and an increase in life satisfaction and perceived social support levels are expected in individuals in the intervention group. These findings aim to demonstrate that wellness coaching not only reduces symptoms but also strengthens the individual's holistic well-being.

The results of this study are expected to provide scientific evidence regarding the integration of structured wellness coaching and mobile app wellness coaching into psychosocial support programs for women newly diagnosed with breast cancer. Furthermore, the study findings aim to contribute to the development of patient-centered and holistic care approaches, guiding the application of digital and behavioral interventions in the field of oncology.

This study has not yet actively recruited participants. The mobile application is not yet active. Estimated participant recruitment is planned to begin in Jun 2026. Study protocol version 1. If any changes are necessary to the study protocol, the relevant sections of the study will be updated, and the changes will be corrected on ClinicalTrials.gov. This study is registered on ClinicalTrials.gov (identifier: NCT07364760). Completion of the study is projected for April 2027.

Strengths and limitations of the study

This study is planned as a randomized controlled trial. Randomized controlled trials are considered the gold standard for evaluating the effectiveness of complex interventions. Within

this context, it is anticipated that the effects of the wellness coaching and mobile application-supported intervention on psychosocial adjustment and well-being will be assessed within a more robust methodological framework.

One of the key strengths of the study is its focus on women newly diagnosed with breast cancer. The early post-diagnosis period is recognized as a critical stage characterized by intense emotional distress, uncertainty, and adaptation difficulties. It is expected that wellness coaching support provided during this period may contribute to enhancing coping processes and psychosocial adjustment.

In addition, the intervention is planned to be supported by a mobile health application, which is expected to facilitate continuous engagement, promote self-monitoring, and enhance accessibility by reducing time and location constraints. The holistic nature of the intervention, which is designed to address emotional, psychological, social, and spiritual dimensions of well-being together, is anticipated to provide an innovative and patient-centered contribution to the field of psychosocial oncology.

However, several limitations are anticipated in this study. Due to the behavioral nature of the intervention, blinding of participants and wellness coaches will not be feasible, which may introduce potential performance bias. Furthermore, reliance on self-report instruments for some outcome measures may increase the risk of response and recall bias. The conduct of the study in a single center may also limit the generalizability of the findings. Finally, as short- and medium-term outcomes will be assessed, longer-term follow-up studies will be required to evaluate the sustained effects of the intervention.

Despite these limitations, the study is expected to provide valuable scientific evidence regarding the potential effects of a wellness coaching and mobile application-supported intervention on psychosocial adjustment and well-being in women newly diagnosed with breast cancer.

Acknowledgment

The authors would like to thank all individuals who contributed to the development of this study protocol.

Conflict of Interest

No conflict of interest has been declared by the authors in relation to the study itself.

Data Availability Statement

The data used to support the findings of this study are available from the corresponding author upon request.

Table 1. Randomization table

Group1	Group2	Group3	Group4
86, 33, 64, 63, 53, 48, 112, 89, 31, 3, 28, 74, 20, 68, 37, 47, 106, 69, 77, 108, 16, 44, 17, 85, 100, 115, 121, 81, 35, 66, 14	13, 84, 7, 87, 12, 32, 93, 46, 110, 71, 107, 1, 123, 113, 75, 30, 38, 50, 34, 92, 11, 105, 109, 22, 57, 95, 103, 18, 79, 27, 43	21, 36, 120, 2, 40, 58, 102, 61, 56, 19, 65, 70, 8, 80, 49, 55, 101, 25, 52, 111, 119, 78, 42, 72, 124, 122, 10, 45, 98, 97, 6	104, 41, 62, 96, 118, 91, 4, 88, 5, 99, 24, 117, 83, 26, 60, 73, 67, 51, 82, 59, 23, 94, 116, 39, 9, 54, 15, 90, 76, 114, 29

Source: <https://www.calculatorsoup.com/calculators/statistics/random-number-generator.php>

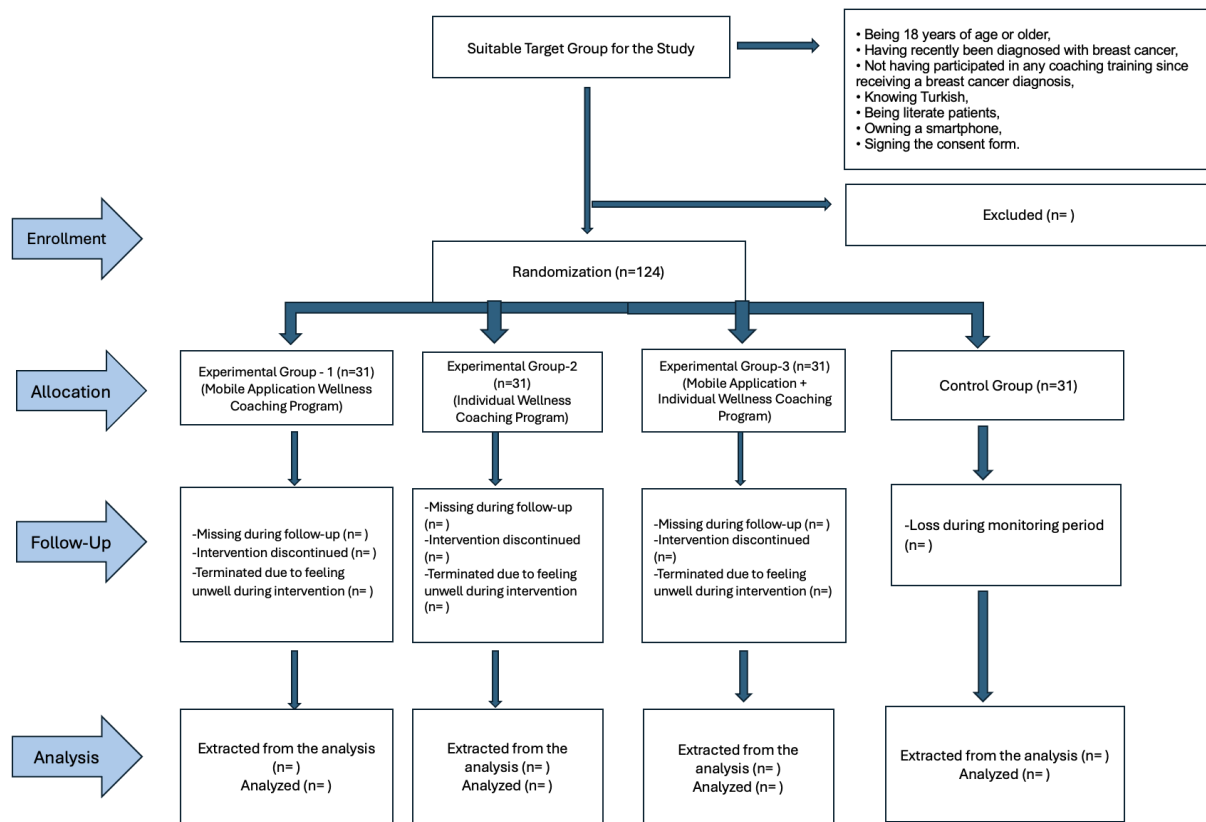


Figure 1. Flowchart of the experimental and control groups of the study CONSORT (2017)

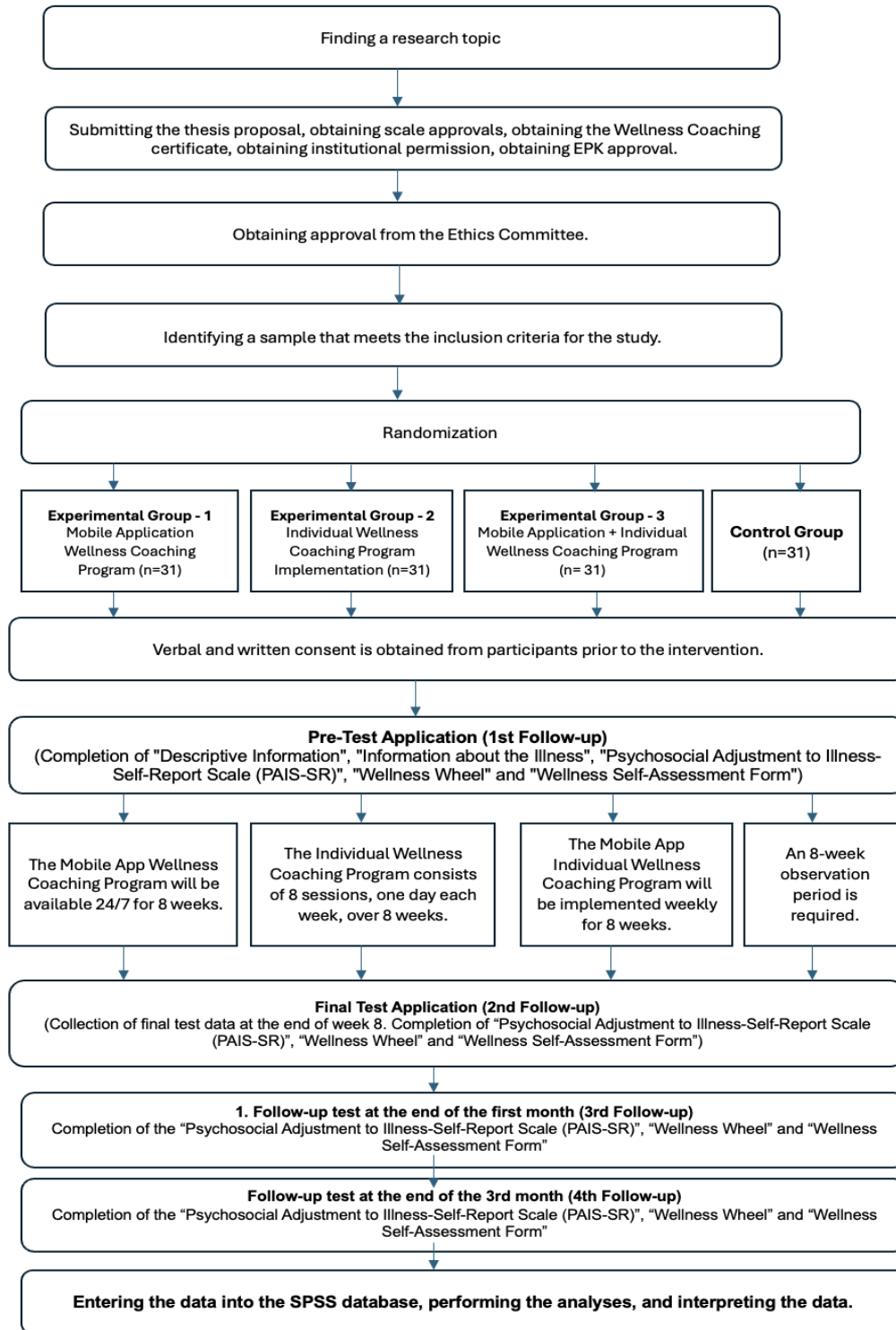


Figure 2. Flowchart of the research

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