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Official Title

Effectiveness of a digital psychoeducational intervention for young adults with fertility related distress following cancer diagnosis: A randomized controlled trial

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1. Purpose of the Study

The purpose of this study will be to evaluate the effectiveness of a digital psychoeducational intervention for young adults with fertility related distress following cancer diagnosis on anxiety, depression, self-efficacy, coping, social support, and quality of life. This intervention will mainly focus on constructing effective coping strategies and social support networks. Efforts made for building coping skills and social support networks will support Young Adults (YAs) with cancer in choosing and practicing appropriate coping strategies, while also helping identify the need for social support and coping assistance more readily. As coping is a life-long process that fluctuates depending on a patient's condition, developing a psychoeducational intervention that supports the development of coping strategies should help directly reduce patients' depression, anxiety and increase their self-efficacy, social support and quality of life. Findings from our study will have important implications in the nursing area in regards to patient care, support, and assessing needs.

To the best of our knowledge, this is the first study that will investigate the effectiveness of a digital psychoeducational intervention for young adults with fertility related distress following cancer diagnosis on anxiety, depression, self-efficacy, coping, social support and quality of life.

1. Significance & Literature Review

Young adulthood often involves numerous life transitions and pivotal development stages such as identity development, educational development, career decision-making, and life planning. Given these young adults (YAs) with cancer face unique physical, psychological, and social challenges compared to younger and older cancer patients. Coping with these life changes alongside a cancer diagnosis and treatment, necessitates effective support, sufficient coping strategies, and often increased sensitivity from others (Richter et al., 2015). Studies have shown that YA cancer survivors experience high rates of cancer related distress, particularly post treatment (Yanez et al., 2013; Kwak et al., 2013). A key factor that contributes to cancer related distress among AY is concerns about fertility.

Fertility plays an important role in the lives of humans and young adulthood is the optimal time to have biological children. Fertility issues following cancer diagnosis and treatment can have complex psychological impacts. YAs with cancer may experience distress, anxiety, depression, low self-esteem, poor quality of life, and challenges with gender identity due to fertility related concerns (Ehrbar and Tschudin 2022; Newton et al., 2021; Patterson et al., 2021). Perceived impaired fertility can negatively affect self-concept, romantic and social relationships, and life planning (Carpentier and Fortenberry, 2010; Halliday et al., 2013; Chapple et al., 2007). These negative effects may increase as YAs progress pass their cancer diagnosis and treatment, and consider staring a family (Benedict et al. 2016). A recent systematic review indicated that fertility related concerns can persist up to decades after a cancer diagnosis and are an important source of YA cancer survivors' psychological distress (Logan et al. 2019). Over time, such fertility related distress can lead to the development of psychological disorders. In addition to psychological effects, reproductive concerns can also affect various aspects of medical treatment, including treatment protocol decision-making and adherence (Printz 2015; Senkus et al., 2014). Over time, these factors can negatively affect the quality of life of young adult cancer survivors (Benedict et al., 2018).

Geue et al. (2014) claims that the majority of young adults with cancer (age >25 years up to 39 years) desire children after overcoming their disease, so providing information about fertility and fertility preservation options is essential for their care. The American Society of Clinical Oncology (ASCO) released updated evidence-based guidelines on fertility preservation in 2018, underscoring the responsibility of healthcare providers caring for young adult cancer patients to address infertility risks with patients and, when appropriate, their parents. ASCO further advised that clinicians should either counsel patients on fertility-preservation strategies or promptly refer them to qualified reproductive specialists prior to the start of cancer treatment (Oktay et al., 2018). Despite these updated guidelines research has indicated that cancer patients remain unsatisfied with the fertility related counseling that they receive (Ehrbar et al., 2019; Harada and Osuga 2019). Additionally, research by Din et al. (2023) suggested that YA cancer survivors have higher perceived risk of fertility complications than actual risk, which increases their psychological distress and warrants the need for further fertility counseling and education. Lack of healthcare professionals' competence in educating YA cancer patients about potential fertility complications and available options also points to the need for better educational opportunities (Tomioka et al. 2022). Given these dynamics this study aims to develop and assess the impacts of a psychoeducational intervention to help educate YA cancer patients about fertility in the context of cancer and more broadly, and assist them to develop effective coping strategies and social support networks.

Most psychoeducational interventions using traditional formats or those combined with automated clinician alerts have proven to be effective in reducing a variety of symptoms (Berger et al., 2013). Psychoeducational interventions are one type of referral intervention widely believed to be an effective multimodal intervention in improving symptom management and QoL among cancer patients, particularly young adult with cancer (McGillion et al., 2008). Psychoeducational interventions consist of a wide range of elements such as educational programs, information, counseling, and supportive interventions. Psychoeducational interventions may involve tailored interventions that directly fulfill individual needs. Approaches used in psychoeducational interventions may include information giving and receiving, discussion of concerns, problem-solving, coping skills training, expression of emotion, and social support (Lukens and McFarlane, 2004). Psychoeducational interventions have proven effective for people varying in age and background (Van Daele et al., 2011).

Technological advancements and digital health resources, such as eHealth, are increasingly being recommended to address the challenges faced in healthcare (Hickey, 2020). By providing a cost-effective means of expanding the reach of clinical care and facilitating efficient patient communication and support, eHealth can improve quality of life in patients and reduce healthcare costs (Capurro et al., 2014), as well as reduce travel time (Barbabella et al., 2017). Considering that most care for people living with serious illness is offered at home, digital formats could be considered a potential way to provide psychoeducational support to patients with cancer through providing training on how to cope with the impact of the disease on their lives (Zhang et al., 2024). A systematic review and meta-analysis examining eHealth/mHealth interventions concluded that guided intervention may have better effects compared with self-guided interventions particularly among cancer patients (Furness et al., 2020; Seiler et al., 2017). Furthermore, a digital web-based education program was found to have efficacy in remote

symptom management and improving the quality of life of cancer patients (Bektas, 2022). Given positive yet continued mixed findings, researchers have called for an increased focus on evidence-based eHealth interventions, the involvement of healthcare providers when developing technology-based psychosocial interventions, and outcome assessments to gauge intervention impact (Urech et al, 2018; Børøsund and Varsi 2019).

A recent systematic review of psychosocial programs (a broader category of interventions that include psychoeducational interventions) to alleviate fertility related distress among cancer patients found limited research on the topic and that most studies conducted on the topic have focused on cancer survivors (Jang et al., 2025). These findings highlight the need for further research and to address the fertility related distress of patients recently diagnosed with cancer as well as those currently being treated. Jang and colleagues' (2025) analysis indicated that programs that target knowledge development can improve fertility-related knowledge specifically as well as health literacy in general. They claim that such education should focus on the potential harmful effects of treatment on reproduction as well as how to process information about treatment options, while providing skills training for long-term family planning. In addition to this, Allison et al. (2023) and Glazer and Schulte (2022) claim that fertility-related psychosocial interventions should not only give patients the opportunity to develop new knowledge about fertility issues but also the ability to discuss their fertility-related concerns. Specifically, they call for interventions that support the development of patients coping skills facilitating them with the long-term ability to cope with their fertility problems.

Lazarus and Folksman's (1991) defines coping as cognitive and behavioral efforts to handle particular demands, both external and internal, that surpass one's available resources. The coping strategies used depend on individuals' appraisal of the situation that they face, and may function to protect or harm their wellbeing (Lazarus, 1993). Research has found that appropriate coping strategies are correlated with better mental health and quality of life (Greer et al., 2020). Therefore, strengthening coping can reduce mental health problems and increase quality of life among cancer survivor. Additionally, Cipolletta et al. (2019) claims that psychosocial interventions that provide patients with information about cancer, typical emotional responses, and effective coping strategies can play an important role in reducing stress, while helping them develop skills to better understand the challenges they face and supporting them to reframe their abilities, behaviors, and daily routines to regain a sense of control.

It is important to note that coping strategies are context specific and cultural awareness is necessary to develop effective psychoeducational interventions that promote coping strategy development. This study will be conducted in Indonesia, a context in which fertility and family are highly valued. While research specifically on the needs of young adult cancer patients is limited, unpublished research suggests that patients lack information about cancer's impact on fertility, and that this is a source of distress for YA cancer patients. Previous research has found that coping is a mediator for mental health problems and quality of life among cancer patients in Indonesia, and religion has proven to be a particularly effective coping strategy (Huda et al. 2021).

In Indonesia, GLOBOCAN 2022 reported 408,661 new cancer cases and 242,099 cancer-related deaths, with the highest prevalence observed in breast (19%), cervical (9%), lung (8%), colorectal (7%), and liver (6%) cancers (Sung et al., 2022). These data indicate that the burden of

cancer continues to rise alongside increasing life expectancy and changes in the pattern of non-communicable diseases (Ministry of Health of the Republic of Indonesia, 2024). Additionally, while research specifically on YA cancer patients is limited, available research suggests that YA survivors in Indonesia experience similar cancer related distress due to fears of recurrence, long-term side effects impacting future endeavors, and social stigma (Wulandari et al., 2021).

2. Research Aims

Our primary research aim is to explore to what extent a digital psychoeducational intervention is effective at managing psychological problems and improving quality of life among young adults with fertility related distress following cancer diagnosis in Indonesia compared to usual care. We hypothesized that the digital psychoeducational intervention will 1) decrease anxiety and depression, and 2) increase self-efficacy, social support, coping and quality of life among young adults with fertility related distress following cancer.

Primary Outcome

- Does the digital psychoeducational intervention reduce anxiety severity compared with usual care?
- Does the digital psychoeducational intervention reduce depression severity compared with usual care?
- Does the digital psychoeducational intervention increase patient's self-efficacy compared with usual care?
- Does the digital psychoeducational intervention increase patient's social support compared with usual care?
- Does the digital psychoeducational intervention increase patient's coping compared with usual care?

Secondary Outcomes

- Does digital psychoeducational intervention increase patients' quality of life compared with usual care?

3. Theoretical Framework

The theoretical framework for this study is grounded in Lazarus and Folkman's (1991) Coping Theory, which defines coping as the cognitive and behavioral efforts used to manage specific internal and external demands that are appraised as taxing or exceeding an individual's resources. According to Lazarus and Folkman (1984), coping mechanisms are mobilized in response to perceived threat. These strategies are considered effective when individuals can dilute unpleasant feelings related to their loss or their threats. The coping strategies chosen by an individual correlate with indicators of depression and anxiety (Saroto and Osario, 2015; Dahal and Meheta, 2018). This theory is particularly relevant to young adult cancer patients, who face distinct physical, developmental, and psychological challenges (De Faye et al., 2006). Coping theory emphasizes that individuals' responses are shaped by their appraisal of the situation, and these strategies can either protect or undermine their wellbeing. Among Yas cancer patients, appraisal processes involve continual interpretation of their circumstances, including psychological concerns such as

anxiety, depression, and perceived self-efficacy (Thomsen et al., 2010), as they attempt to manage the burdens of cancer and treatment.

Bandura's (1997) self-efficacy theory deepens this understanding of coping by identifying self-efficacy as a core component of secondary appraisal within the coping process. Self-efficacy influences whether individuals believe they can effectively manage stressors, engage in problem-solving, and maintain emotional regulation. Higher self-efficacy supports the use of adaptive coping strategies, whereas lower self-efficacy may increase vulnerability to distress. Social support further interacts with these processes. A substantial body of nursing and psycho-oncology literature demonstrates that social support enhances individuals' appraisal of control, reduces perceived threat, and directly strengthens self-efficacy (Helgeson and Cohen, 1996; Northouse et al., 2010; Zebrack, 2011). In cancer care, social support from partners, peers, and healthcare professionals has consistently been shown to protect against psychological distress, promote adaptive coping, and improve perceived ability to manage illness-related challenges (Northouse et al., 2012; Hou et al., 2015). These findings are particularly relevant for YA cancer patients coping with fertility-related concerns, who often report heightened isolation and uncertainty. Supportive interactions can validate concerns, reduce emotional burden, and encourage confidence in navigating fertility-related decisions.

Tying together coping theory, self-efficacy, and social support provides a strong theoretical basis for developing psychoeducational interventions, especially among young adult cancer patients. Psychoeducation aims to improve knowledge, normalize emotional responses, teach coping strategies, and provides role modeling, all of which support self-efficacy and facilitate more adaptive coping. When delivered in supportive contexts, psychoeducation can also strengthen social support networks. Thus, a psychoeducational intervention that utilizes multiple interconnected mechanisms (e.g., appraisal, perceived control, interpersonal support) may help reduce fertility-related distress among young adults with cancer.

4. Methods

a. Research Design

This research will consist of 4 research stages. The aim of Stage 1, Literature Review, is to identify relevant existing interventions that will then be used to develop the framework for our digital psychoeducational intervention. During Stage 2, Content Validity Testing, the content of the intervention developed during Stage 1 will be assessed and revised via the input of an expert team and feedback from various stakeholders. Validity testing will be conducted through two means. First, seven experts from diverse areas will be invited to assess the content of the intervention. The experts will consist of two experts from nursing (holding a doctoral degree with a minimum of 5 years of experience in nursing), two experts from medicine (holding an oncology specialist degree and at least 5 years of clinical experience), two head nurses (with bachelor degrees and 10 years of experience in oncology wards), two fertility specialists, and one clinical psychologist (holding a magister degree in psychology and 5 years of experience in oncology). In Stage 3, Intervention Trial, the intervention will be trialed with 10 patients to determine acceptability, comprehensiveness, and the proposed use of the intervention. Qualitative interviews will be conducted with the trial patients and based on their feedback and the results of the trial the

intervention will be revised again. At the end of Stage 3, the final intervention will be launched and primary data collection will commence. Stage 4 is the main stage of this research where the effectiveness of the digital psychoeducational intervention will be assessed. This study will consist of a randomized control trial (RCT) that has been designed using the Consolidated Standards of Reporting Trials (CONSORT) statement. Both the study quality and conduct will be enhanced by utilizing this format in all stages, particularly since this format is currently recognized as the standard for all published RCT.

b. Subject and Setting

This study will be conducted at the Oncology Inward Unit of Arifin Ahmad Hospital, Pekanbaru, Indonesia. The sample size has already been calculated using free-to-use software, namely G*Power for Windows V.3.1.9.6. The effect size is 0.81, type 1 error (α)=5% (two-tailed), power (1−β) 90% and the allocation ratio between the groups is 1:1. The effect size was set with reference to previous studies with similar outcomes (Bani Mohammad and Ahmad, 2019). With consideration of an expected dropout rate of 10%, the sample size will be 38 patients per group. Purposive sampling will be used to select individuals who meet the inclusion and exclusion criteria. To be eligible, patients must be diagnosed with cancer, self-report fertility related distress, be aged ≥18-40 years old, be able to speak Bahasa (the national language of Indonesia), and have a performance status ECOG score of 0–2. Patients will be excluded if they have a severe medical condition which impacts their level of consciousness, have been diagnosed with a major psychiatric comorbidity, or are unable to fill out the study questionnaires. Written informed consent will be obtained from all participants. This study is currently under ethical review by the Ethical Review Board for Medicine and Health Research, Faculty of Nursing at the University of Riau.

c. Instruments

The measurement tools will be divided into two parts which include participants' characteristic questionnaires and 5 validated questionnaires for measuring the outcomes. Participant characteristics will consist of the following information: gender, age, marital status, religion, education level, occupation, and income. Information about patients' type of cancer, time of diagnosis, and kind of treatment will be gathered from the patients and double-checked with their medical charts. For the outcomes, The Depression, Anxiety, and Stress Scale (DASS-D and DASS-A) will be used to measure depression and anxiety. The Brief Coping Orientation to Problems Experienced Inventory (Brief COPE) will measure coping. Cancer Behavior Inventory will be used to measure self-efficacy. The Multidimensional Scale of Perceived Social Support will measure participants' perceived level of social support. The Functional Assessment of Cancer Therapy-G will be used to measure quality of life. All of the questionnaires have been translated into Bahasa and have good validity and reliability (Huda et al., 2022; Susanti, et al., 2022; Laksmita, et al., 2020; Widyaningsih, 2013; Rosyani, 2012).

Depression, Anxiety, and Stress Scale (DASS)

The DASS is comprised of three subscales including the DASS-Stress, DASS-Anxiety, and DASS Depression that investigate stress, anxiety, and depression, respectively, 1 week before the survey

(Lovibond & Lovibond, 1995). The Subscale DASS-A and DASS D will be used to measure anxiety and depression. Each subscale contains 14 questions with a Likert scale from 0 to 3: 0, does not apply to me at all, 1, applies to me to some degree or some of the time, 2, applies to me to a considerable degree or a good part of the time, and 3, applies to me very much or most of the time. Scores for depression, anxiety, and stress are calculated by summing the scores for the relevant items of each subscale. A higher score indicates a higher severity of each subscale.

Brief Coping Orientation to Problems Experienced Inventory (Brief COPE)

The Brief COPE is the most commonly used measure to identify the nature of coping strategies implemented by individuals and explores 14 coping strategies (Carver, 1997). Every strategy has two items. In total, it contains 28 items and is rated on a 4-point Likert scale. In this study, coping strategies will be divided into problem-focus coping (PFC) and emotional-focus coping (EFC). PFC consists of acceptance, religion, planning, humor, positive reframing, instrumental support, active coping, and emotional support. Self-distraction, venting, self-blame, behavioral disengagement, denial, and substance use are classified as EFC (Carver, 1997) A higher score represents greater coping strategies used by respondents. The Indonesian version of the Brief COPE exhibited good reliability with $\alpha = 0.825$ (Rosyani, 2012).

Cancer Behavior Inventory (CBI-B V1.0-12)

The *cancer behavior inventory (cbi-b v1.0-12) is* the questionnaire that will measures self-efficacy when dealing with cancer. It consists of 12 questions with a scale range of 1-9 where the higher the score, the higher self-efficacy. The assessment of the questions used a Likert scale from 1 to 9 (1 = absolutely not sure, 5 = sure, 9 = absolutely sure). Its reliability of test result had a Cronbach's alpha value of 0.954

The Multidimensional Scale of Perceived Social Support (MSPSS)

The Multidimensional Scale of Perceived Social Support (MSPSS) is a short instrument designed to measure an individual's perception of support from 3 sources: family, friends and a significant other. This instrument is 12 questions long and has been widely used and well validated. Across many studies, the MSPSS has been shown to have good internal and test-retest reliability, good validity, and a fairly stable factorial structure. The MSPSS is a self-administered measurement tool with 3 subscales: Family (items 3, 4, 8, and 11), Friends (items 6, 7, 9, and 12), and Significant Others (items 1, 2, 5, and 10). Every item uses a seven-point Likert scale ranging from 1 (very strongly disagree) to 7 (very strongly agree). A higher score indicates greater perceived social support. The total possible score ranges from 12 to 84, or it can be scored according to its subscales by adding the items in each subscale and then dividing by 4. The original version of the MSPSS has very good internal reliability with an α coefficient of 0.88 for the total scale, 0.87 for the Family subscale, 0.85 for the Friends subscale, and 0.91 for the Significant Others subscale (Zimet et al., 1988). The Indonesian version has good reliability values (>0.7) and the items in the same construct have been assessed as strongly correlated and reliable (Laksmita et al., 2020).

Functional Assessment of Cancer Therapy-G (FACT-G)

The FACT-G is used for measuring QoL of cancer patients and is considered appropriate to use for any form of cancer and the general population (Cella et al., 1993). The FACT-G consists of 27 items of general questions divided into 4 primary QoL domains: physical wellbeing (PWB), social/family wellbeing (SWB), emotional wellbeing (EWB), and functional wellbeing (FWB). The total FACT-G score is obtained by summing individual subscale scores. Therefore, a higher score indicates a higher QoL. The Indonesian version of the FACT-G showed good reliability with $\alpha = 0.84$ (Widyaningsih, 2013).

d. Procedures

Recruitment and Researchers

The recruitment of respondents will involve the head nurse and primary nurse from the oncology wards. Patients will be selected using purposive sampling achieved through identifying patients who meet the inclusion criteria based on a review of medical records and inquiring about their fertility concerns. Afterwards, the head nurse, primary nurse, and researcher will discuss who will be included. Patients who are interested in participating in the study will meet with the research nurse who will explain the study and seek written informed consent.

Patients will be divided into two groups: experimental and control. Assignment to either the intervention or the control group will be randomly determined by the lucky draw method, where the patients themselves will select an unlabeled envelope. The head nurse will have no foreknowledge of group assignment, hence, protecting patients and the head nurse from influencing consent. Once the group assignment is completed, the head nurse will have no further involvement in the intervention. The experimental group will be exposed to psychoeducational materials: 4 educational sessions with 4 psychoeducational modules delivered via an initial face to face session followed by digital intervention (mobile application installed on mobile phone). For the control group, they will receive standard care. All participants will complete the questionnaires.

Given that this is a psychoeducational intervention where participants may be aware of and eager to know about the program that is being received by the other group, efforts will have to be made by the researchers to minimize cross contamination such as limiting psychoeducational materials to only the experimental group, educating patients about study confidentiality for both the control and experimental groups and clearly explaining information about the purpose and the nature of the study.

Data will be collected by the principal researcher and a research assistant who will be blinded to group allocation. The research assistant must meet certain criteria such as being a registered nurse and having two years of nursing experience. The research assistant will undergo training to familiarize them with the study. The training materials will include how to collect data at three different time points, how to deal with drop outs, ethical considerations, inform consent, and psychoeducational principles and the intended learning outcomes achieved by respondents. The principal researcher will also strictly monitor the research assistant and make sure they follow the research protocol.

Data Collection and Psychoeducational Intervention

After agreeing to participant in the study written informed consent will be sought from participants in both the experimental and control groups. Afterwards, the research assistant will administer the questionnaires and gather demographic data from patients in both groups at a time suitable for them.

The psychoeducation intervention will begin with an introductory session that will be conducted as a one-time, in-person structured individual or group session led by healthcare study personnel trained by a clinical health psychologist. This session will allow participants to develop a relationship with a counsellor in case they need follow-up care and explore their needs related to the education. In this session, the research team will introduce participants to the application and provide help downloading the application from the App store or Google play, and give instructions in how to use the program.

Following the initial session 4 thematic modules will be delivered through the application. The themes of these modules include: (1) Cancer and Fertility: general cancer, fertility and sexual health education, potential fertility complications posted by cancer treatment, available assisted reproductive technology options; (2) Development of Coping Skills: education related to constructing problem-focused coping that involves changing the situation to reduce stress and emotion-focused coping that involves managing feelings when situations cannot be changed; (3) Self-Efficacy: ability to complete tasks and achieve goals; and (4) Social-Support: equipping individuals with the skills needed to provide and receive support. See Appendix 3 for additional information about each module.

Each module will consist of an e-booklet, video, and quizzes. It will take between 35 and 50 minutes if completed in one setting without interruption. To encourage content practice, each thematic module will be required to be open for 2 days before the next module will open. To provide structure, the modules will be sequential. To motivate continued use of the application, participants will receive messages such as: “Very good! You have now completed Module 2!” In addition, participants will have the option to receive daily reminders from the application and will be able to choose their own timing for receiving the reminder. Furthermore, participant will also be given direct access to a counsellor through the app where they can send messages and questions through the application.

Program progress will be monitored by the research team through app activity. All participants in the intervention group will receive a follow-up phone call from study staff 2 weeks after the introduction session. The use of telephone is quite convenient since it is commonly used in low- and middle-income countries, such as Indonesia. During the follow-up call participants will be asked if they are experiencing any difficulties using the application and will be encouraged to use the app and apply the coping strategies and the social support skills that they are learning. Verbal feedback will also be sought about the sessions during the follow-up calls. (The flow of participation and the timing of measurements are clearly presented in Appendix 2.)

Participants in the control group will receive standard treatment from HCPs (oncologists, nurses, and psychologist) from Arifin Ahmad Hospital. Oncologists usually provide brief explanations about cancer, treatment, and symptoms that patients may experience with some focus on fertility

issues and give instructions to patients about their medication, therapy, side effects of therapy, follow up, and routine advice. Nurses are more focused on doing nursing general assessments that include physical and psychological problems that patients might have while psychologist commonly focus on patients' counselling needs. At the end of the data collection period, patients in the control group will receive the same psychoeducational materials that the intervention group received.

For both the experimental and control groups questionnaires will be administered at fourth time points: (1) upon enrollment in the study, (2) after the fourth module (experimental group) or two weeks following enrollment in the study (control group), (3) 3 weeks following the completion of modules (experimental group) or 5 weeks following enrollment in the study (control group) and (4) 12 weeks following the completion modules (experimental group) or 14 weeks following enrollment in the study. During the second, third time and fourth time points participants will be verbally asked if they have experienced any stressful or traumatic events since enrolling in the study unrelated to their illness. This will allow us to better determine if outside factors are impacting the participant's wellbeing.

e. Plan for Data Management/Analysis

The Statistical Package for the Social Sciences (SPSS) version 21 will be used to analyze the data. P value less than 0.05 will be set as the level of significance. Frequency analysis will be taken to check for coding errors, outliers, and missing values. Univariate and bivariate analyses will be used in this study. Descriptive statistics will be used to describe demographic data. Kolmogorov-Smirnov test and the Shapiro-Wilk test will be used to check the normal distribution of the variables. Means and SDs will be presented with normally distributed continuous data, while medians and ranges will be used for skewed data. Based on the normality test, either Independent T tests or Mann Whitney tests will be used to identify the differences between groups. Chi-square tests or Fisher's extract tests (when the expected frequency in any cell is less than five) will be used to determine significant differences in baseline characteristics of categorical variables between the experimental and control groups. Generalized Estimating Equation (GEE) will also be used. Missing data will be unavoidable in this study since this study involves vulnerable patients who have been diagnosed with cancer. Researchers will employ strategies to manage any missing data such as single and multiple imputation, and completed or available data analysis.

Subgroup analysis will also be performed. Participants will be stratified based on two levels of adherence to the program: high and low. High activity will be defined as having opened at least half of the modules and spent a total of at least 20 minutes on the application (general activity) and having answered ≥50% of the quizzes (interactivity). All participants who do not meet these criteria will be categorized as having *low activity*, which could also include not having logged on to the program at all.

f. Limitations

This study has several limitations. First, the attrition rate and the possibility of missing data for this study may be high. Therefore, missing data management should be incorporated into this study. Second, since the data collection has 4 time points, we will not be able to control for outside

stressors. However, we will try to address this problem by asking participants if they have had any stressful or traumatic experiences since their enrollment in the study. Third, we will include all types of cancers, some of which have higher fertility risk than others, which may increase the experience of stress and/or pressure for some participants. Lastly, since the intervention has been tailored to the specific Indonesian context, such as involving religious coping strategies, the findings might not be completely generalizable to other population.

g. Human Subject Research & IRB

Most YA with cancer will have the capacity to make the decision whether or not they are willing to participate in this study. However, if a patient is not able to decide to participate in this study due to cognitive impairment, decreasing consciousness level, or they have difficulty verbalizing their wishes, they will be excluded from this study. Patients also have the authority to decide either to accept or refuse to participate in this study after they have been provided with sufficient information about the study. Even after they sign the consent form, the researcher still must determine whether the patient clearly understands the study and all procedures and any potential consequences. Patients will be provided with as much time as necessary to read and understand the Participant Information Sheet. Patients will also be allowed to discuss their participation in the study with their family if they wish. The only foreseen potential risks of this study are discomfort and tiredness from completing the modules and the questionnaires. Patients will be advised that if they feel tired or discomfort, they can take some rest.

In this study, the researcher will measure patients' depression and anxiety. If the researcher finds that the patient expresses that they are very depressed or anxious, the researcher will re-assess the patient's level of depression and anxiety. If assessment results show that the patient has severe depression and anxiety, the patient will be referred to the counselling services at Arifin Ahmad General Hospital.

All patients that participate in this study will have the right to refuse to be involve in or to withdraw from the study at any time. If they refuse to participate or withdraw from this study, they will still receive healthcare services as standard care and there will be no impact to their future care. If there are any questions or discussions that make the patient feel uncomfortable or confused, they can choose not to answer the question or not to continue their involvement in the study.

This study is currently under ethical review by the Ethical Review Board for Medicine and Health Research, Faculty of Nursing at the University of Riau.

5. Time Frame

	2026											**2027**				
Task	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5
Renew IRB					X	X										
Complete the administrative procedure in the hospital for data collection					X	X										

Preparing the application					X	X										
Data collection						X	X	X	X	X	X					
Data analysis									X	X	X	X	X			
Write report & manuscript drafts												X	X	X		
Submit manuscript draft														X	X	
Complete research report														X	X	X

Support

Facilities and Resources:
The study will take place at Arifin Ahmad Hospital. This hospital is affiliated with the Nursing Faculty at Universitas Riau where the PI is employed and serves as the clinical supervisor in the oncology wards. The hospital system, the staff, and the patients are familiar with the PI and open to helping facilitate research. In this study, we will involve the head nurse and primary nurse in the oncology wards to assist with screening patients for inclusion as described in the recruitment procedures.

Collaborative Arrangements**:**
The study will collaborate with Arifin Ahmad Hospital where the study will be applied. The hospital will provide space in the oncological wards to support the intervention particularly initial counselling. The nursing managers and head nurse will be directly involved in the study from stage 2 until stage 4 as experts or collecting data. Mrs Ade Dila Ruri MN, the head of the nursing committee has given her consent and support for this study.

Consultative Support:
To assure that this project can be completed during the proposed timeframe, we will hire a consultant. The consultant will guide us in constructing the application and monitor our intervention. The main consultant will be Prof. Dr.Eng. Ir. Muhammad Ilhamdi Rusydi, S.T.M.T from the Faculty of Engineering, Universitas Andalas, Indonesia. He has obtained many international and national research grants related to assistive technology. His expertise in assistive technology will add value insight to our research. He will also help review the intervention application. Since this study will also involve quantitative data analysis, we will invite a statistician to provide statistical guidance. Asst. Prof Bayu Satria Wiratama from the Biostatistics Centre of Universitas Gadjah Mada, Indonesia has agreed to be our statistics consultant.

References

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