**ORIGINAL ARTICLE** 

# A Design and Development Research Approach to Developing an E-Health Intervention for Individuals with Breast Cancer: A Study Protocol

#### NURDIANA MOHAMMAD HUSSIN<sup>1</sup>, NIK RUZYANEI NIK JAAFAR<sup>2</sup>, IDAYU BADILLA IDRIS<sup>1</sup>, AZMAWATI MOHAMMED NAWI<sup>1\*</sup>

<sup>1</sup>Department of Public Health Medicine, Faculty of Medicine, Universiti Kebangsaan Malaysia, 56000 Cheras, Kuala Lumpur, Malaysia

<sup>2</sup>Department of Psychiatry, Faculty of Medicine, Universiti Kebangsaan Malaysia, 56000 Cheras, Kuala Lumpur, Malaysia

Received: 19 September 2024 / Accepted: 24 October 2024

#### ABSTRAK

Individu yang menghidap kanser payudara sering mengalami tekanan psikologi, tetapi sering kali tidak memanfaatkan sepenuhnya perkhidmatan sokongan kesihatan mental. Intervensi e-kesihatan berpotensi meningkatkan akses dan penglibatan dengan menggunakan perkhidmatan kesihatan mental. Kajian ini bertujuan untuk membangunkan dan menilai intervensi video e-kesihatan berasaskan bukti yang direka untuk meningkatkan niat dan tingkah laku mencari bantuan kesihatan mental dalam kalangan penghidap kanser payudara di Malaysia. Kajian ini akan menggunakan pendekatan penyelidikan reka bentuk dan pembangunan yang melibatkan tiga fasa kajian iaitu (i) analisis keperluan yang dijalankan melalui tinjauan keratan rentas dengan individu yang menghidap kanser payudara; (ii) reka bentuk dan pembangunan video e-kesihatan yang menggabungkan pandangan profesional kesihatan menggunakan teknik kumpulan nominal dan temubual mendalam dengan individu yang menghidap kanser payudara; dan (iii) penilaian keberkesanan intervensi menggunakan reka bentuk kuasi-eksperimen. Hasil utama kajian ini merangkumi niat dan tingkah laku mencari bantuan, manakala hasil kedua ialah celik kesihatan mental, stigma diri dan sikap terhadap pencarian bantuan. Protokol ini menggariskan pendekatan pelbagai fasa dalam membangunkan dan menilai intervensi e-kesihatan yang bertujuan untuk menambahbaik kesihatan mental individu yang menghidap kanser payudara. Intervensi yang dihasilkan boleh mempengaruhi amalan klinikal dan dasar kesihatan dalam menangani keperluan kesihatan mental di Malaysia. Selain itu, kaedah ini boleh dijadikan model untuk membangunkan intervensi serupa bagi penyakit kronik lain sekaligus menyumbang kepada kemajuan e-kesihatan serta penjagaan pesakit secara keseluruhan.

Kata kunci: Pembangunan konsensus; penilaian keperluan; penilaian program; tekanan psikologi

Address for correspondence and reprint requests: Azmawati Mohammed Nawi. Department of Public Health Medicine, Faculty of Medicine, Universiti Kebangsaan Malaysia, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Cheras, Kuala Lumpur, Malaysia. Tel: +603-91458780 Email: azmawati@hctm.ukm.edu.my

#### ABSTRACT

Individuals with breast cancer (BC) frequently experience psychological distress, yet often underutilise mental health support services. E-health interventions hold promise for improving access to and engagement with mental health services. The current study aimed to develop and evaluate an evidence-based e-health video intervention designed to enhance the mental helpseeking intentions and behaviours of Malaysian individuals with BC. This study used the design and development research approach. There were three study phases: (i) needs analysis conducted through surveys with individuals with BC; (ii) e-health video design and development integrating healthcare professionals' insights using the nominal group technique and in-depth interviews with individuals with BC; and (iii) evaluation of the intervention effectiveness with a quasi-experimental design. The primary outcomes included help-seeking intentions and behaviours, while the secondary outcomes were mental health literacy, self-stigma and attitudes towards help-seeking. This protocol outlined a multi-phase approach to developing and evaluating an e-health intervention to support mental health of individuals with BC. The resulting intervention could significantly influence clinical practice and health policy by addressing the mental health needs of individuals with BC across the multicultural Malaysian population. Additionally, the methodology could be a model for developing similar interventions for other chronic illnesses and contribute to the broader field of e-health and patient-centered care.

Keywords: Consensus development; needs assessment; program evaluation; psychological distress

#### INTRODUCTION

Breast cancer (BC) is the most prevalent cancer and the leading cause of cancer-related death among women worldwide (Ali Salman 2023). BC diagnosis and treatment have significant physical effects and profoundly affect patients' psychological well-being (Erdal et al. 2023). Individuals with BC are at the highest risk of experiencing depression at the time of diagnosis, but this risk can persist at any point during their illness, whether related to treatment or independently (Zainal et al. 2013). BC treatments, which include surgery, chemotherapy and radiotherapy, are often accompanied by burdensome side effects that can manifest as distress, anxiety and depression. Prolonged distress directly influences the patient's healthcare utilisation (Abdelhadi et al. 2022) and can lead to other challenges, such as decreased quality of life, sleep disturbances and difficulties in maintaining social relationships (Reich et al. 2008).

Several factors have been identified as barriers to seeking help for mental health issues. The World Mental Health Surveys found that low perceived needs and negative attitudes towards treatment were major reasons contributing to underutilised or inadequate help-seeking behaviours (Andrade et al. 2014). Additionally, poor mental health literacy impairs problem recognition and perceived need, serving as another significant barrier (Jorm 2012). Recent systematic reviews also indicate the existence of stigma surrounding mental illness and its impact on affected individuals (Schnyder et al. 2017). Addressing the underutilisation of mental health support among BC individuals requires addressing barriers such as low perceived need, negative attitudes towards treatment, poor mental health literacy and stigma. The underutilisation

of mental health support among cancer patients is a significant concern that needs to be addressed.

E-health interventions have emerged as an easily accessible and potentially effective alternative to improve the psychological well-being and quality of life of individuals with BC (Singleton et al. 2022). E-health interventions involve a range of technologies, including mobile applications and online platforms (Singleton et al. 2022), which offer several potential benefits for individuals with BC. First, such interventions provide access to psychological support, even for patients in remote locations or patients with limited mobility, thus overcoming geographical barriers that often impede access to traditional mental health services (Zhu et al. 2018). Second, these interventions offer flexibility, allowing patients to engage with support at times more convenient to their needs, which is particularly beneficial for patients experiencing fluctuating energy levels and unpredictable treatment side effects (Zhu et al. 2018). Third, e-health interventions are potentially more cost-effective than traditional face-to-face therapy sessions (Mendes-Santos et al. 2019). By reducing the need for frequent clinic visits and optimising resource allocation, these digital solutions can aid in alleviating the financial burden on patients and healthcare systems.

Despite the potential benefits of e-health interventions, there is a lack of culturally tailored, evidence-based e-health resources specifically designed for Malaysian individuals with BC to address their mental health needs. This study aimed to bridge this gap by developing an e-health intervention and evaluating its effectiveness in improving mental help-seeking intention and behaviour, improving overall mental health outcomes, and increasing the quality of life of Malaysian individuals with BC. A targeted e-health video was created using a multi-method approach and the design and development research (DDR) methodology, and its effectiveness was assessed with a quasi-experimental study.

DDR is a practical approach that empirically tests theories and validates practices (Richey & Klein 2014). A primary advantage of DDR is that it can bridge the gap between research and practice. DDR involves stakeholders and potential users throughout the design and development process, ensuring the resulting interventions are theoretically sound and practically applicable (Barab & Squire 2016). This approach also enables iterative refinement based on feedback and empirical evidence, leading to more reliable and effective solutions (Wang & Hannafin 2005). Furthermore, DDR provides a structured framework for documenting the development process, which can inform future research and development efforts in similar contexts (Kelly 2016).

Despite many benefits, DDR also presents challenges. The iterative design and evaluation process is time-intensive, which can lead to longer research timelines and higher costs (Anderson & Shattuck 2012). There is also the risk of researcher bias, as the same individuals are frequently involved in the intervention development and evaluation (Dede 2016). Additionally, the context-specific DDR results can sometimes limit their generalisability to other settings or populations (Hoadley 2004). Notwithstanding these limitations, DDR remains a powerful methodology for creating evidence-based interventions in e-health and education when applied rigorously (Bakker & Van Eerde 2015).

The DDR encompasses a broad range of activities and interests, primarily categorised into type 1 (product and tool research) and type 2 (model research) research projects (Richey & Klein 2014). Type 1 DDR focuses

on thoroughly examining and evaluating the design and development process within specific contexts, leading to a final product. This approach involves carefully documenting each phase of instructional system design (ISD): analysis, design, development and formative evaluation (Branch 2009). Type 2 DDR emphasises the study of models and processes rather than their demonstration (Richey & Klein 2014). Type 2 DDR typically follows three systematic phases: (i) needs analysis; (ii) design and development; and (iii) evaluation (Mustapha 2017; Saleh 2016). Type 2 DDR often involves developing, validating, and applying new or existing models with a focus on identifying and describing the conditions that lead to successful design and development (Richey & Klein 2014).

The primary study objective was to develop and evaluate an evidence-based e-health video intervention aimed at enhancing the mental help-seeking intentions and behaviours of Malaysian individuals with BC. The secondary objectives were to assess the intervention's effect on (i) self-stigma related to help-seeking; (ii) attitudes towards mental help-seeking; (iii) subjective norms; (iv) perceived behavioural control (PBC); (v) mental health literacy (MHL); and (vi) anxiety and depression levels.

# MATERIALS AND METHODS

This study was approved by the Medical Research Ethics Committee of Universiti Kebangsaan Malaysia (protocol code: JEP-2024-400; approval date: July 9, 2024). Furthermore, this study had been registered with ClinicalTrials (Clinicaltrials.gov: NCT06566937).

This study used type 2 DDR approach and is based on the theory of planned behaviour (TPB) and the health belief model (HBM). First, a needs analysis was conducted to understand the urgent need to develop the intervention. Subsequently, a culturally tailored e-health video intervention was designed and developed, incorporating insights from healthcare professionals and individuals with BC. The intervention validity and usability were assessed before its effectiveness was evaluated in a quasiexperimental study. This study also aimed to contribute to the broader understanding of e-health interventions in oncology care for BC individuals by investigating the determinants that most significantly influence help-seeking intentions and behaviours. Figure 1 illustrated the methodology framework of the study.

# Phase 1: Needs Analysis

Needs analysis determines the need to develop an intervention, assesses the focus of research and importantly, identifies the needs of BC individuals (Siraj et al. 2020). The phase 1 methodology is a cross-sectional quantitative study that uses a Google Forms survey questionnaire and manual forms distributed to individuals with BC undergoing treatment or follow-up at Institut Kanser Negara (IKN), Putrajaya. The survey questionnaire was developed incorporating four validated psychological assessment instruments; (i) Hospital Anxiety and Depression Scale (HADS) (Yahya & Othman 2015) for anxiety and depression measurement; (ii) TPB questionnaire for behavioral assessment; (iii) Mental Health Literacy Scale (MHLS) (Siti Nor Amirah et al. 2020) for mental health literacy evaluation; and (iv) Self Stigma of Seeking Help (SSOSH) (Ibrahim et al. 2019) for help-seeking stigma assessment. IKN was chosen for its extensive cancer care services and substantial patient population, providing a diverse and pertinent sample for the study. This approach will ensure that the data represent the wider

population of individuals with BC, thus improving the validity of the outcomes. IKN treated 957, 941, and 933 individuals with BC in 2021, 2022, and 2023, respectively, which underscores its role as a major BC treatment center. These patient numbers highlight the extensive reach of IKN and the potential for the survey to capture a wide array of patient insights and perspectives.

The inclusion criteria for phase 1 were: (i) individuals with any-stage BC currently undergoing treatment at IKN; (ii) aged 18 years;



FIGURE 1: Development of the e-health video using the design and development research (DDR) approach

and (iii) individuals who understand either Malay or English. The exclusion criteria were: (i) individuals with BC and metastasis to the brain; (ii) individuals diagnosed with mental illness; and (iii) individuals with Eastern Cooperative Oncology Group (ECOG) performance status  $\geq$  3. The ECOG performance status was crucial in this study as it excluded patients with severely limited physical capacity (scores  $\geq$  3), ensuring participants can effectively engage with and potentially benefit from the e-health video intervention.

The study employed the Malay versions of the HADS (Yahya & Othman 2015), the MHLS (Siti Nor Amirah et al. 2020), and the SSOSH (Ibrahim et al. 2019) questionnaire, all of which had been previously translated and validated for use in the Malaysian context. The TPB questionnaire had undergone a forward-backward translation. Subsequently, the translated TPB questionnaire underwent comprehensive validity and reliability testing. Content validity was established through health expert review, while individuals with BC assessed the face validity. Internal consistency reliability was evaluated using Cronbach's alpha coefficient. These processes ensured that the newly translated and validated TPB questionnaire is psychometrically and culturally appropriate for Malaysian individuals with BC. Figure 2 depicted the needs analysis flowchart.

# Phase 2: Design and Development

Design and development is the pivotal stage of the research process, and primarily focuses on crucial decisions related to the module design and development (Jamil & Noh 2020). Design and development used three measurement methods. The first method involved formulating initial themes from the literature and the needs analysis results (phase 1). The researcher



FIGURE 2: The need analysis flowchart

integrated the phase 1 results and literature reviews to form a foundational guide for video development. The second method involved discussions with health professionals using the nominal group technique (NGT) after forming the initial content themes. The third method involved assessing the views, knowledge, and suggestions of individuals with BC as potential video users via TPB-guided in-depth interviews (IDIs).

# The nominal group technique

The e-health video content, design, and approach were collaboratively developed using the NGT. This technique ensured active participant involvement, safeguarding against biases that could arise from facilitator interpretation or dominance by more outspoken group members (Burrows et al. 2011). In NGT, every group member contributes in a structured manner without influencing others, allowing for the collective identification of common viewpoints on a specific topic (Kennedy & Clinton 2009). The health professionals were selected with purposive sampling and were listed in Table 1. Following the NGT, the results were refined and prioritised using the fuzzy Delphi method (FDM) (Jamil & Noh 2020). The FDM used a survey to obtain expert consensus and rank the top priorities regarding the video content, design, and approach, as agreed upon in the video development NGT.

# The in-depth interviews

The IDI qualitatively explored the views, feedback, and suggestions of individuals with BC as potential video users of the e-health video content, design and approach (Lubberding et al. 2015). Additionally, the IDI complemented the needs analysis by delving deeper into understanding the MHL, help-seeking intentions, attitudes and self-stigma of individuals with BC. The IDIs included individuals diagnosed with BC (any stage) who

are at least 18 years old and can communicate fluently in either Malay or English. Exclusion criteria comprised individuals with cognitive impairments affecting their ability to participate and those too ill to engage in a lengthy interview (e.g. ECOG performance status  $\geq$  3). The sampling aimed to represent sociodemographic characteristics diverse including education level, ethnicity, cancer stage and marital status. The minimum number of respondents was 8; however, IDIs was conducted until data saturation was achieved. Two gualitative experts reviewed and validated the IDI protocol, confirming its suitability. The data was analysed using deductive thematic analysis guided by existing TPB and HBM themes (Braun & Clarke 2006).

# E-health video validity

Once the e-health video was developed, it underwent validation. The content validity was evaluated by health professionals and media experts using the content validity index (CVI).

Professional Title	Expertise/Relevance	Number
Oncologist	Expert in the treatment of BC and its significance in comprehending the medical facets of the research.	1
Breast Surgeon	Expert in the treatment of BC and its significance in comprehending the medical facets of the research.	1
Public Health Specialist	Provide insights on the public health implications and strategies for BC awareness.	2
Psychiatrist	Essential for understanding the psychological impacts of BC and managing mental health in treatment and recovery.	1
Clinical Psychologist	Expert in psychological assessment and therapy, addressing mental health issues through various therapeutic techniques and providing interventions for mental health support.	1
Family Medicine Specialist	Provides a holistic view of patient health and preventive care, crucial for understanding BC's overall impact and coordinating treatment across specialities.	1
Total respondents		7

TABLE 1: Health Professionals in the implementation of NGT

CVI is an index of agreement among evaluators within a group of experts and is a critical step in the development process of new instruments, measuring complex constructs in healthcare research (Donizetti-Trevisan et al. 2020). The CVI evaluation is based on the average scale. The CVI value at the item level (I-CVI) and the average CVI score across all items (SCVI/Ave) exceeding 0.8 indicates good content validity (Polit et al. 2007). Concurrently, a diverse group of individuals with BC assessed the video usability through the video engagement scale (VES). The scale evaluated viewer engagement using 15 statements on a 7-point Likert scale. High VES scores indicated good ecological validity and video usability, as the study considered ecological validity conceptually rather than statistically (Visser et al. 2016).

# Phase 3: Evaluation

Phase 3 was the concluding phase of the DDR study, which was critical for evaluating the effectiveness of the developed e-health intervention video The effectiveness was assessed using a quasi-experimental approach involving the analysis of the primary and secondary outcomes. The evaluation used similar study tools to phase 1 but with additional help-seeking behaviour questionnaires. Given the inherent limitations of a quasi-experiment in ensuring internal validity, potential confounding variables was managed with advanced statistical analyses. Where an experimental design was not feasible or practical, relying on statistical techniques became crucial for researchers to minimise the influence of uncontrolled confounders (Pourhoseingholi et al. 2012). Phase 3 involved individuals with BC currently receiving treatment or follow-up care at IKN. Contamination between groups was prevented by studying the control group first, followed by the intervention group. The intervention effectiveness was assessed at baseline (before the intervention), 4 weeks post-intervention and 12 weeks post-intervention.

#### **Outcomes and Measures**

#### **Primary outcomes**

# - The TPB questionnaire and help-seeking behaviour questionnaires

The primary study outcome is the participants' help-seeking intentions and behaviours, measured by the TPB questionnaire and helpseeking behaviour questionnaires (Table 2). Help-seeking intentions are measured on a 3-item scale. Responses are rated on a 6-point Likert scale, with higher scores indicating higher levels of help-seeking intention. The scale demonstrated strong reliability (coefficient = 0.97) (Mo & Mak 2009). Actual help-seeking behaviour is assessed using a simple yes/ no questionnaire. This questionnaire asked participants whether they had engaged in specific help-seeking behaviours within a defined time period, such as consulting a mental health professional, discussing mental health concerns with a primary care provider, or seeking information about mental health services.

# Secondary outcomes - The Mental Health Literacy Scale

The participants' MHL are evaluated using self-report instruments, specifically the MHLS, which consisted of 28 items. The original version of the MHLS had demonstrated strong internal consistency (Cronbach's alpha = 0.873). This study used the Malay adaptation of the MHLS which had also demonstrated solid reliability (Cronbach's alpha = 0.759) (Siti Nor Amirah et al. 2020).

Outcomes Measures	Measurement Tools	Baseline	4 weeks follow-up	12 weeks follow-up
Primary outcome				
Help-seeking intention	Theory of Planned Behaviour (TPB) Questionnaires	/	/	/
Help-seeking behaviour	Help-Seeking Behaviour Questionnaires		/	/
Secondary outcome				
Self-stigma of seeking help	Self-Stigma of Seeking Help Questionnaires	/	/	/
Mental health literacy	Mental Health Literacy Scale	/	/	/
Attitude of seeking-help		/	/	/
Subjective norm	Theory of Planned	/	/	/
Perceived behavioural control	Behaviour Questionnaires	/	/	/
Additional outcome				
Depression and anxiety	Hospital Anxiety & Depression Scale	/	/	/

#### - The Self-Stigma of Seeking-help

The SSOSH will be assessed using the SSOSH questionnaire, which consists of 10 items. The SSOSH questionnaire was designed to evaluate self-stigma in seeking help, irrespective of whether the individual has been diagnosed with a mental illness or not (Vogel et al. 2017). The questionnaire has demonstrated good reliability ( $\alpha = 0.86$ ). The SSOSH questionnaire has been translated and adapted into Malay, ensuring its cultural and linguistic appropriateness for the Malaysian population (lbrahim et al. 2019).

# - Attitudes towards seeking help, subjective norms and PBC

In addition to measuring help-seeking intention, the TPB questionnaire assesses three key subscales: attitudes towards help-seeking,

subjective norms, and PBC. Attitudes towards help-seeking will be measured using five items on a 6-point semantic differential scale, with higher scores indicating a more favourable attitude (Cronbach's alpha = 0.84). Subjective norms will be evaluated using a 3-item scale on a 6-point Likert scale, with higher scores representing higher levels of subjective norms (Cronbach's alpha = 0.88). PBC will also be measured on a 3-item scale using a 6-point Likert scale, where higher scores indicate higher levels of behavioural control (Cronbach's alpha = 0.77). All three subscales have demonstrated solid reliability (Mo & Mak 2009).

# Additional outcomes - Anxiety and depression

Anxiety and depression levels will be measured using the HADS, a self-reported questionnaire consisting of 14 items designed for screening anxiety and depression in hospital settings. This study will use the Malay version of the HADS, which has been translated and validated (Yahya & Othman 2015). The Malay-version HADS has eight cut-off points for HADS-A (anxiety) and nine cut-off points for HADS-D (depression), compared to the conventional HADS cut-off points of 10/11, respectively.

#### Statistical Analysis

The data will be analysed using SPSS version 22.0. Table 3 summarised the analytical approaches for each study phase. In phase 1, sociodemographic data and the relationships between key variables will be examined using descriptive statistics and Pearson's correlation coefficient. In phase 2, the intervention will be refined using quantitative (FDM survey) and qualitative (thematic analysis) methods. Lastly, phase 3 will assess the intervention effectiveness on mental help-seeking

intentions and behaviours with repeated measures analysis of variance (ANOVA), analysis of covariance (ANCOVA) and multiple logistic regression.

# Privacy, Confidentiality and Data Management

All personal data, including sociodemographic information and questionnaire responses, will be managed by trained researchers adhering to strict confidentiality protocols. Anonymity will be ensured by removing personally identifiable information from the datasets and replacing it with unique alphanumeric codes assigned at recruitment. For the IDIs, audio will be recorded using secure devices, with participants identified only by their assigned codes. All data will be stored on passwordprotected computers accessible only to the research team. Following data collection, all information will be securely archived and

Phase	Research Outcome	Data Analysis	Inferential Statistic
Phase 1: Need Analysis	Sociodemographic data	Frequency (Percentage) for categorical data; Mean (SD) for continuous data	NA
	TPB Score, Mental Health Literacy, Self-Stigma of Seeking Help, Anxiety and Distress	Mean (SD)	Pearson's correlation coefficient
Phase 2: Design and Development	Nominal Group Technique Data	FDM Survey	N/A
	In-Depth Interview Data	Deductive Thematic Analysis	N/A
Validation	Content Validity Index (CVI) Video Engagement Scale (VES)	N/A	N/A
Phase 3: Evaluation	TPB Score, Mental Health Literacy, Self-Stigma of Seeking Help, Anxiety and Distress	Mean (SD)	Repeated measures ANOVA and ANCOVA
_	Help-Seeking Behavior	Frequency (Percentage)	Multiple logistic regression

TABLE 3: Summary of data analysis methods across study phases

subsequently destroyed in accordance with institutional guidelines.

#### DISCUSSION

This study protocol presents a comprehensive approach to developing and evaluating an e-health video intervention aimed at improving the mental help-seeking intentions and behaviours of Malaysian individuals with BC. This study will integrate theoretical frameworks such as the TPB and HBM and use DDR methodology to bridge a critical gap in psychosocial oncology care. The multiphase design will incorporate needs analysis, iterative development with stakeholder input and potential users, and a quasi-experimental evaluation to provide a strong foundation for developing culturally tailored interventions. If successful, this e-health video can be an adaptable and cost-effective tool to enhance mental health support for individuals with BC, potentially improving their mental helpseeking intentions and behaviours and overall quality of life. Moreover, the methodology outlined in this protocol could inform the development of similar interventions for other chronic illnesses, contributing to the broader field of e-health and patient-centered care.

#### Limitations

The potential study limitations are the focus on individuals with BC at a single institution (IKN), which may not fully represent the diverse Malaysian population with BC (Clarke et al. 2017). While the study aims to develop a culturally tailored intervention, the multiethnic composition of Malaysian society, with its diverse cultural backgrounds and languages, renders it challenging to create an intervention that is equally effective and relevant for all ethnic groups. This diversity underscores the importance of considering cultural nuances in developing and implementing the e-health video intervention (Terragni et al. 2018). Additionally, the reliance on self-reported measures and the potential for selection bias in participant recruitment should be considered when interpreting the results. Future research directions could expand on this study by implementing the e-health video intervention across several cancer centers in Malaysia, capturing a broader representation of the multi-ethnic Malaysian population. Long-term follow-up studies could assess the sustained effects of the intervention on the mental health outcomes and help-seeking behaviours of individuals with BC. Additionally, investigating the integration of this e-health video into existing oncology care pathways could provide insights into its practical implementation and potential for widespread adoption within the Malaysian healthcare system.

# CONCLUSION

This study protocol outlines a multi-phase approach to developing and evaluating an e-health video intervention aimed at enhancing mental help-seeking intentions and behaviours among Malaysian individuals with BC. The study addresses a critical gap in psychosocial oncology care by employing the DDR methodology and incorporating theoretical frameworks such as the TPB and HBM. The e-health intervention is predicted to significantly improve access to mental health support for BC individuals, potentially enhancing their quality of life. Moreover, the methodology presented in this study could serve as a model for developing similar interventions for other chronic illnesses, contributing to the advancement of e-health and patient-centered care in diverse cultural contexts.

Authors contributions: Concept, design, definition of intellectual content, literature search, manuscript preparation, manuscript editing: NMH; concept, design, definition of intellectual content, literature search, manuscript editing, manuscript review: AMN; manuscript editing, manuscript review: NRNJ; manuscript editing, manuscript review: IBI.

**Funding:** The authors received no specific funding for this work.

Acknowledgement: The authors thank Universiti Kebangsaan Malaysia for their support and technical guidance throughout this study. The study was approved by the Universiti Kebangsaan Malaysia Medical Research Ethics Committee (protocol code: JEP-2024-400; approval date: July 9, 2024). Furthermore, this study has been registered with ClinicalTrials (Clinicaltrials.gov: NCT06566937).

**Conflict of interest:** All authors declare no conflicts of interest.

#### REFERENCES

- Abdelhadi, O.A., Pollock, B.H., Joseph, J.G., Keegan, T.H.M. 2022. Psychological distress and associated additional medical expenditures in adolescent and young adult cancer survivors. *Cancer* 128(7): 1523-31.
- Ali Salman, R. 2023. Prevalence of women breast cancer. *Cell Mol Biomed Rep* 3(4): 185-96.
- Anderson, T., Shattuck, J. 2012. Design-based research: A decade of progress in education research? *Educational researcher* **41**(1): 16-25.
- Andrade, L.H., Alonso, J., Mneimneh, Z., Wells, J., Al-Hamzawi, A., Borges, G., Bromet, E., Bruffaerts, R., De Girolamo, G., De Graaf, R. 2014. Barriers to mental health treatment: results from the WHO World Mental Health surveys. *Psychol Med* 44(6): 1303-17.
- Bakker, A., Van Eerde, D. 2015. An introduction to design-based research with an example from statistics education. In *Doing qualitative research: Methodology and methods in mathematics education.* Edited by Bikner-Ahsbahs A, Knipping C, Presmeg N. New York:

Springer; 429-66.

- Barab, S., Squire, K. 2016. Design-based research: Putting a stake in the ground. *J Learn Sci* 13(1): 1-14.
- Branch, R.M. 2009. Instructional design: The ADDIE approach. Vol. 722 USA: Springer.
- Braun, V., Clarke, V. 2006. Using thematic analysis in psychology. *Qual Res Psychol* 3(2): 77-101.
- Burrows, T., Findlay, N., Killen, C., Dempsey, S. E., Hunter, S., Chiarelli, P., Snodgrass, S. 2011. Using nominal group technique to develop a consensus derived model for peer review of teaching across a multi-school faculty. *J Univ Teach Learn Pract* 8(2): 8.
- Clarke, C.A., Glaser, S.L., Leung, R., Davidson-Allen, K., Gomez, S.L., Keegan, T.H. 2017. Prevalence and characteristics of cancer patients receiving care from single vs. multiple institutions. *Cancer epidemiology* **46**: 27-33.
- Dede, C. 2016. If design-based research is the answer, what is the question? A commentary on Collins, Joseph, and Bielaczyc; diSessa and Cobb; and Fishman, Marx, Blumenthal, Krajcik, and Soloway in the JLS special issue on designbased research. In *Design-based Research*. Edited by Barab SA, Squire K. New York: Psychology Press; 105-14.
- Donizetti-Trevisan, D., Nazário-Aoki, R., Wopereis-Groot, M.M., Aurélio-Boes, M., De Souza Oliveira-Kumakura, A.R. 2020. Validation and applicability of instrument for documenting the nursing process in intensive care. *Enfermería Clínica (English Edition)* **30**(1): 4-15.
- Erdal, G.Ş., Balcio lu, S.S.K., Namli, M.N. 2023. Distress tolerance in patients with metastatic and non-metastatic breast cancer: A singlecenter experience. *Acıbadem Üniversitesi Sa lık Bilimleri Dergisi* 14(3): 409-14.
- Hoadley, C.M. 2004. Methodological alignment in design-based research. *Educ Psychol* **39**(4): 203-12.
- Ibrahim, N., Amit, N., Shahar, S., Wee, L.H., Ismail, R., Khairuddin, R., Siau, C.S., Safien, A.M. 2019. Do depression literacy, mental illness beliefs and stigma influence mental health help-seeking attitude? A cross-sectional study of secondary school and university students from B40 households in Malaysia. *BMC Public Health* 19: 1-8.
- Jamil, M.R.M., Noh, N.M. 2020. Kepelbagaian metodologi dalam penyelidikan reka bentuk dan pembangunan. *Qaisar Prestige Resources*:
- Jorm, A.F. 2012. Mental health literacy: Empowering the community to take action for better mental health. *American psychologist* **67**(3): 231.
- Kelly, A.E. 2016. Design research in education: Yes, but is it methodological? In *Design-based Research: Clarifying the terms. introduction* to the learning sciences methodology strand

Psychology Press; 115-28.

- Kennedy, A., Clinton, C. 2009. Identifying the professional development needs of early career teachers in Scotland using nominal group technique. *Teacher development* **13**(1): 29-41.
- Lubberding, S., Van Uden-Kraan, C.F., Te Velde, E.A., Cuijpers, P., Leemans, C.R., Verdonck-De Leeuw, I.M. 2015. Improving access to supportive cancer care through an e H ealth application: a qualitative needs assessment among cancer survivors. *J Clin Nurs* 24(9-10): 1367-79.
- Mendes-Santos, C., Weiderpass, E., Santana, R., Andersson, G. 2019. A guided internetdelivered individually-tailored ACT-influenced cognitive behavioural intervention to improve psychosocial outcomes in breast cancer survivors (iNNOVBC): Study protocol. *Internet Interv* 17: 100236.
- Mo, P.K., Mak, W.W. 2009. Help-seeking for mental health problems among Chinese: The application and extension of the theory of planned behavior. Soc Psychiatry Psychiatr Epidemiol 44(8): 675-84.
- Mustapha, R. 2017. Reka bentuk Model Integriti Akademik berasaskan Penghayatan Rohan. *Thesis Book*. University of Malaya (Malaysia)
- Polit, D.F., Beck, C.T., Owen, S.V. 2007. Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. *Res Nurs Health* **30**(4): 459-67.
- Pourhoseingholi, M.A., Baghestani, A.R., Vahedi, M. 2012. How to control confounding effects by statistical analysis. *Castroenterol Hepatol Bed Bench* 5(2): 79-83.
- Reich, M., Lesur, A., Perdrizet-Chevallier, C. 2008. Depression, quality of life and breast cancer: A review of the literature. *Breast Cancer Res Treat* **110**(1): 9-17.
- Richey, R.C., Klein, J.D. 2014. Design and development research. Handbook of research on educational communications and technology: 141-150.
- Saleh, M.P. 2016. *Model pengajaran M-Pembelajaran* berasaskan kaedah inkuiri mata pelajaran Sejarah peringkat menengah. Thesis book. University of Malaya (Malaysia).
- Schnyder, N., Panczak, R., Groth, N., Schultze-Lutter, F. 2017. Association between mental health-related stigma and active help-seeking: Systematic review and meta-analysis. *Bri J Psychiatry* 210(4): 261-8.

- Singleton, A.C., Raeside, R., Hyun, K.K., Partridge, S. R., Di Tanna, G.L., Hafiz, N., Tu, Q., Tat-Ko, J., Sum, S.C.M., Sherman, K.A., Redfern, J. 2022. Electronic health interventions for patients with breast cancer: Systematic review and metaanalyses. J Clin Oncol 40(20): 2257-70.
- Siraj, S., Abdullah, M.R.T.L., Rozkee, R.M. 2020. Pendekatan penyelidikan rekabentuk dan pembangunan: Aplikasi kepada penyelidikan pendidikan. Penerbit UPSI
- Siti Nor Amirah, M.H., Husna, H., Muhamad Afnan, A., Suriani, I., Ahmad Iqmer Nashriq, M.N. 2020. Sociodemographic factors of mental health literacy among housewives living in low cost apartments in Puchong, Selangor, Malaysia. *Malays J Med Health Sci* 16(1): 121-5.
- Terragni, L., Beune, E., Stronks, K., Davidson, E., Qureshi, S., Kumar, B., Diaz, E. 2018. Developing culturally adapted lifestyle interventions for South Asian migrant populations: A qualitative study of the key success factors and main challenges. *Public Health* 161: 50-8.
- Visser, L.N., Hillen, M.A., Verdam, M.G., Bol, N., De Haes, H.C., Smets, E.M. 2016. Assessing engagement while viewing video vignettes; Validation of the Video Engagement Scale (VES). *Patient Educ Couns* **99**(2): 227-35.
- Vogel, D.L., Strass, H.A., Heath, P.J., Al-Darmaki, F.R., Armstrong, P.I., Baptista, M.N., Brenner, R.E., Gonçalves, M., Lannin, D.G., Liao, H.Y. 2017. Stigma of seeking psychological services: Examining college students across ten countries/ regions. *Counsel Psychol* **45**(2): 170-92.
- Wang, F., Hannafin, M.J. 2005. Design-based research and technology-enhanced learning environments. *Educational technology research and development* **53**(4): 5-23.
- Yahya, F., Othman, Z. 2015. Validation of the Malay version of hospital anxiety and depression scale (HADS) in Hospital Universiti Sains Malaysia. *Int Med J* 22(2): 80-82.
- Zainal, N.Z., Nik-Jaafar, N.R., Baharudin, A., Sabki, Z.A., Ng, C.G. 2013. Prevalence of depression in breast cancer survivors: A systematic review of observational studies. *Asian Pac J Cancer Prev* 14(4): 2649-56.
- Zhu, J., Ebert, L., Liu, X., Wei, D., Chan, S.W.C. 2018. Mobile breast cancer e-support program for Chinese women with breast cancer undergoing chemotherapy (part 2): Multicenter randomized controlled trial. *JMIR mHealth uHealth* **6**(4): e104.