

Exploring psychological distress and expressive writing in Chinese breast cancer patients

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Abbreviations

NCCN: National Comprehensive Cancer Network

EIS: Emotional Inhibition Scale

HAMD: Hamilton Depression Rating Scale

RCT: randomized controlled trial

CTT: classic theory test

IRT: item response theory

POMS: Profile of Mood States

SDS: Self-Rating Depression Scale

SAS: Self-Rating Anxiety Scale

HADS: Hospital Anxiety and Depression Scale

EFAs: exploratory factor analyses

CFAs: confirmatory factor analyses

ICC: intraclass correlation coefficients

OR: odds ratio

DPA: Data Protection Act 1998

PROs: patient-reported outcomes

FACT-B: Functional Assessment of Cancer Therapy-Breast Cancer Version

Acknowledgements

The research presented in the portfolio of works was completed over a six-year period. I would like to express my sincere gratitude to the following people, who have helped me during the long journey. Without their help, I would not have been able to complete this thesis.

First of all, I want to acknowledge my supervisor Professor Alison Brettle. She was also my supervisor when I studied my second Master's degree in the University of Salford between 2016 and 2017. I can still remember clearly that one day, when I was discussing thesis in her office, she showed me a series of PhD theses displayed on her office bookshelf and told me that you can also gain a PhD. Then, Professor Alison Brettle introduced me to how to prepare for a PhD by published works. This is the first time I started thinking about being a PhD student. In my opinion, a great supervisor is not only to teach students knowledge, but also to encourage, lead, and inspire students. Without this support and direction, it is unlikely that I would be able to submit my PhD by published works today.

Over the years of conducting projects within the portfolio, Professor Alison Brettle continued to support, advise, and encourage me. In addition, I particularly value the support from all my collaborators in the project, such as Professor Chunlan Zhou, Dr Michelle Howarth, Dr Huihui Zhao, Liping Liu, Xiaojin Li, and Professor Shengli An, and the head nurses from the Breast Surgery Department of the five tertiary hospitals in Guangdong Province in China: Wenji Li, Wanting Zheng, Chunrao Zheng, Min Xu, and Xiaohong Chen.

The final phase of this PhD was writing the thesis to put all the published studies together. During the time period, I would like to express my sincere thanks to my supervisors Professor Alison Brettle and Dr Cathy Ure and my personal tutor Professor Paula Ormandy for continuing support, encouragement, inspiration, and advice on the PhD thesis and the period of study. They guided me how to write this kind of thesis and encouraged me over the study journey.

Finally, sincere thanks must also be given to my family. First, my parents have been helping me take care of my children during my study. During the period of preparing the portfolio of works, my little son, who is three years old now, was born. And in particular my “mom” is always there for me to in providing childcare support. Without their support, I would not have been able to finish my two Master’s degrees and the PhD thesis, or achieved so much in my career over the last few years. Second, I would like to say a special thank you to my husband. I am extremely grateful for his support, especially to support me to go abroad to finish my Master’s and Doctor’s degrees despite his busy job. Without the support from my family, this portfolio of works would not have been possible.

Declaration

This thesis includes a portfolio of publications that have been published in peer-reviewed journals, which can be found in Appendix 1. The author's original contributions, verified by the collaborating authors, can be found in Appendix 2 and 3.

Abstract

Breast cancer patients undergoing chemotherapy experience intense psychological distress and emotional suppression, which lowers the survivors' quality of life and impacts their adherence to treatment. Given the insufficient identification and intervention of psychological distress and the specific traditional cultural beliefs and emotional reactions of Chinese breast cancer patients, there is an overwhelming need for exploring the current situation and providing culturally-appropriate psychosocial support that is congruent with the beliefs and values of the target group. Expressive writing, a convenient and culturally sensitive intervention, still needs much more exploration to identify factors that may moderate the effects of such writing exercises in breast cancer patients; thus, helping clinicians to identify the individuals most likely to benefit from expressive writing in China.

This portfolio of six published papers and fifteen supporting publications makes a unique contribution to existing knowledge by exploring psychological distress in breast cancer patients receiving chemotherapy, and evaluating the effects of expressive writing on health outcomes in this population, particularly in the Chinese context.

Collectively, this work provides a body of knowledge which suggest that there was relatively low concordance between breast cancer patients' reports and caregivers' perceptions of psychological distress. Family caregivers tended to underestimate breast cancer patients' psychological distress. In addition, given the non-lasting momentum of expressive writing that we have identified in the meta-analysis, this work makes a unique contribution to knowledge by first confirmation that writing dosage does not moderate the effects of expressive writing on breast cancer patients undergoing chemotherapy. Furthermore, this is the first study to provide evidence that the level of emotional expressivity and the pattern of affective word use could be factors that moderate the effects of expressive writing on the quality of life of breast cancer patients. These results have expanded our knowledge on the expressive writing in patients with breast cancer.

Articles included in the portfolio of published works

To better distinguish papers in the portfolio from other citations, papers included in the submission are cited in bold throughout the thesis (e.g., **Yanni, 2021**). Full texts of these papers are located in Appendix 1, in the order in which they appear in the portfolio.

- Paper 1. Liu, L., **Wu, Y.**, Cong, W., Hu, M., Li, X., & Zhou, C. (2021). Experience of women with breast cancer undergoing chemotherapy: a systematic review of qualitative research. *Quality of Life Research*, 30(5), 1249–1265.
- Paper 2. Zhao, H., Li, X., Zhou, C., **Wu, Y.**, Li, W., & Chen, L. (2022). Psychological distress among Chinese patients with breast cancer undergoing chemotherapy: Concordance between patient and family caregiver reports. *Journal of Advanced Nursing*, 78(3), 750–764.
- Paper 3. Liu, L., Xu, Y., **Wu, Y.**, Li, X., & Zhou, C. (2021). Cross-Cultural Adaptation and Validation of the Emotional Inhibition Scale in a Chinese Cancer Sample. *Frontiers in Psychology*, 12, 654777.
- Paper 4. Zhou, C., **Wu, Y.**, An, S., & Li, X. (2015). Effect of Expressive Writing Intervention on Health Outcomes in Breast Cancer Patients: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *PloS One*, 10(7), e0131802. (co-first & co-corresponding author)
- Paper 5. **Wu, Y.**, Liu, L., Zheng, W., Zheng, C., Xu, M., Chen, X., Li, W., Xie, L., Zhang, P., Zhu, X., Zhan, C., & Zhou, C. (2021). Effect of prolonged expressive writing on health outcomes in breast cancer patients receiving chemotherapy: a multicenter randomized controlled trial. *Supportive Care in Cancer*, 29(2), 1091–1101.
- Paper 6. **Wu, Y.**, Yang, D., Jian, B., Li, C., Liu, L., Li, W., Li, X., & Zhou, C. (2021). Can emotional expressivity and writing content predict beneficial effects of expressive writing among breast cancer patients receiving chemotherapy? A secondary analysis of randomized controlled trial data from China. *Psychological Medicine*, 1–15. Advance online publication.

Supportive evidence

In addition to the six papers, there are also a number of supporting published papers that provide additional information on understanding of the concepts covered in the portfolio of the thesis. To help with identification, these supporting works are cited throughout the thesis in bold italics (e.g., **Yanni, 2020**) and are listed below:

- Paper 7. **Wu, Y.**, Li, W., Stephenson, M., Cong, W., & Zhou, C. (2020). Pre-treatment assessment for patients with breast cancer undergoing chemotherapy: a best practice implementation project. *JBI Evidence Synthesis*, 18(1), 212–223.
- Paper 8. **Wu, Y.**, Brett, A., Zhou, C., Ou, J., Wang, Y., & Wang, S. (2018). Do educational interventions aimed at nurses to support the implementation of evidence-based practice improve patient outcomes? A systematic review. *Nurse Education Today*, 70, 109–114.
- Paper 9. **Wu, Y.**, Howarth, M., Zhou, C., Ji, X., Ou, J., & Li, X. (2019). Reporting of ethical considerations in clinical trials in Chinese nursing journals. *Nursing Ethics*, 26(4), 973–983.
- Paper 10. **Wu, Y.**, Howarth, M., Zhou, C., Hu, M., & Cong, W. (2019). Reporting of ethical approval and informed consent in clinical research published in leading nursing journals: a retrospective observational study. *BMC Medical Ethics*, 20(1), 94.
- Paper 11. **Wu, Y.**, Howarth, M., Zhou, C., Yang, L., Ye, X., Wang, R., Li, C., Hu, M., & Cong, W. (2021). Ethical considerations referred to in child health research published in leading nursing journals: 2015-2019. *International Journal of Nursing Practice*, 27(3), e12886.
- Paper 12. Zhao, H., **Wu, Y.**, Tao, Y., Zhou, C., De Vrieze, T., Li, X., & Chen, L. (2022). Psychometric Validation of the Chinese Version of the Lymphedema Functioning, Disability, and Health Questionnaire for Upper Limb Lymphedema in Patients with Breast Cancer-Related Lymphedema. *Cancer Nursing*, 45(1), 70–82. **(Co-first author)**
- Paper 13. Cong, W., **Wu, Y.**, Liu, L., Hu, M., & Zhou, C. (2020). A Chinese version of the chemotherapy-induced alopecia distress scale based on reliability and validity assessment in breast cancer patients. *Supportive Care in Cancer*, 28(9), 4327–4336.

- Paper 14. Zhao, H., **Wu, Y.**, Zhou, C., Li, W., Li, X., & Chen, L. (2021). Breast cancer-related lymphedema patient and healthcare professional experiences in lymphedema self-management: a qualitative study. *Supportive Care in Cancer*, 29(12), 8027–8044.
- Paper 15. Li, X., Zhou, C., **Wu, Y.**, & Chen, X. (2020). Relationship between formulaic breast volume and risk of breast cancer based on linear measurements. *BMC Cancer*, 20(1), 989.
- Paper 16. Zhao, H., Zhou, C., **Wu, Y.**, Li, W., Li, X., & Chen, L. (2020). Clinical management of patients with breast cancer-related lymphedema: a best practice implementation project. *JBIC Evidence Implementation*, 18(3), 327–336.
- Paper 17. Zhou, C., Wang, S., Wang, Y., Ou, J., & **Wu, Y.** (2019). A Chinese version of the Patient Perceptions of Patient-Empowering Nurse Behaviours Scale: Reliability and validity assessment in chronically ill patients. *Journal of Clinical Nursing*, 28(3-4), 444–457. **(Corresponding author)**
- Paper 18. Zhou, C., Ji, X., Tan, J., & **Wu, Y.** (2016). Psychometric properties of the Chinese version of the Client Empowerment Scale in chronic patients. *SpringerPlus*, 5(1), 1636.
- Paper 19. Zhang, L., Zhou, C., **Wu, Y.**, Du, D., He, L., He, L., Xie, G., Wang, L., & Chen, P. (2022). Assessment and nonpharmacological management for patients with cancer anorexia-cachexia syndrome: a best practice implementation project. *JBIC Evidence Implementation*, 10.1097/XEB.0000000000000315. Advance online publication.
- Paper 20. Zhang, L., Zhou, C., He, L., **Wu, Y.**, Xie, G., & Chen, P. (2021). Implementation of strategies to improve nutritional intervention for patients with cancer treatment-related oral mucositis: a best practice implementation project. *JBIC Evidence Implementation*, 19(4), 377–386.
- Paper 21. Wang, R., Zhou, C., **Wu, Y.**, Sun, M., Yang, L., Ye, X., & Zhang, M. (2022). Patient empowerment and self-management behaviour of chronic disease patients: A moderated mediation model of self-efficacy and health locus of control. *Journal of Advanced Nursing*, 78(4), 1055–1065.

Position/roles at the time of the research

At the time of the research, I played four roles. First, I worked as a research nurse in a tertiary teaching hospital in Guangdong Province in China. In my previous clinical practice and research, I felt the heavy physical and psychological health problems of breast cancer patients, especially those who were undergoing chemotherapy. During the interactions with breast cancer patients, I was deeply moved by their feelings of hopelessness and mental health problems. As a researcher, I always told myself that you can do more to alleviate the suffering of breast cancer patients. Hence, most of my clinical studies focused on mental and physical health management of breast cancer patients.

Second, I also have been working as an academic editor for the *Journal of Nursing (China)*, which is a top peer reviewed Chinese nursing journal, for sixteen years after I graduated from university. In the editing work, my research knowledge, critical thinking ability, and skills in writing academic paper have been improved by reviewing manuscripts of different research designs. This working experience has also improved my understanding of the importance of nursing scientific research in resolving clinical problems and increased my passion for conducting research.

Third, I have been approved as a formal postgraduate supervisor of Southern Medical University in China since 2019. Currently, I have 14 ongoing postgraduate students in the Southern Medical University. Since 2009, I helped my leader Professor Zhou, who was also my supervisor when I got my first Master's degree in China, to supervise and guide her postgraduate students to conduct research. This working experience improved my research knowledge and skills. Therefore, for the first three articles included in the portfolio of published works and some articles in the supportive publications, the first authors are postgraduate students and I was responsible for guiding and supervising them to design and conduct the study.

In addition, I am a champion of evidence-based practice and also hold a number of academic positions in the area, including the Vice-Chair of the Evidence-based Nursing Committee in Guangdong Province (since 2014), Associate Director of the

Nanfang Nursing Centre for Evidence-based Practice: A JBI Centre of Excellence (since 2017), Vice-Chair of the Nursing Management Branch of Guangdong Medical Association (since 2021), evidence implementation trainer of the JBI (since 2021), and Chair of the Asian Region in the JBI (since 2022). These experiences of practicing and learning evidence-based nursing have significantly influenced my research. Hence, I am used to dealing with evidence implementation strategies to manage health outcomes in breast cancer patients.

A reflective log was used to further journal my position/roles at the time of the research and the influence this might have on the studies presented in this portfolio of works, which can be found in Chapter Four of the thesis.

Introduction and overview

The aim of this portfolio of published works was to explore psychological distress in breast cancer patients receiving chemotherapy, especially in a Chinese context, and to evaluate the effects of an expressive writing intervention on health outcomes in this population.

This thesis is split into five chapters. Chapter one sets the context of the thesis by providing an overview of the prevalence of psychological distress in breast cancer patients receiving chemotherapy, the specific Chinese cultural values associated with psychological functioning during their experiences with cancer, and the current debates regarding the effects of an expressive writing intervention in breast cancer patients. Chapter two provides a rationale for the published works, thesis aim and objectives, methodology, and details the contribution of included articles to explore psychological distress in Chinese breast cancer patients and identify the factors that may moderate the effects of expressive writing in this population whose culture particularly discourages emotional disclosure. Chapter three provides an overview of the portfolio of published works, critical analysis of the strengths and limitations of each paper, and critiques the publications by thesis objectives. Chapter four examines ethical considerations, methodology and limitations, rationale for data collection, and the author's reflections on conducting the studies in the work. Finally, chapter five summarizes the thesis' key outcomes, whilst also providing recommendations for practice, future research, and policy.

Chapter One: Background

In this chapter, an overview of the background of the thesis is provided, including the prevalence of psychological distress in breast cancer patients receiving chemotherapy, the specific Chinese cultural values associated with psychological functioning during their experiences with cancer, and the current debates regarding the effects of an expressive writing intervention in breast cancer patients.

1.1 Psychological distress in Chinese breast cancer patients receiving chemotherapy

1.1.1 Prevalence of psychological distress in breast cancer patients receiving chemotherapy

Worldwide, breast cancer has now surpassed lung cancer as the most commonly occurring cancer (Ferlay et al., 2021). Of the estimated 2.26 million new cases annually, one in every eight cancers diagnosed in 2020 was breast cancer (Ferlay et al., 2021). The mortality-to-incidence ratio of breast cancer is 15%, with 685,000 deaths in 2020 globally (Ferlay et al., 2021; Siegel et al., 2021). In China, as the most common cancer in females, approximately 416,371 new breast cancer cases were diagnosed in 2020 (World Health Organization, 2021). With the development of neoadjuvant therapy, chemotherapy has been widely accepted as a standard treatment for breast cancer patients (Ibragimova et al., 2022; Loibl et al., 2021). The use of adjuvant chemotherapy generally reduces the risk of recurrence by approximately 30% in breast cancer patients (Peto et al., 2012). In addition, the disease-free survival and overall survival has been significantly improved for breast cancer patients receiving chemotherapy, even when the disease is operable (Cortazar et al., 2014; Loibl et al., 2021).

Although the use of chemotherapy is highly effective, the development of side effects has been proven to be related to a higher level of psychological distress in patients with breast cancer compared to other treatments, with approximately 90% of breast cancer patients experiencing some level of distress which does not significantly decrease over time (Brown et al., 2021; Gibbons & Groarke, 2018; Lim et al., 2011;

Oh & Cho, 2020). The National Comprehensive Cancer Network (NCCN) defined distress as an unpleasant and multifactorial experience of a psychological (e.g., cognitive, emotional), physical, social and spiritual nature (National Comprehensive Cancer Network, 2020). This distress might be a “normal” psychological feeling to the diagnosis and treatment of cancer (e.g., worry, fears, and sadness), or a more clinically defined condition (e.g., depression, anxiety, emotional suppression, and social isolation) (National Comprehensive Cancer Network, 2020).

Several studies indicate that women with breast cancer receiving chemotherapy experience substantial changes in their psychological status, physical functioning, and quality of life given the chemotherapy-induced toxicities (Ferreira et al., 2019; Marino et al., 2016; Tao et al., 2015). For example, depression, anxiety, and emotional suppression are commonly reported by breast cancer patients which might further negatively impact survivors’ quality of life, particularly those who receiving chemotherapy (Alquraan et al., 2020; H. Li et al., 2020). Oh and Cho (2020) investigated the level of psychological distress in 50 women with breast cancer at different times from before chemotherapy to follow-up and the results showed that the number of breast cancer patients who experienced moderate to severe depression and anxiety increased from 6.0% before the beginning of chemotherapy to 36.0% after chemotherapy. Furthermore, it has been demonstrated that emotional suppression, a term used to describe the conscious efforts to inhibit expressive elements of thoughts and feelings, is related to the increased side effects of chemotherapy treatment in breast cancer patients (Alquraan et al., 2020; Brown et al., 2021). Collectively, these results indicate that during chemotherapy, breast cancer patients undergo intense psychological distress and emotional suppression, which lowers the survivors’ quality of life and adherence of treatment (de Souza et al., 2014; Malgaroli et al., 2022). The increased survival rate for breast cancer, reaching 90% at five years after diagnosis, emphasizes the importance of developing various kinds of psychosocial support that can advance the psychological wellbeing and thus improve the quality of life of breast cancer patients receiving chemotherapy from before the treatment to follow-up (Mogal et al., 2017; Siegel et al., 2022).

1.1.2 Psychological distress in the context of Chinese culture

Given the different forms of emotional expression and cultural beliefs about cancer, the population of Chinese breast cancer patients has shown a number of specific cultural values associated with psychological functioning during their experiences with cancer (S. Chen & Zhou, 2019; Luo et al., 2013; J. Xu et al., 2021). First, Chinese culture strongly discourages emotional disclosure compared to Western cultures which emphasise sociability (Louie et al., 2013; Ting & George, 2012; W. Tsai & Lu, 2018). Confucianism, Taoism, and Buddhism constitute the essence of the traditional Chinese culture and serve as three fundamental philosophies to structure beliefs and ideology of life (Xie & Wong, 2021). Confucianism highlights the optimal way for living in harmony with others; Taoism emphasizes the proper way for a person to live a harmonious life with the universe; and Buddhism is a philosophy and religion which provides a way of life (Kupperman, 1999). These three fundamental philosophies have shaped cultural beliefs about illness and life for Chinese breast cancer patients who value emotional suppression, such as expressing less anger and sadness, to maintain social harmony (Lin et al., 2021). For example, Kagawa-Singer and Wellisch (2003) found major differences in the area of communication among different groups of breast cancer patients: Euro-American groups appearing to value verbal communication over non-verbal; Asian groups, however, showed to value non-verbal communication over verbal. In addition, S. Chen and Zhou (2019) also found that cultural values, such as collectivism and conformity, is a salient factor in the emotional expressivity of Chinese American immigrant populations.

Most studies identified that high levels of emotional suppression are linked to poorer interpersonal functioning and greater psychological distress in both clinical samples and healthy individuals (Q. Lu et al., 2017; Schlatter & Cameron, 2010; I. H. C. Wu et al., 2019). For example, Q. Lu et al. (2015) identified a relationship between ambivalence over emotional expression and the increased risk of depressive symptoms in Chinese breast cancer survivors. Accordingly, Chinese individuals may be reluctant to seek help from others or to share personal problems with others, for fear of burdening others and causing worry about them (Wei et al., 2013).

However, some studies suggested that emotional suppression may have some positive functions in Chinese cultures (Bebko et al., 2019; Chiang, 2012). For example, individuals from Asian cultures, interdependent cultures like Chinese, tend to value emotional self-control and restraint (e.g., emotional suppression) to maintain interpersonal harmony; whereas individuals from Western cultures, independent cultures, may not suppress their emotions for this purpose (Wei et al., 2013). In addition, Chiang (2012) suggested that it is essential to preserve relationships because Chinese culture values emotional suppression.

Second, given the culturally salient illness beliefs, Chinese cancer survivors are particularly vulnerable to cancer-related stigma (Bedi & Devins, 2016; Yeung et al., 2019). In the context of Chinese language, the word “cancer” itself is frightening, which means calamity (W. Tsai et al., 2019; Wong-Kim et al., 2005). To avoid burdening others or bringing shame, Chinese individuals might hide their illness and suppress emotional expression to preserve social harmony (Vrinten et al., 2017; Wei et al., 2013). For example, Vrinten et al. (2017) conducted a systematic review to explore what people fear about cancer and found that nearly half of included studies mentioned fears about other’s reactions of a cancer diagnosis, such as being blamed or stigmatized. Fear of stigmatization (e.g., cancer brings shame to the family) has been particularly identified in traditional Chinese culture: “Women are worried about what people say.....” (Kwok et al., 2005; Yeung et al., 2019). This could potentially explain why Chinese cancer survivors may not be willing to seek out support and share their cancer diagnosis with others. Furthermore, cancer-related stigma has also been found to reduce psychological and physical quality of life through increasing self-perceived burden in Chinese American breast cancer survivors (Yeung et al., 2019). Numerous studies demonstrated that even after years of immigration, Chinese cultural beliefs may still guide a proportion of Chinese American breast cancer patients to continue to endorse self-stigma, especially for those who are less acculturated to mainstream American culture (Lee-Lin et al., 2012; T. I. Tsai et al., 2011; W. Tsai et al., 2019). In contrast, among highly acculturated Chinese American breast cancer patients, who have social interactions with Americans and are English

proficient, public stigma will be reduced and they might have a greater willingness to share their emotional feelings and cancer-related distress with others (Graves et al., 2012; Wong-Kim et al., 2005; Yoon et al., 2013).

In addition, some culturally prominent gender role norms such as “women should prioritise family over self” are also frequently endorsed by Chinese people (T. I. Tsai et al., 2011; Warmoth et al., 2017; Wen et al., 2014; Yeung et al., 2019). Such norms dictate that women should be self-sacrificing, nurture their husband and family, and practice as a caregiver rather than a dependent (Wen et al., 2014). Furthermore, although this is a commonly recognized gender role norm for all women worldwide, some studies identified the extent of cultural sensitivity in different groups (Ashing-Giwa et al., 2004). For example, Kagawa-Singer and Wellisch (2003) engaged 46 breast cancer patients from three groups (Euro-American women, Japanese-American women, and Chinese-American women), and the results showed that few differences have been identified among the three groups on women’s perceptions of their husbands’ support in the results of quantitative investigation; however, at the level of qualitative data, it appeared that Euro-American women were able to be emotionally dependent, while Asian-American women were expected to nurture their family and make self-sacrifices. These culture differences on gender roles have also been supported by Yeung et al. (2018), who identified that Western assumptions on the benefits of support seeking from husband caregivers do not directly apply to the Chinese culture, practitioners should consider the cultural background of the caregivers. Therefore, these gender-specific, culturally self-perceived burdens may be particularly related to the psychological well-being of Chinese breast cancer survivors (C. L. Park et al., 2009).

From the above discussion, it is clear that culture influences how Chinese individuals cope with breast cancer and perceive their health (both psychological and physical aspects). For example, Tsai, Morisky, Kagawa-Singer, and Ashing-Giwa (2011) reported that traditional cultural beliefs about illness and life consistently influence how Chinese individuals react to breast cancer in their given context and sociocultural environment. Hence, given the special traditional cultural beliefs and

emotional reactions of Chinese breast cancer survivors, exploring the current situation and providing culturally-appropriate psychosocial support that is congruent with the beliefs and values of the target group is critical.

1.1.3 Current interventions on psychological distress

The significance of psychological management for cancer patients has been recognized and highlighted by many institutions. For example, the NCCN highlighted that distress is a significant sequelae linked with cancer treatment and diagnosis and it is essential to assess and manage distress for cancer patients (National Comprehensive Cancer Network, 2020).

Although the importance of psychological management has been highlighted, the detection and intervention of psychological problems are often insufficient in breast cancer patients (Sun et al., 2021). First, it is challenging to identify psychological or emotional distress in breast cancer survivors (Syrowatka et al., 2017). For example, given the side effects and experiences in different cycles and periods of chemotherapy, it may be unclear when “normal” feelings of treatment such as sadness transition to a point requiring formal psychological support and intervention (H. Li et al., 2020; Maurer et al., 2021; Schenker et al., 2022; Syrowatka et al., 2017). To address this, clinical practice guidelines commonly recommend that formal routine screening and managing of psychological distress as an integral part of the care to cancer patients, including diagnosis, progression, remission, recurrence, and different periods of treatment (Fu et al., 2022; Mahabaleshwarkar et al., 2015; National Comprehensive Cancer Network, 2020). However, numerous studies found that only a moderate proportion of cancer patients are willing to use routine psycho-oncological support services during cancer care (Normen et al., 2021; Tondorf et al., 2018; Zwahlen, 2019; Zwahlen et al., 2017).

Identification of psychological distress is particularly challenging for breast cancer survivors from a Chinese culture, which strongly discourages emotional disclosure (S. Chen & Zhou, 2019; Louie et al., 2013). Those from a Chinese culture may be reluctant to express their emotional feelings or problems to other people, including their families (Segrin et al., 2021; I. H. C. Wu et al., 2019). Emotional

suppression related to disease has been identified as an underlying cause of psychological distress and poorer health outcomes (Q. Lu et al., 2018; Zimmermann et al., 2015). Meanwhile, emotional support from family caregivers has been recognized as an effective way to identify distress for breast cancer survivors (Segrin et al., 2021). Given the lack of shared understanding of breast cancer patients' stress, it is important to explore the degree of patient-caregiver dyads concordances in psychological distress especially in the context of Chinese culture (Hou et al., 2018).

Furthermore, a substantial body of evidence showed that many psychological needs of breast cancer patients are not met and the intervention is often insufficient (Barr et al., 2020; Ktistaki et al., 2017; Rao et al., 2019; Samami et al., 2022). First, in relation to high-income countries, Llewellyn et al. (2019) interviewed thirteen breast cancer survivors in the UK and the results showed that although many advances have been achieved in patient-centred care, participants highlighted the need for greater access to emotional support for future service development. Second, for low-income countries, the level of unmet psychological needs is also high. For example, Shaikh et al. (2022) interviewed 140 women in Kenya living with metastatic breast cancer and found that most women (63%) have high unmet needs around psychological care. Third, unmet psychological needs are also highly identified in the context of Chinese culture (Cai et al., 2021). For example, Chou et al. (2020) reported that the most unmet need of breast cancer patients in Taiwan was in the psychological domain (40.4%).

Given the high level of psychological distress in breast cancer patients, numerous psychological intervention strategies have been tested to help them cope with their psychological challenges. For example, many previous studies have evaluated the efficacy of antidepressants such as mianserin (van Heeringen & Zivkov, 1996), paroxetine (Pezzella et al., 2001), and escitalopram (H. Y. Park et al., 2012) in breast cancer patients undergoing chemotherapy to alleviate distress (Navari et al., 2008). Most patients meet the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR) diagnostic criteria for a current major depressive episode (American Psychiatric Association, 2013) and score 16 or higher on the Hamilton Depression

Rating Scale (HAMD) (Hamilton, 1960) will be required to receive pharmacological therapy, while patients with mild to moderately severe mental distress are recommended to receive psychotherapy (Ostuzzi et al., 2015; Pitman et al., 2018). Currently, several typical psychotherapies, including psychoeducation interventions (P. H. Wu et al., 2018), group therapy (Jelvehzadeh et al., 2022), mindfulness-based cognitive therapy (J. Y. Zhang et al., 2022), problem-solving treatment (Bokaie et al., 2022), yoga (Cramer et al., 2017), acupuncture (D'Alessandro et al., 2022), progressive muscle relaxation training (PMRT) (Sinha et al., 2021), hypnotherapy (Téllez et al., 2017), and music therapy (Lima et al., 2020) were found to be effective in reducing breast cancer patients' anxiety, tension, depression, and overall negative mood.

China has made significant strides in improving mental health services in the past decade (Z. Xu et al., 2022). However, recent research indicates that underserved breast cancer patients experience the following barriers to obtaining mental health services (W. Li & Reavley, 2020; Que et al., 2019). First, mental health services suffer a large shortage of well-trained counsellors and clinical psychologists (Que et al., 2019; Z. Xu et al., 2022), and there are still limited resources and inequities in access to mental health care in rural and remote areas in China (Liang et al., 2018; Phillips, 2013; S. Wang et al., 2018; Z. Xu et al., 2022). Second, disparities in insurance benefits and the persistent financial burdens among patients have been a key problem that prevent breast cancer patients from seeking psychological assistance, as health insurance does not support psychotherapy (Liang et al., 2018; Z. Xu et al., 2022). Therefore, because of insufficient resources, inefficient or unprofessional help, and inadequate finances, psychologists may not be the patients' first choice of a help-seeking source (Yin et al., 2019). As a result, they may have lower psychological intervention adherence rates, are more likely to experience delays in care, and to be at increased risk for distress (Allen et al., 2008; Madore et al., 2014; K. J. Wells et al., 2008). Furthermore, social stigma functions as a substantial societal and cultural barrier to psychological care for breast cancer patients in China (Yeung et al., 2019; Z. Zhang et al., 2019). Psychological counseling is perceived as embarrassing and

patients tend to disguise their psychological distress and attempt to rely on their own resources (V. Patel et al., 2016; S. Wang et al., 2018; Z. Xu et al., 2022; Z. Xu et al., 2017). Additionally, language and communication barriers including low health literacy levels among underserved patients impact understanding and comprehension of important medical information, leading to poor adherence to medical advice and inadequate follow-up care (Que et al., 2019; Z. Xu et al., 2022).

Although numerous psychological intervention strategies were influential in distress management for breast cancer patients undergoing chemotherapy, not every breast cancer survivor who suffered distress received psychological care in the Chinese context (Rao et al., 2019). Moreover, incorporation of psychological components of care in the routine cancer care delivery in healthcare settings is crucial and challenging (Que et al., 2019). There is significant demand to develop various kinds of interventions which may help breast cancer survivors to cope with psychological distress (Cai et al., 2021). Emotional expression, a kind of psychological intervention, has been studied for many years, demonstrating positive impacts on mental and physical wellbeing (Brandão et al., 2016; Cummings, 2007; Heilman, 2021; McInnerney et al., 2019). Given the high level of emotional suppression in breast cancer survivors especially for Chinese individuals, emotional expression has attracted more attention in recent years to help patients express their emotions and release depressed feelings (Chu, Wu, & Lu, 2020; Ji et al., 2019; W. Tsai et al., 2019; G. Wang et al., 2021).

1.2 Expressive writing interventions

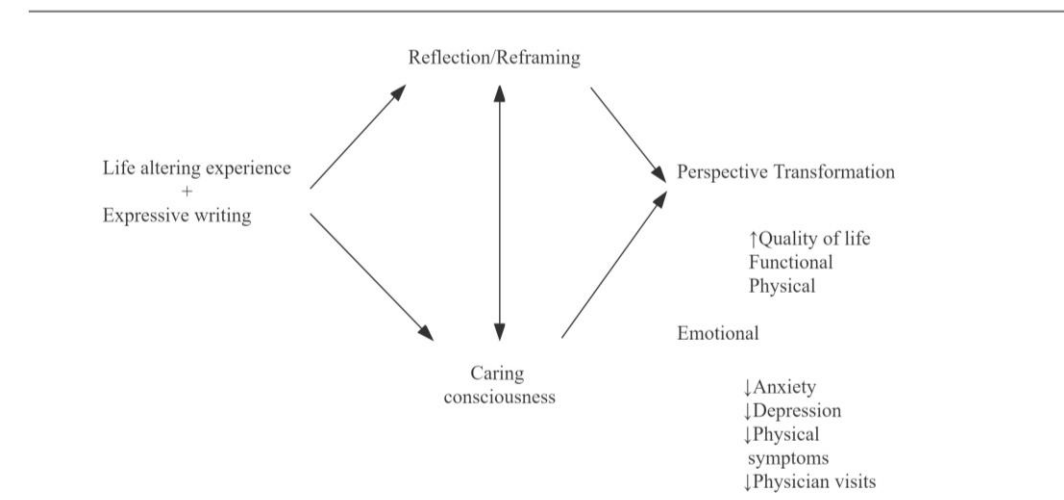
1.2.1 Definition and theories of expressive writing interventions

Expressive writing, which is a brief emotional expression intervention, was first implemented in college students by Pennebaker and Beall (1986) to facilitate disclosure through solitary and unlimited writing about their deepest thoughts and emotional feelings regarding stressful events for approximately 20 minutes over four consecutive days. According to the standard Pennebaker paradigm of expressive writing, participants were required to write in a private place and they can choose

whether to write about the same issue or different issues each time, and during the writing process, they can write continuously without worrying about sentence structure or grammar mistakes (Ames et al., 2005; Pennebaker & Beall, 1986; Seyedfatemi et al., 2021).

Several theoretical frameworks have been proposed to explain the mechanisms behind the benefits of expressive writing interventions, including emotional inhibition, self-regulation, and cognitive-processing (Frattaroli, 2006). Notably, it has been suggested that there is likely a complex combination of interconnected explanatory routes, rather than a single influential process (Merz et al., 2014). Early explanations of the benefits of expressive writing suggest that the writing exercise serves a cathartic function, allowing participants to release and express their traumatic feelings, which in turn improves their psychological or physical wellbeing (Pennebaker & Chung, 2007). As more studies were conducted, however, evidence proposed that this inhibition theory might not be fully sufficient to explain the benefits of expressive writing (Frattaroli, 2006). Another explanation is that expressive writing creates opportunities for writers to elicit the process of self-regulation and personal mastery (J. D. Creswell et al., 2007). Expressive writing might enable people to make sense of the traumatic events, observe how they handled their emotional feelings of the event, and increase their confidence of regulating and managing their stress, behaviors, and thoughts (Andersson & Conley, 2008). In addition, Pennebaker and Chung (2011) proposed that cognitive restructuring may also explain the benefits of expressive writing. That is, although repeatedly writing about one's traumatic feelings might lead to initial psychological distress, it also allows the participants to process, reflect, and reframe their emotions, extinguishing the connection between their emotional experience and the traumatic event, and integrating it into one's self-schema (Low et al., 2006; Pennebaker & Chung, 2011). Based on the cognitive change explanation, Craft et al. (2013) proposed an expressive writing conceptual framework: writing enables breast cancer patients to reflect on their life-altering emotional feelings, reconstruct meaning and transform actions to support coping (Figure 1).

Figure 1: Expressive writing conceptual framework (Craft et al., 2013)



1.2.2 Expressive writing in the management of psychological distress

Findings from the original research conducted by Pennebaker and Beall (1986) showed that expressive writing is a potentially effective intervention on psychological and physical adjustment. Numerous studies have since been conducted to extend expressive writing in various kinds of groups of people, including healthy individuals (Abuhamda & Soliman, 2016; Ames et al., 2005; Cowen et al., 2016; Hijazi et al., 2011; Marschin & Herbert, 2021; Myers et al., 2021; Tavakoli et al., 2009) as well as patients with lupus or rheumatoid arthritis (Danoff-Burg et al., 2006), cardiovascular disease (Regina et al., 2011), sexual dysfunction (Pulverman et al., 2015; B. E. Wells et al., 2022), HIV (Rivkin et al., 2006), and eating pathology (Kupeli et al., 2018).

With the increasing number of expressive writing intervention studies, several systematic reviews and meta-analyses have been conducted to synthesise and assess the effectiveness of expressive writing on psychological distress among different populations (Davis et al., 2020; Jones et al., 2021; Merz et al., 2014; Oh & Kim, 2016; Slade et al., 2021). Some reviews demonstrated positive effects of expressive writing interventions on health outcomes. For example, Qian et al. (2020) conducted a meta-analysis of randomized controlled trials (RCTs) and demonstrated that an expressive writing intervention was an effective way for decreasing women's post-traumatic stress disorder. This is in line with the meta-analysis conducted by Travagin et al. (2015) who found significant effects of expressive writing for the

domains of emotional distress in adolescents. In addition, a meta-analysis conducted by Gallo et al. (2015), Frattaroli (2006), and Frisina et al. (2004) also found positive effects of expressive writing for cancer patients, both healthy and unhealthy people, and various clinical populations.

However, some reviews reached a negative conclusion on the benefits of expressive writing to manage psychological distress. For example, the meta-analysis conducted by Mogk et al. (2006) demonstrated little effects of expressive writing on psychological health variables in different populations such as students, patient with asthma, university employees, patients with cancer, and British school children. Furthermore, Oh and Kim (2016) found little effect of expressive writing on psychological outcomes among patients with cancer, which is inconsistent with the meta-analysis by Gallo et al. (2015) who found positive effects of expressive writing for psychological symptoms among cancer patients. The conflicting pooled results of the two meta-analyses focused on cancer patients might because of the diversity of included studies. Oh and Kim (2016) involved 13 RCTs and 1 non-RCT and expressive writing interventions were compared with a neutral writing intervention or usual care (no writing), whilst Gallo et al. (2015) included 7 RCTs and expressive writing interventions were compared with a neutral writing intervention. Some reviews suggested that more research needs to be conducted to make a definite conclusion about expressive writing in cancer populations (Boinon et al., 2011; Merz et al., 2014; Zachariae & O' Toole, 2015).

The diversity of the populations included and the heterogeneity of the meta-analyses are likely to be a major reason for the inconsistency in the conclusions on the expressive writing intervention. Conflicting results of these meta-analyses on psychological distress in different populations might suggest that expressive writing, as a convenient psychological intervention, is in need of further clarification to determine if culture, personality, education, and other possible factors may be associated with the effects of this kind of writing exercise intervention.

1.2.3 Expressive writing in breast cancer patients

Because emotional inhibition was commonly reported by breast cancer survivors, the

benefits of expressive writing in breast cancer patients has been extensively studied (Alquraan et al., 2020; H. Li et al., 2020). Since Walker et al. (1999) first explored the potential effects of expressive writing in a breast cancer cohort, numerous RCTs have been performed based on Pennebaker's prompt to test the effectiveness of expressive writing on health outcomes in breast cancer patients (de Moor et al., 2008; Henry et al., 2010; Jensen-Johansen et al., 2013; Jensen-Johansen et al., 2018; Stanton, 2002).

Given the specific cultural beliefs and forms of emotional expression in the context of China, numerous studies have been conducted to test the effectiveness of expressive writing in the population of Chinese breast cancer patients (Chu, Wu, Tang, et al., 2020; Ji et al., 2020; Qian Lu et al., 2015; Qian Lu et al., 2012). Previous studies have identified a number of culturally salient illness beliefs associated with emotional expression in Chinese or Chinese immigrants (Lin et al., 2021; J. Xu et al., 2021). Numerous studies suggested that expressive writing might be a culturally sensitive intervention for Chinese cancer individuals because it allows them to engage in interpersonal emotional disclosure without experiencing shame, stigma, and disrupting their relationships with other people (Gallagher et al., 2018; W. Tsai & Lu, 2018). Notably, cultural differences are tendencies that do not obliterate the individual difference that exist in any culture. For example, Leung & Cohen (2011) proposed the CuPS (Culture $\times$ Person $\times$ Situation) approach attempts to jointly consider culture and individual differences. Hence, testing the effects of expressive writing in different cultures could help us to further understand both within and between-culture variation.

Similarly, studies on expressive writing in breast cancer patients also arrived at conflicting findings. Some studies identified positive effects of expressive writing on the psychological or physical wellbeing of this particular population (Chu, Wu, & Lu, 2020; de Moor et al., 2008; Laccetti, 2007; Q. Lu et al., 2019; Qian Lu et al., 2012), but others failed to confirm the benefit of expressive writing (Jensen-Johansen et al., 2013; Jensen-Johansen et al., 2018; Low et al., 2010; Sohl et al., 2017). Characteristics of the existing expressive writing intervention studies were diverse. For example, although writing intervention of these studies were based on the

Pennebaker's paradigm, the number of expressive writing sessions ranged from 1-6 with at least 20 minutes of writing for each session (Craft et al., 2013; Henry et al., 2010; Jensen-Johansen et al., 2013; E. Y. Park & Yi, 2012). One study involved participants enrolled 4 years after a diagnosis of stage-4 breast cancer (Mosher et al., 2012); one study included breast cancer patients enrolled 151 ± 55 days since surgery (Jensen-Johansen et al., 2013); while some of the studies reported the average time since diagnosis of breast cancer of participants was from 28.4 weeks to 7.9 years (Craft et al., 2013; Henry et al., 2010; Low et al., 2010; Stanton, 2002). In addition, the follow-up time after the expressive writing also showed poor homogeneity: ranging from 1 week to 9 months (Gellaitry et al., 2010; Henry et al., 2010; Jensen-Johansen et al., 2013; Walker et al., 1999). These results indicate that the effects of expressive writing might differ due to different factors such as stage of breast cancer, writing dosage, the context of culture, where an individual is on their diagnosis, treatment and recovery, personality, and emotional expressivity of individuals (Chu et al., 2019; Gallagher et al., 2018; Ji et al., 2020). Therefore, it is essential to investigate the individuals most likely to benefit from such an emotional disclosure intervention.

1.3 Summary

In this chapter, the prevalence and current interventions on psychological distress in breast cancer patients receiving chemotherapy have been examined, especially in the context of Chinese culture. Given the insufficient identification and intervention of psychological distress and the specific traditional cultural beliefs and emotional reactions of Chinese breast cancer survivors, there is an overwhelming need for exploring the current situation and providing culturally-appropriate psychosocial support that is congruent with the beliefs and values of the target group. Expressive writing, a low-cost, self-administered, convenient, and culturally sensitive intervention, still needs further exploration to identify any factors that may moderate the effects of such writing exercises in breast cancer survivors, which might help clinicians identify the individuals most likely to benefit from expressive writing in

China.

These gaps in the literature will be explored in more detail in the next chapter, which provides a rationale for the published works, thesis aim and objectives, methodology, and details the contribution of included articles to explore psychological distress in Chinese breast cancer patients and identify the factors that may moderate the effects of expressive writing in this population whose culture particularly discourages emotional disclosure.

Chapter Two: Rationale, thesis aim and objectives, methodology, and published works

This chapter provides a rationale for the published works, thesis aim and objectives, and methodology. It details the contribution of the included articles to explore psychological distress in Chinese breast cancer patients and to identify the factors that may moderate the effects of expressive writing in this population.

2.1 Rationale for the published works

Studies have found that breast cancer patients undergoing chemotherapy experience intense psychological distress and emotional suppression, which lowers the survivors' quality of life and impacts their adherence to treatment (de Souza et al., 2014; Malgaroli et al., 2022). Therefore, the importance of addressing breast cancer patients' psychological distress is clear, especially for those undergoing chemotherapy. Given the traditional cultural beliefs and emotional reactions of Chinese breast cancer survivors, exploring the current situation and providing culturally-appropriate psychosocial support that is congruent with the beliefs and values of the target group is critical (Lin et al., 2021; Xie & Wong, 2021; Yeung et al., 2019).

Family caregivers play an important role in providing first-line psychological and emotional support to breast cancer patients (Segrin et al., 2021). It is essential to understand whether family caregivers have a good understanding of psychological distress of breast cancer patients in China, whose culture particularly discourages emotional disclosure (Louie et al., 2013). Under- or overestimating breast cancer patients' psychological symptoms might impede appropriate psychological interventions to help them cope with psychological distress (Silveira et al., 2010). Yet there is a dearth of research that has explored the patient-caregiver dyad concordances in experiencing psychological distress among Chinese breast cancer patients receiving chemotherapy and their family caregivers. In addition, given the high level of emotional suppression of Chinese breast cancer patients (H. Li et al., 2020), identifying individuals who might be at risk of emotional disorders could help

healthcare providers develop specialized psychological interventions for them. However, a lack of assessment tools has limited the understanding of the emotional situation of breast cancer patients in China. To address these gaps, this body of work examines patient-caregiver concordances about psychological distress in Chinese breast cancer patients receiving chemotherapy (**Zhao et al., 2022**). Furthermore, the Emotional Inhibition Scale (EIS) (**Liu, Wu, et al., 2021**) has been adapted and tested in the context of Chinese culture to better understand psychological distress in this population in China.

Given the insufficient psychological intervention and the high level of emotional suppression in breast cancer patients, expressive writing has attracted more attention to help patients express their traumatic feelings and release depressed feelings (Alquraan et al., 2020; Low et al., 2010; Pennebaker & Chung, 2011). However, as a convenient and culturally sensitive intervention, expressive writing still requires further exploration to determine the effects and identify any factors that may moderate the effects of such writing exercises in breast cancer survivors. This portfolio of published works seeks to address some of these gaps in the literature, **Zhou et al., (2015)** conducted a meta-analysis to test the effects of expressive writing in breast cancer patients. The meta-analysis found that expressive writing might have a positive effect on health outcomes in breast cancer patients, but the benefit may not last long. To address the non-lasting effects of an expressive writing intervention, **Y. Wu, Liu, et al., (2021)** conducted a multicenter RCT to test the hypothesis that increasing the writing dosage could improve the effects of expressive writing on health outcomes in breast cancer patients undergoing chemotherapy. However, the hypothesis was not confirmed. Then, to explore other factors that may moderate the effects of expressive writing, a secondary analysis of this RCT has been conducted (**Y. Wu, Yang, et al., 2021**), which found that the level of emotional expressivity and the pattern of affective word use could be factors that might moderate the effects of expressive writing in breast cancer patients receiving chemotherapy. These results could help healthcare providers identify the individuals most likely to benefit from expressive writing in China, and potentially other cultures.

The portfolio of papers in this thesis provides new evidence in the field of psychological distress in breast cancer patients undergoing chemotherapy to answer these following questions. What is the experience of women with breast cancer undergoing chemotherapy? Do family caregivers have a good understanding of psychological distress of Chinese breast cancer patients undergoing chemotherapy? Is the Emotional Inhibition Scale (EIS) an appropriate tool to assess cancer patients' situation of emotional disorders in the context of China? Is expressive writing an effective intervention for breast cancer patients undergoing chemotherapy? Furthermore, are there any factors that could moderate the effects of expressive writing? (Liu, Wu, et al., 2021; Liu, Xu, et al., 2021; Y. Wu, Yang, et al., 2021; Y. Wu, Liu, et al., 2021; Zhao et al., 2022; Zhou et al., 2015).

2.2 Thesis aim and objectives

The aim of this thesis was to explore psychological distress in breast cancer patients receiving chemotherapy, especially in a Chinese context, and to evaluate the effects of an expressive writing intervention on health outcomes in this population.

The key objectives were to:

1. Explore psychological distress in breast cancer patients receiving chemotherapy.
2. Adapt and examine the Emotional Inhibition Scale (EIS) to provide a measure to assess the psychological health status in Chinese patients with cancer.
3. Test the effects of an expressive writing intervention on health outcomes in breast cancer patients.
4. Identify the factors that may moderate the effects of expressive writing in breast cancer patients receiving chemotherapy.

2.3 Contribution of included articles

Table 1 provides an overview of the contribution of each of the six papers to the research objectives. In addition, the author's original contribution, verified by the

collaborating authors, can be found in Appendix 2 and 3.

Table 1: Details of the published works and the contribution made.

Study	Study Objectives	Contribution Made	Thesis Objectives
Paper 1: Liu, L., Wu, Y. , Cong, W., Hu, M., Li, X., & Zhou, C. (2021). Experience of women with breast cancer undergoing chemotherapy: a systematic review of qualitative research. <i>Quality of life research: an international journal of quality of life aspects of treatment, care and rehabilitation</i> , 30(5), 1249–1265.	To (a) explore the experience of women with breast cancer undergoing chemotherapy, (b) identify how do they cope with distress during the process, and (c) explore the link between their experience and coping strategies.	This paper has identified three synthesized findings reflecting the experience and coping strategies of women with breast cancer undergoing chemotherapy. The link between experience and coping strategies is based on the Lazarus' stress and coping theory. Provides evidence of the need for support to help breast cancer patients to cope with distress.	Explore psychological distress in breast cancer patients receiving chemotherapy (Objective 1) .
Paper 2: Zhao, H., Li, X., Zhou, C., Wu, Y. , Li, W., & Chen, L. (2022). Psychological distress among Chinese patients with breast cancer undergoing chemotherapy: Concordance between patient and family caregiver reports. <i>Journal of advanced nursing</i> , 78(3), 750–764.	To examine patient-caregiver concordances about psychological distress in Chinese breast cancer patients undergoing chemotherapy and identify factors of concordance among patients and their family caregivers.	This paper found that there was relatively low psychological distress concordance between breast cancer patients' reports and caregivers' perceptions. Family caregivers tended to underestimate breast cancer patients' psychological distress. Provide evidence on the need of more psychological care and emotional support for Chinese breast cancer patients receiving chemotherapy by family caregivers and healthcare providers.	Explore psychological distress in breast cancer patients receiving chemotherapy (Objective 1) .
Paper 3: Liu, L., Xu, Y., Wu, Y. , Li, X., & Zhou, C. (2021). Cross-Cultural Adaptation and Validation of the Emotional	To translate, cross-culturally adapt, and evaluate use of the Emotional Inhibition Scale (EIS) with	The EIS demonstrated acceptable validity and reliability for assessing emotional inhibition in Chinese cancer patients.	Adapt and examine the Emotional Inhibition Scale (EIS) to provide a

Inhibition Scale in a Chinese Cancer Sample. <i>Frontiers in psychology</i> , 12, 654777.	Chinese cancer patients.	Provide a useful measure to better understand emotional inhibition in Chinese patients with cancer to help healthcare providers develop specialized psychological interventions for cancer patients in the future.	measure to assess the psychological health status in Chinese patients with cancer (Objective 2).
Paper 4: Zhou, C., Wu, Y. , An, S., & Li, X. (2015). Effect of Expressive Writing Intervention on Health Outcomes in Breast Cancer Patients: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. <i>PloS one</i> , 10(7), e0131802.	To test the effects of expressive writing, which is a brief emotional expression intervention, on physical and psychological health outcomes in breast cancer patients.	This meta-analysis has identified that expressive writing might have a positive effect on health outcomes in breast cancer patients, but the benefit may not last long. The non-lasting effects of expressive writing need to be explored more to determine any possible factors that may moderate the effects of this writing intervention.	Test the effects of an expressive writing intervention on health outcomes in breast cancer patients (Objective 3).
Paper 5: Wu, Y. , Liu, L., Zheng, W., Zheng, C., Xu, M., Chen, X., Li, W., Xie, L., Zhang, P., Zhu, X., Zhan, C., & Zhou, C. (2021). Effect of prolonged expressive writing on health outcomes in breast cancer patients receiving chemotherapy: a multicenter randomized controlled trial. <i>Supportive care in cancer: official journal of the Multinational Association of Supportive Care in Cancer</i> , 29(2), 1091–1101.	To test the hypothesis that increasing the writing dosage (a 3-fold “dosage” compared to the classical dose) could improve the effects of an expressive writing intervention on health outcomes in breast cancer patients undergoing chemotherapy.	This multicenter, prospective, parallel RCT first demonstrated that the writing dosage does not moderate the effects of expressive writing in breast cancer patients undergoing chemotherapy. The null finding suggests that additional research needs to be conducted to explore whether other possible moderates are associated with the effects of an expressive writing intervention in breast cancer patients receiving chemotherapy.	Identify the factors that may moderate the effects of expressive writing in breast cancer patients receiving chemotherapy (Objective 4).
Paper 6: Wu, Y. , Yang, D., Jian, B., Li, C., Liu, L., Li, W., Li, X., & Zhou, C. (2021). Can emotional expressivity and	To explore whether emotional expressivity and writing content could predict benefits of expressive writing in	This study first identified that the level of emotional expressivity and the pattern of affective word use could be factors that might	Identify the factors that may moderate the effects of expressive writing in breast cancer

writing content predict beneficial effects of expressive writing among breast cancer patients receiving chemotherapy? A secondary analysis of randomized controlled trial data from China. <i>Psychological medicine</i> , 1–15. Advance online publication.	breast cancer patients receiving chemotherapy.	moderate the effects of expressive writing in breast cancer patients receiving chemotherapy, which could help healthcare providers identify the individuals most likely to benefit from expressive writing in China.	patients receiving chemotherapy (Objective 4).
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2.4 Pragmatic paradigm and methodology

A research paradigm is a conceptual framework comprised of a set of common values and beliefs shared between scientists, which guides how research should be conducted and addressed (Morgan, 2007). The adoption of a paradigm reflects a researcher's ontological commitments, epistemological beliefs, and methodological preferences (Glogowska, 2011). Some key paradigms such as postpositivism, interpretivism, participatory, and pragmatism are commonly adopted by researchers to conceptualize their beliefs in relation to the nature of knowledge and support them to select research methods (Lincoln et al., 2018). Pragmatism as a philosophy derives from the work of Cherryholmes (1992). Patton (1990) and Murphy (1990) convey the importance of pragmatism in addressing research problems. The pragmatic research paradigm is based on the premise that researchers should utilize the best suitable methodological approach to address real-world problems, allowing the adoption of a wide range of methods to answer research questions (Allemang et al., 2022; Andrew & Halcomb, 2006). This means that pragmatists do not privilege one type of research philosophy over another. Instead, pragmatists are free to choose different type of methods to address problems within a given context, recognizing that methodologies are tools to support one's understanding of the world (Anthony & Leech, 2005). Pragmatism, therefore, serves as a paradigm that allows for the use of mixed and multimethod research, which utilizes multiple forms of qualitative and quantitative research data to answer research questions (Brierley, 2017).

In this body of works, a pragmatic paradigm approach was used, which meant the

researcher had freedom of choice to use methods that most suitable to address the research problem (Hothersall, 2019). Both qualitative and quantitative approaches are essential to pragmatists because they provide research options to address issues at hand (Brierley, 2017). The qualitative approach is identified as an interpretivist research epistemology to provide an in-depth way to understand and explore a social or human problem such as participants' experience about a phenomenon; the quantitative approach, however, is accepted as a positivism or postpositivism research epistemology to test the relationship between variables (J. W. Creswell, 2014). Given the limitations of each approach, pragmatists focus on the research problem and advocate using either quantitative or qualitative approaches as necessary to provide a more comprehensive understanding of a research question (Andrew & Halcomb, 2006; Brierley, 2017). Consequently, in the portfolio of works, one of the papers used qualitative research to understand the experience of breast cancer patients undergoing chemotherapy (**Liu, Wu, et al., 2021**). Five papers utilized quantitative approaches, in keeping with the positivist paradigms, to test the effects of expressive writing and investigate the situation of psychological distress of breast cancer patients receiving chemotherapy (**Liu, Xu, et al., 2021; Y. Wu, Yang, et al., 2021; Y. Wu, Liu, et al., 2021; Zhao et al., 2022; Zhou et al., 2015**). Research methods in the portfolio of works were selected to best address the research questions and objectives.

In paper one (**Liu, Wu, et al., 2021**), a systematic review of qualitative research was used to understand the experience of women with breast cancer undergoing chemotherapy. The qualitative research method is underpinned by the interpretive paradigm that seeks to understand the complexity of human phenomena and facilitates the analysis of human experience and social phenomena (Ailing, 2003). In the context of healthcare, the qualitative research approach "...seeks to understand and interpret personal experience; the illness experience; or the impact of human suffering" (Wong et al., 2004). In this paper, qualitative research findings were synthesized based on the process of a meta-aggregative approach (Lockwood et al., 2015).

In paper two (**Zhao et al., 2022**) and paper three (**Liu, Xu, et al., 2021**), a

cross-sectional study was adopted to examine patient-caregiver concordances about psychological distress in Chinese breast cancer patients undergoing chemotherapy and test the validity and reliability of the Chinese version of the Emotional Inhibition Scale (EIS). Descriptive surveys can be used to describe what exists, to examine relationships, and to explore possible links between variables in a given population (Gerrish & Lacey, 2010). These two studies used questionnaires to investigate psychological distress and emotional disorders among breast cancer patients, which was consistent with the data collection methods in surveys (J. W. Creswell, 2014).

In paper four (**Zhou et al., 2015**), a meta-analysis was used to assess the effects of expressive writing in breast cancer patients. A meta-analysis is a systematic review of trials with pooled data (Cleophas & Zwinderman, 2017). Although some limitations of meta-analysis have been found such as publication bias and poor homogeneity of included studies, it is still widely acknowledged that meta-analysis is an essential way to combine the effect size of numerous similar trials to improve the power of results to obtain more certainty (Aalaei-Andabili & Alavian, 2012; Cleophas & Zwinderman, 2017). Nowadays, meta-analysis even has been identified as the top of the evidence-based medicine pyramid (Cleophas & Zwinderman, 2017). This meta-analysis pooled results from 11 RCTs, and the effects of expressive writing have been appropriately addressed by the pooled results.

In paper five (**Y. Wu, Liu, et al., 2021**) and paper six (**Y. Wu, Yang, et al., 2021**), a multicenter RCT was used to test the effects of expressive writing on health outcomes in breast cancer patients receiving chemotherapy. RCTs rely on quantitative measures to test effect and cause and use deductive approaches to establish causal effect (Cartwright, 2010). Deductive approaches test out theory and reduce complex variables such as distress to capture and quantify effect (J. W. Creswell, 2014). As such, RCTs are widely taken as the gold standard method to reduce and control bias in relation to the outcomes of intervention (Parahoo, 2014). Furthermore, until now, the RCT remains the most appropriate and common research method to test the effects of an expressive writing intervention in breast cancer patients among the current articles (**Zhou et al., 2015**). In addition, these two papers used a parallel RCT because a

parallel study would be more beneficial if any carryover effects would be presented and might also be more appropriate if the disease is likely having a chance of progression over time like breast cancer (Parab & Bhalerao, 2010).

2.5 Summary

In this chapter, the rationale for the published works, thesis aim and objectives, contribution of each of the six papers to the research objectives, and research paradigm and methodology of each paper have been addressed. The next chapter will provide an overview of the portfolio of published works, critically analyse the strengths and limitations of each paper, critique the publications by thesis objectives, and explore the unique contribution of the portfolio of works to knowledge.

Chapter Three: Critique of the presented publications

This chapter provides an overview of the portfolio of published works, critical analysis of the strengths and limitations of each paper and critiques the publications in relation to the thesis objectives.

3.1 Overview of the publications

First, to better understand the situation of psychological distress of breast cancer patients undergoing chemotherapy, **Liu, Wu, et al. (2021)** conducted a systematic review of qualitative research to gain a comprehensive understanding of the breast cancer patients' experience of chemotherapy (objective 1). Then, **Zhao et al. (2022)** demonstrated the low concordance between breast cancer patients' reports and caregivers' perceptions of psychological distress, which may help healthcare providers better interpret caregiver assessments (objective 1). In addition, given the lack of assessment tools of emotional inhibition in Chinese breast cancer patients, **Liu, Xu, et al. (2021)** adapted and validated the Emotional Inhibition Scale (EIS) to provide a useful measure of the level of emotional inhibition for cancer patients in China (objective 2).

Furthermore, given the high level of psychological distress and emotional suppression in breast cancer patients identified in the previous studies (Alquraan et al., 2021; Brown et al., 2021; **Liu, Wu, et al., 2021**; **Zhao et al., 2022**), **Zhou et al. (2015)** conducted a meta-analysis to reveal that expressive writing may have a significantly positive impact in breast cancer patients, but the benefit may not last long (objective 3). To further explore whether some factors may predict beneficial effects of expressive writing, **Y. Wu, Liu, et al. (2021)** conducted a multicenter RCT and demonstrated that the writing dosage does not moderate the effects of expressive writing on breast cancer patients undergoing chemotherapy (objective 4). Then, **Y. Wu, Yang, et al. (2021)** conducted a secondary analysis of the RCT. The study first confirmed the relationship between emotional expressivity and health outcomes in expressive writing in breast cancer patients and its role in influencing the patterns of

affective word use in writing texts. The findings of the present study may help clinicians identify the individuals most likely to benefit from such nurse-led writing exercises in China (objective 4). These papers can be found in Appendix 1.

3.2 Presentation and critique of the publications

Paper 1: Liu, L., Wu, Y., Cong, W., Hu, M., Li, X., & Zhou, C. (2021). Experience of women with breast cancer undergoing chemotherapy: a systematic review of qualitative research. *Quality of Life Research*, 30(5), 1249–1265.

Study Overview

This systematic review synthesized existing findings to better understand the experience of women with breast cancer undergoing chemotherapy to guide future research (objective 1). Specifically, the objectives of the review were to analyze the following questions: (a) What is the experience of women with breast cancer receiving chemotherapy? (b) How do they cope with distress during this process? (c) What is the link between their experience and coping strategies? Eight databases and other sources, including 4 grey literature databases and reference lists and citation of identified articles, were searched to identify all the published and unpublished qualitative research studies focused on the perspectives of women with breast cancer reporting their experiences of chemotherapy. Of the 5580 titles and abstracts screened, 5502 were excluded. After we read the remaining 78 full-text articles, 66 were excluded for the following reasons: chemotherapy was not the focus, patients' experiences were not the focus, or breast cancer was not the focus. Finally, 12 qualitative studies presenting findings from 184 women with breast cancer who had received chemotherapy were included in the review. Three synthesized findings were identified from nine categories based on 91 original findings: (1) Women living with chemotherapy experienced various stressful side effects, and their lives were changed (including four categories—physical changes, emotional distress, cognitive changes, and life changes). (2) Supportive care to address needs is essential to help women get through this difficult time (including two categories—the need for information and the need for social support). (3) They engaged in numerous types of coping strategies to deal with side effects and adapt to this difficult journey (including three

categories—problem-focused coping strategies, behavioral coping strategies, and emotion-focused coping strategies).

Contribution and critique of the Liu, Wu, et al. (2021) study

An understanding of the current experience and coping strategies of women with breast cancer undergoing chemotherapy may help healthcare providers design supportive care or interventions to better prepare and manage the adverse effects of chemotherapy (objective 1). Previous related qualitative reviews focused on the symptoms experienced during chemotherapy (Tanay et al., 2017), driving and disabling factors for chemotherapy (Dowling et al., 2019; Johnson, 2012), experience and survivorship of patients with breast cancer (Howard et al., 2007), or the experience of patients with other types of cancer receiving chemotherapy (Manning & Gyi, 2008). Although research on the chemotherapy experience during different periods of cancer and treatment with different drugs and across different regions has increased, no qualitative reviews have focused on the experience and coping strategies of women with breast cancer.

This review contributes to knowledge by first synthesizing the literature of the experience and coping strategies of women with breast cancer undergoing chemotherapy based on the Contextual Model of Lazarus' Stress and Coping Theory (Figure 2). The synthesized findings provide evidence on the experience of side effects during chemotherapy, coping strategies to address these adverse effects, and the need for supportive care to cope with distressful events.

Qualitative research findings were summarized using the standardized data extraction tool from the JBI System for the Unified Management, Assessment and Review of Information (JBI-SUMARI). Meta-aggregation involves the synthesis or aggregation of findings to generate a set of statements that represent the aggregation through the assembly of the findings rated according to their quality and categorizing these findings based on similarity in meaning. These categories were then subjected to a meta-aggregation procedure to produce a single comprehensive set of synthesized findings that were used as a basis for evidence-based practice. These categories were then mapped according to the principles and framework of Lazarus' Psychological

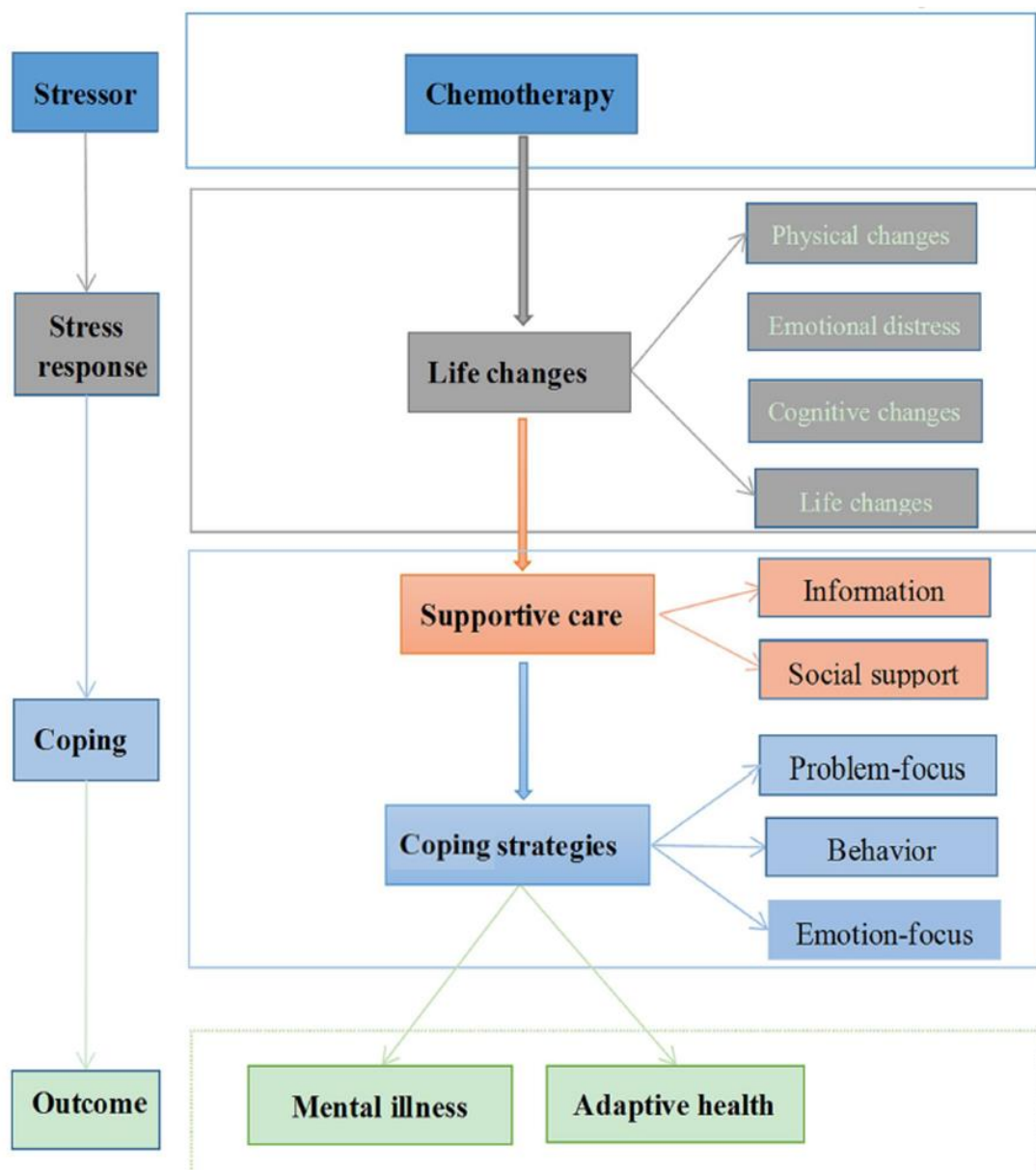
Stress and Coping Theory (Biggs et al., 2017; Lazarus, 1974). The synthesized findings from this meta-aggregation suggested that when women experienced various stressful side effects, supportive care to address needs and effective coping strategies such as pre-chemotherapy care programs, emotion-focused coping strategies, information support systems, and social support groups are essential to help them adapt to this difficult journey. The studies included in this review were conducted in a range of high and low income countries: USA ($n = 2$), UK ($n = 2$), Turkey ($n = 2$), Nigeria ($n = 1$), China ($n = 2$), Pakistan ($n = 1$), Sweden ($n = 1$), and Syria ($n = 1$), and the cultural diversity of these breast cancer patients increases the representativeness and extensibility of the synthesized findings. In addition, this study developed a comprehensive search strategy and an explicit and clearly reported quality assessment of the included studies and data extraction and synthesis process.

This systematic review has highlighted the link between the chemotherapy experience and coping strategies (Figure 2). Chemotherapy is an external stressor for women with breast cancer, which leads to various physiological and psychological side effects (fear, stress, anxiety, and depression). This stress motivates individuals to seek coping strategies that will prevent further psychological disorders and maintain psychological well-being. This finding is consistent with the views of previous studies (Sari et al., 2019; Thiagarajan et al., 2016; Yahaya et al., 2015). A quantitative study by Sari et al. (2019) showed that adequate social support and effective coping strategies significantly reduce the symptom-related distress of patients undergoing chemotherapy. In addition, another study by Chirico et al. (2017) found an inverse relationship between self-efficacy for coping and distress from chemotherapy and a positive relationship between self-efficacy for coping and quality of life.

Moreover, we found that the results of this review matched the Contextual Model of Lazarus' Stress and Coping Theory, which was helpful in describing and organizing the results (Figure 2). This theory is a system for assessing the process of coping with stressful experiences. Stressful encounters are interpreted as individual-environment transactions, which depend on the impact of the external stressor (Biggs et al., 2017; Lazarus, 1974). All individuals have resources and skills known as coping

mechanisms that are used to relieve stress. Anything that causes stress endangers life, unless it is met by adequate adaptive responses; conversely, anything that endangers life causes stress and adaptive responses (Lazarus & Folkman, 1984). The application of this theory would allow nurse practitioners to include a plan to relieve patient stress and to incorporate this plan into short-term goals with the aim of ensuring safety. The ability of patients to successfully complete chemotherapy depends on their coping skills, which will decrease stressors and allow the patient to move towards a more positive outlook and lifestyle.

Figure 2: The synthesized findings and framework of Lazarus’s psychological and coping theory



However, there are some limitations that should also be noted. First, because of the language limitations, a number of high-quality non-English studies might have been missed. Second, the systematic review protocol used in this study was not registered prior to the study. Prospective registration of systematic reviews could promote the transparency and help to avoid bias as possible in the conduct and reporting of reviews (Stewart et al., 2012). Third, the experience and coping strategies among women of different cultures, treated with different chemotherapy regimens and with different stages of breast cancer may vary, but we were unable to conduct the analysis separately in this review because of the failure to obtain complete related data from most of the original studies. Therefore, the results from this study are relevant for some but not all patients. All these might lead to possible biases in the results of the review (Cleophas & Zwinderman, 2017).

Roles played by candidate

The first author of the study is a Master's student in the Southern Medical University, China. The corresponding author of the study is the formal supervisor of the student and also the leader of the candidate. In this study the candidate played the role of co-supervisor of the student to identify gaps in the literature, advise and lead on study design, supervise the review process, and help the student to conduct evidence searches and data extraction, critical appraisal, write and revise the paper. The candidate's original contributions, verified by the collaborating authors, can be found in Appendix 2 and 3.

Paper 2: Zhao, H., Li, X., Zhou, C., Wu, Y., Li, W., & Chen, L. (2022). Psychological distress among Chinese patients with breast cancer undergoing chemotherapy: Concordance between patient and family caregiver reports. *Journal of Advanced Nursing*, 78(3), 750–764.

Study Overview

This cross-sectional study examined patient-caregiver concordances about psychological distress among Chinese patients with breast cancer undergoing chemotherapy and identified factors related to concordance among patients and family caregivers (objective 1). A total of 137 dyads of breast cancer patients undergoing

chemotherapy and caregivers were enrolled in the study. Sociodemographic information, the distress thermometer (including the problem list), the Distress Disclosure Index and the Family Adaptability and Cohesion Evaluation Scale were used to collect data. Data were analyzed using intraclass correlation coefficients (ICC), kappa statistics, two related samples test, chi-square tests and/or Fisher's exact tests and binary logistic regression. Overall, this study found that there was relatively low concordance between breast cancer patients' reports and caregivers' perceptions of psychological distress. Family caregivers tended to underestimate breast cancer patients' psychological distress. The results provide evidence on the need of more psychological care and emotional support for Chinese breast cancer patients receiving chemotherapy by family caregivers. In addition, patient and caregiver education should be implemented to improve this concordance.

Contribution and critique of the Zhao et al. (2022) study

Psychological distress in breast cancer patients is often underestimated and under-treated (Sun et al., 2021). Identification of psychological distress during cancer survivors is challenging (Syrowatka et al., 2017). Expressive suppression and stigma related to disease or psychological problems are barriers to distress assessment and management (Q. Lu et al., 2018; Z. Zhang et al., 2019). These patients may be reluctant to express their emotional problems to others, including their families. Family caregivers play an essential role in providing first-line social support to patients (Segrin et al., 2021). It is crucial to understand whether family caregivers have a good understanding of patients' psychological symptoms. Over – or underestimating patients' psychological distress may impede appropriate support to cope with patients' psychological impairments (Silveira et al., 2010). If family caregivers recognized patients' distress, more emotional support might be provided. Furthermore, family caregivers are important communication links between patients and healthcare providers (Yeşilbalkan & Okgün, 2010), contributing to better distress assessment by healthcare providers. For these reasons, it is necessary to know about whether caregivers' understanding of patients' negative emotions is consistent with patients' self-reports. A substantial body of evidence focused on the concordances

between patient and caregiver/partner reports of the perceptions about symptom, cancer-related concerns and social support (Hou et al., 2018; Martinez et al., 2020; Silveira et al., 2010).

Contrary to the straightforward and open communication ways in western countries, China has a unique cultural context (Williamson et al., 2012). Chinese cancer patients often expect their family caregivers to ‘mind-read’ their thoughts and needs (Hou et al., 2018). To the best of our knowledge, little is known about the patient-caregiver dyad concordances in psychological distress perceptions among Chinese breast cancer patients undergoing chemotherapy and their family caregivers. Therefore, the specific aims of this study were (1) to investigate the concordance between patients’ reports and caregivers’ perceptions of psychological distress and (2) to identify the factors that contributes to the concordances, namely, whether participants’ characteristics, individual levels of distress disclosure and adaptability and cohesion of families may affect the concordances.

This study contributes to knowledge by identifying relatively low agreement between the Chinese breast cancer patient and caregiver ratings in distress thermometer and problem list assessment results ($ICC = 0.528$). Patients reported significantly higher distress thermometer scores than caregivers’ reports. This underestimation of psychological distress is similar to previous studies in that caregivers were poor evaluators of cancer patients’ distress levels (Silveira et al., 2010; Yeşilbalkan & Okgün, 2010). In comparison with psychological distress, healthcare providers or family caregivers tend to pay more attention to the physical symptoms of cancer patients (Madden, 2006; Silveira et al., 2010). In addition, caregivers experienced the same or greater levels of distress than cancer patients themselves (Segrin et al., 2020). Caregivers also needed a psychological adjustment process, so that they might ignore the patients’ psychological problems.

Identifying the number of distressing factors and specific items is crucial to the process of assessing distress. For the problem list of the distress thermometer, our study indicates that the five most frequently reported problems by breast cancer patients were: restricted in physical activity ($n = 79, 57.7\%$), fatigue ($n = 77, 56.2\%$),

appearance ($n = 72$, 52.6%), worry ($n = 64$, 46.7%) and sleep ($n = 62$, 45.3%); Among caregiver reports, the five most frequently reported problems were: restricted in physical activity ($n = 50$, 36.6%), nausea ($n = 45$, 32.8%), appearance ($n = 45$, 32.8%), nervousness ($n = 35$, 25.5%) and depression ($n = 34$, 24.8%). Concerning the sources that contributed to distress, physical and emotional problems reported by caregivers were partially congruent with patients' reports. Our study shows that caregivers believed that the observable symptoms such as nausea and appearance influenced patients more than fatigue. Fatigue is one of the distressing side effects of cancer treatments that may affect patients' quality of life for a lifetime, and the highest prevalence of fatigue was found among patients undergoing chemotherapy (Reinertsen et al., 2017). Our findings suggest that fatigue received little attention from caregivers. Caregiver education is needed to heighten fatigue awareness, to alleviate negative impacts on emotion further.

The findings of this study also suggest that emotional suppression (OR, 0.402; 95% CI, 0.186-0.868) and a comorbid condition (odds ratio [OR], 0.352; 95% CI, 0.155-0.798) contributed to the incongruence between patient and caregivers. Comorbidities are prevalent among breast cancer patients undergoing chemotherapy (H. S. Wu et al., 2019). Compared with others, patients with comorbidities are more likely to have more symptoms and poorer quality of life (H. S. Wu et al., 2019). It is possible that patients' health status may decline because of comorbidities, and caregivers cannot evaluate and report patients' emotional conditions. Emotional expression can influence patients' psychological adaptation, which is beneficial to relieving their psychological distress (Brandão et al., 2016). The current study shows that better agreement was more likely to occur among patients with higher distress disclosure, which was in line with a previous finding that satisfaction with partner support for breast cancer patients was relevant to high patient disclosure (Carlson et al., 2001). The findings of this study also suggest that disclosure communication plays a fundamental role in the agreement between patients' and caregivers' reports. Positive emotional communication between cancer patients and caregivers helps share the thoughts and feelings and regulating dyad coping mechanisms, thereby improving

surrogate accuracy (J. Li et al., 2020). However, many Chinese breast cancer patients were reluctant to share their distressing feelings with their family caregivers (Ji et al., 2019). They felt they could not benefit from talking about their distressing problems with caregivers, or they were ashamed to disclose their negative emotions because of disease stigma (W. Tsai et al., 2019). Family caregivers need to perform caregiving tasks and balance obligations at work (Yeung et al., 2020). If caregivers are busy with their work, it is difficult for patients to have emotional communication with them. These findings suggest that much remains to be done to improve the psychological care for breast cancer patients undergoing chemotherapy in China.

Congruency in psychological distress may provide crucial information about how patients with breast cancer and caregivers cope with the psychological impacts of cancer. Our findings demonstrate caregivers lack awareness of patients' psychological distress and indicates the direction needed for dyadic psychological education for women undergoing chemotherapy and their caregivers. Patient education should encourage women to share their distressing thoughts and feelings and take advantage of emotional support (especially family-based support). Furthermore, healthcare providers should educate caregivers to improve their perceptions of patients' psychological distress, especially in relation to factors that caregivers underestimate such as fatigue.

This study has certain limitations. First, all participants were recruited from one hospital, which may generate selection bias (H. Lu et al., 2022). Second, as the study was done with female patients with breast cancer undergoing chemotherapy, the results may not be generalizable to other cancer diagnosed or males. Third, other factors related to the concordance between patient and caregiver reports such as health literacy need to be further explored in the future research. Finally, whether the concordances in patients' and caregivers' perception of psychological distress positively or negatively affect patients' or caregivers' health outcomes was not explored. Hence, future multicenter studies including patients with different genders and examination of the effects of concordances are recommended.

Roles played by candidate

The first author of the study is a Master's student in the Southern Medical University. The corresponding author of the study is the formal supervisor of the student and also the leader of the candidate. In this study the candidate played the role of co-supervisor of the student to advise on study design and help the student to revise the paper. The candidate's original contributions, verified by the collaborating authors, can be found in Appendix 2 and 3.

Paper 3: Liu, L., Xu, Y., Wu, Y., Li, X., & Zhou, C. (2021). Cross-Cultural Adaptation and Validation of the Emotional Inhibition Scale in a Chinese Cancer Sample. *Frontiers in Psychology*, 12, 654777.

Study Overview

This cross-sectional study was used to adapt the Emotional Inhibition Scale (EIS) to Chinese conditions and examine the psychometric characteristics of the scale in patients with cancer. The recruited participants comprised a sample of 100 patients (sample 1) and a sample of 202 patients (sample 2) with cancer. This study identified that the EIS demonstrated acceptable reliability and validity for assessing the level of emotional inhibition in Chinese-speaking patients with cancer. The study provides a useful measure to better understand emotional inhibition in Chinese patients with cancer to help healthcare providers develop specialized psychological interventions for cancer patients (objective 2).

Contribution and critique of the Liu, Xu, et al. (2021) study

This study was undertaken given the lack of tools to assess the level of emotional inhibition in Chinese patients with cancer. Assessing and managing the inhibition of emotions are important because previous studies strongly related emotional inhibition to anxiety disorders (Peh et al., 2017; Zimmermann et al., 2015), depression (Langner et al., 2012; L. Li et al., 2015), and borderline personality disorder (Popolo et al., 2014; Salvatore et al., 2016). In addition, our previous studies also identified emotional distress as a category in the synthesized findings. Fourteen findings extracted from eight studies indicated that women with breast cancer experienced a myriad of psychological burdens during the chemotherapy periods, such as worry, fear, anxiety, anger, depression, uncertainty, and isolation (Liu, Wu, et al., 2021) and low

levels of self-disclosure of Chinese breast cancer patients in communicating with caregivers (**Zhao et al., 2022**). This study provides initial evidence for the reliability, construct validity, content validity, and convergent validity of the Chinese version of the EIS in a sample of Chinese patients with cancer.

The EIS was developed by Robert Kellner in 1986 as a self-rating instrument based on clinometric principles that are used to evaluate the beliefs of a person in suppressing feelings and emotions (Grandi et al., 2011; Kellner, 1986). The EIS is the only reliable instrument that explains the behavior and intrinsic features of emotional inhibition. In addition, the EIS is brief, which is a 16-item instrument rated on 5-point Likert-type scale, and may be completed within 10 min. The current study contributes to a better understanding of emotional inhibition in Chinese patients with cancer to help medical staff develop specialized psychological interventions for these patients in the future.

Inconsistent with other studies in the portfolio of published works that focused on the population of breast cancer patients, this study adapted the EIS to Chinese conditions and examined the psychometric characteristics of the EIS in patients with cancer. To improve the generalizability of the EIS in China, this study scales up the research population to a wider range of cancer patients rather than the breast cancer population alone. The EIS might be useful in studies of the physiology of emotional inhibition and influencing factors in patients with cancer. In addition, this simple assessment could also be used in clinical practice as an emotional disclosure intervention. In recent years, this version of the EIS has been used in other areas of cancer care in China. For example, Chen, M. (2022) used the EIS in Chinese oral cancer patients to assess the association of anxiety and depression, emotional inhibition and posttraumatic growth to provide a scientific and reasonable basis for the intervention plan of anxiety and depression of oral cancer patients. Furthermore, Shang et al. (2022) used the EIS as an outcome assessment tool to assess the effect of spouse synchronous empowerment education on emotional inhibition and fear of cancer recurrence in patients with ovarian cancer undergoing chemotherapy in China. Moreover, the EIS also has been used to investigate the status quo of emotional

inhibition and analyze its possible influencing factors in 324 breast cancer patients in China (Peng et al., 2022).

This study also provides evidence that patients with later stages of cancer had higher levels of emotional inhibition, which reminds healthcare professionals to pay more attention to patients with more malignant cancer. The EIS serves as a reminder to healthcare professionals to provide ongoing evaluation and intervention in patients with different stages of cancer.

Whilst this paper provided reliability and validity evidence of the Chinese version of the EIS, there are some limitations to consider. First, the patients from this study were limited to those with cancer at a tertiary hospital in Guangdong Province, China, so it is less persuasive to generalize these results to other populations and regions in China (J. W. Creswell, 2014). Future studies should recruit more representative samples to replicate and verify the results in other populations and various regions of China and establish the Chinese norm of the EIS. It is also necessary to evaluate the minimum clinically important difference in future research before we use the EIS as a primary or secondary outcome in RCTs. Second, this study depended exclusively on the self-report data collection method, which may have some serious issues, such as bias or inaccurate reporting (Parahoo, 2014). Future research may include another objective approach to assess the influence of emotional inhibition and its consequences, such as behavioral and physiological measures and experimental paradigms. Third, this validation study was based on the classic theory test (CTT), and it will be useful to perform item response theory (IRT) in future research to provide additional important information (Ye et al., 2019; Ye et al., 2020).

Roles played by candidate

The first author of the study is a Master's student in the Southern Medical University. The corresponding author of the study is the formal supervisor of the student and also the leader of the candidate. In this study the candidate played the role of co-supervisor of the student to help to identify the scale in the literature, supervise the research process, perform the analysis, revise the manuscript, and help the student to translate and culturally adapt the scale. The candidate's original contributions, verified by the

collaborating authors, can be found in Appendix 2 and 3.

Paper 4: Zhou, C., Wu, Y., An, S., & Li, X. (2015). Effect of Expressive Writing Intervention on Health Outcomes in Breast Cancer Patients: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *PloS One*, 10(7), e0131802.

Study Overview

Given the unmet needs of psychological care and the high level of emotional suppression in breast cancer patients (Bar et al., 2020; Lally et al., 2020; **Liu, Wu, et al., 2021; Liu, Xu, et al., 2021; Zhao et al., 2022**), this meta-analysis evaluated the effects of expressive writing, which is a brief emotional expression intervention, on physical and psychological health outcomes in breast cancer patients (objective 3). Of the 5,232 titles screened, 11 RCTs with a total of 1,178 participants were identified in the study. The pooled results revealed that an expressive writing intervention might have a significantly positive effect on health outcomes in breast cancer patients, but the benefit may not last long. This paper suggests that the non-lasting effects of expressive writing need to be explored in future studies to determine any possible factors that may moderate the effects of this writing intervention.

Contribution and critique of the Zhou et al. (2015) study

This review contributes to knowledge by first synthesizing the literature to test the hypothesis that expressive writing might be a promising clinical intervention to improve the health outcomes in breast cancer patients. We tried to determine whether expressive writing was beneficial for breast cancer patients, what were the benefits, and how effective was expressive writing in relieving physical and psychological symptoms. Based on the physical health indexes, we found that the negative somatic symptoms of breast cancer patients (measured by the *Negative Somatic Symptoms Scale*) were significantly relieved after an expressive writing intervention for ≤ 3 months using either an emotional prompt or a benefit-finding prompt compared with the control group. This study also identified a significant effect of expressive writing on medical appointments for cancer-related morbidities, worst pain (measured by *Brief Pain Inventory*) and physical symptoms (measured by the *Physical Health*

Measure instrument). Although negative somatic symptoms, medical appointments for cancer-related morbidities, worst pain and physical symptoms are different indexes adopted by different assessment instruments, they have, in fact, much in common. They all assess status of physical health in breast cancer patients from different points of views or with different focuses or using different terms. Taken together, the RCTs that evaluated these indexes supported the efficacy of expressive writing on relieving negative physical symptoms in breast cancer patients. Consequently, we can safely conclude that expressive writing may benefit the physical health of breast cancer patients. However, we found that this benefit became insignificant >3 months after expressive writing, which means the positive effect of current expressive writing intervention may not last long. This is in agreement with one of Mogk's conclusions about the health effects of expressive writing (Mogk et al., 2006). However, we believe that the duration of effectiveness of expressive writing is an important issue that needs further investigation. Is it associated with writing dosages or characteristics of breast cancer patients or a limitation of expressive writing itself?

Furthermore, as for the psychological health of breast cancer patients, this study identified no significant effectiveness of expressive writing intervention either >3-month follow-up group or ≤3-month follow-up group except that only one study reported that expressive writing with a benefit-finding prompt for ≤3 months significantly reduced the negative mood level in breast cancer patients. This finding was rather surprising, because as a means of psychological adjustment expressive writing was expected to exert a positive effect on psychological health.

Other meta-analyses on the expressive writing intervention also have arrived at conflicting conclusions. The findings from this study are broadly consistent with the meta-analysis by Frisina et al. (2004) who determined that written emotional disclosure had a significant effect on the physical but not the psychological health of various clinical populations, and with that by Frattaroli (2006) who found expressive writing was effective in both healthy and unhealthy people. However, Harris (2006) found expressive writing was effective in healthy people but not in samples defined

by medical diagnosis or psychological criteria. Our findings are inconsistent with the meta-analysis by Mogk et al. (2006) who concluded that expressive writing had minor or no effects on the healthy or unhealthy subjects in their study. Obviously, the diversity of the populations included and the heterogeneity of the meta-analyses are likely to be a major reason for the inconsistency in the conclusion on the expressive writing intervention. This was also the reason why we decided to conduct a meta-analysis on expressive writing specifically in breast cancer populations.

The poor homogeneity of the limited number of current meta-analyses on expressive writing intervention, including ours, reflects a fact that research findings on expressive writing as an adjuvant therapy for patients are still diversified. The assessment instruments, indexes, outcome measures, samples included, indications, intervention methods, and conclusions are all varied. There is a long way to go before expressive writing can be used as a well-developed intervention in clinic.

The poor homogeneity of the RCTs investigating expressive writing intervention also led to the chief limitations of this meta-analysis. Firstly, because of inconsistent outcome measures by different instruments and incomplete data, the majority of the indexes were unable to be pooled for meta-analysis, leading to inclusion of N=1 tests in the results. For example, of the 11 studies included in this meta-analysis, only five addressed negative mood as an index of psychological health using the same instrument Profile of Mood States (POMS) with emotional prompt, benefit-finding prompt, or multiple prompts. Of the five studies, only three provided detailed data we were able to retrieve for sub-group analysis of whether different prompts in expressive writing intervention might have an effect on the intervention outcomes. Other studies measured the effects of expressive writing on psychological health using other instruments or other indexes. In addition, the limited number of studies available made it very difficult for us to investigate the potential publication bias influencing the analysis. The power of Egger's test is too low to distinguish chance from real asymmetry. Secondly, inconsistent factors or indexes, such as characteristics of the subjects and writing prompt and cycle of expressive writing intervention, might have caused biases in results. Thirdly, it was unfeasible to determine more specific

efficacy of expressive writing by further sub-group analyses according to age, education, or breast cancer staging because the data were lacking or because the sample size was limited. Moreover, we did not perform manual retrievals due to time and condition limitations. In addition, three studies failed to provide complete data for five observation indexes even after consultation with the authors (Gellaitry et al., 2010; Henry et al., 2010; Stanton, 2002), and the full text and data of three conference papers were unavailable despite trying to contact their authors. All these might have missed some important data on expressive writing as an intervention in breast cancer patients, leading to possible biases in our results (Cleophas & Zwinderman, 2017).

In summary, this meta-analysis has found that expressive writing interventions may have a positive effect on the physical health rather than the psychological health of breast cancer patients. It relieves negative physical symptoms in the short term rather than in a long term. The non-lasting momentum of expressive writing intervention is an interesting issue to explore. As a nurse-led, convenient, low-cost, and self-administered adjunctive intervention for breast cancer patients, expressive writing needs further exploration. To determine if writing dosage, personality, culture, age, education, breast cancer stage, intervention time since diagnosis, and other possible factors would be associated with the intervention effect of expressive writing, it is necessary to do further research in large populations of breast cancer patients.

Roles played by candidate

The candidate is the co-first author and the co-corresponding author of the paper. The first author of the paper is the leader of the candidate. The candidate finished a course for systematic review & meta-analysis training at the Department of Biostatistics of Southern Medical University from January 10th to 17th 2014. After the training, the candidate conducted the meta-analysis. The candidate played the role of the principle investigator of the study, including responsibility for the overall project management, identifying gaps in the literature, designing the study, defining the inclusion and exclusion criteria, conducting data analysis under the supervision of a statistician, designing the search strategy and performing the search in cooperation with other researchers, writing and revising the paper. The candidate's original contributions,

verified by the collaborating authors, can be found in Appendix 2 and 3.

Paper 5: Wu, Y., Liu, L., Zheng, W., Zheng, C., Xu, M., Chen, X., Li, W., Xie, L., Zhang, P., Zhu, X., Zhan, C., & Zhou, C. (2021). Effect of prolonged expressive writing on health outcomes in breast cancer patients receiving chemotherapy: a multicenter randomized controlled trial. *Supportive Care in Cancer*, 29(2), 1091–1101.

Study Overview

Given the non-lasting momentum of expressive writing interventions identified in the meta-analysis (Zhou et al., 2015), this multicenter RCT first tested the hypothesis that increasing the writing dosage could improve the efficacy of expressive writing intervention in breast cancer patients undergoing chemotherapy (objective 4). This study was a multicenter, prospective, parallel RCT with a 6-month follow-up and was carried out at five large tertiary hospitals distributed across four cities in Guangdong Province in China. The study was registered in the Chinese Clinical Trial Registry (ChiCTR) (registration number: ChiCTR1800016278, at <http://www.chictr.org.cn/>).

A total of 112 breast cancer patients undergoing chemotherapy were randomly allocated to the expressive writing group ($n=56$) or the prolonged expressive writing group ($n=56$). The expressive writing group received the standard expressive writing intervention based on Pennebaker's prompt to write for at least 20 min over four consecutive days (4 sessions). The prolonged expressive writing group used a modified prompt: write for at least 20 min 3 times a week over a 4-week period (12 sessions); patients could choose whether to write on consecutive days or not. All participants were required to write about their traumatic feelings about breast cancer. Outcomes were assessed and compared at baseline, as well as 1 month, 3 months, and 6 months post intervention. However, this RCT found a null main effect, which suggests that increasing the writing dosage does not appear to improve the efficacy of expressive writing in breast cancer patients undergoing chemotherapy. There was no significant difference in the patients' quality of life, or physical or psychological wellbeing between the expressive writing group and the prolonged expressive writing group at any time point (all $p > 0.05$). The quality of life of breast cancer patients

significantly decreased in the two groups over time ($F = 40.64, p < 0.001$).

Contribution and critique of the Y. Wu, Liu, et al. (2021) study

This multicenter RCT contributes to existing knowledge by first identifying that writing dosage does not moderate the effects of expressive writing in breast cancer patients undergoing chemotherapy. The hypothesis of the research—that the efficacy of expressive writing is associated with the dosage—is based on a prior research by Smyth (1998), who conducted a meta-analysis and examined three different “doses” of expressive writing. The meta-analysis found that the number of expressive writing sessions (ranging from 1 to 5) and the length of each expressive writing session (from 15 to 30 min) were unrelated to the efficacy of expressive writing. The time period of writing (from 1 to 28 days) was a potential moderator: expressive writing sessions spaced out over longer periods of time showed greater effects on some health outcomes. Furthermore, Frattaroli (2006), Denise M. Sloan and Marx (2004), and Craft et al. (2013) also suggested that the spacing and the number of writing sessions may moderate the effects of expressive writing interventions and should be examined in-depth by researchers. However, the current RCT found a null main effect, which suggests that the writing dosage does not moderate the effects of expressive writing on breast cancer patients undergoing chemotherapy. We found that the studies included in the meta-analysis by Smyth (1998) were all focused on healthy participants rather than cancer patients. This is the first study identified that increasing the dosage of expressive writing failed to show any main effects among breast cancer patients undergoing chemotherapy.

This study also found that the quality of life of breast cancer patients undergoing chemotherapy in both groups worsened over time and was lower than that in prior studies on breast cancer patients at different stages along the pathway (Craft et al., 2013; Gellaitry et al., 2010; Sohl et al., 2017; Stanton, 2002). This is mainly because adjuvant chemotherapy has been proven to be related to increased physical and mental health problems in breast cancer patients, and these problems do not significantly decrease over time (Mohamady et al., 2017; Stafford et al., 2013; Waks & Winer, 2019). Thus, breast cancer patients often experience severe somatic symptoms and a

decreased quality of life while undergoing chemotherapy (Hennigs et al., 2016; van der Kloot et al., 2016). On average, breast cancer patients in the current study in the two groups still had four remaining chemotherapy cycles upon beginning the intervention.

The limitations of the present study warrant mention. First, the physical and psychological health outcome measures relied on self-report, which could introduce some bias (Parahoo, 2014). Second, although the sample of 56 breast cancer patients in each group is larger than the sample sizes in previous expressive writing intervention studies reporting main effects (Craft et al., 2013; Gellaitry et al., 2010; Henry et al., 2010; Low et al., 2010; Low et al., 2006; Mosher et al., 2012; E. Y. Park & Yi, 2012), the present study may have been underpowered to detect main effects. However, the reporting and interpretation of effect sizes in each group would have been helpful for explaining the results of our study. Furthermore, the generalizability of the findings to men and breast cancer patients of different cultures needs further investigation. In addition, breast cancer patients and the research assistants in the study were not totally blinded due to the nature of the expressive writing intervention; each participant and researcher had to know the writing tasks and methods, which could introduce some risks of performance bias (J. W. Creswell, 2014). Finally, given that the purpose of the current study is to try to understand how the dosage of the expressive writing intervention might be a moderator in breast cancer patients, there was no inactive control group in this study. The absence of an inactive control conditions limits conclusions in the study.

Despite the limitations, the research has several strengths. First, to our knowledge, this is the first RCT focused on exploring the moderating effects of writing dosage on expressive writing in cancer patients. The research improved our understanding of what factors moderate the efficacy of expressive writing in patients with cancer. Although Q. Lu et al. (2019) conducted expressive writing-related research among breast cancer patients undergoing chemotherapy in China, their research focused on exploring the effects of three different writing conditions. Second, this is a multicenter RCT including five large tertiary hospitals from four different

cities in China (two hospitals in Guangzhou city with nearly 3000 beds and 1000 beds, one hospital in Zhanjiang city with nearly 1200 beds, one hospital in Shantou city with nearly 2000 beds, and one hospital in Shenzhen city with nearly 3000 beds), thus reducing the influence of hospital site. In addition, to maintain follow-ups, we engaged with and trained all the head nurses from the Breast Surgery Departments of the five tertiary hospitals. The five head nurses helped research assistants communicate with participants and contact them through WeChat (social media platform) during the follow-up time to maintain compliance with the research.

Based on the findings of the present study, the prolonged expressive writing intervention showed no beneficial effects over the original expressive writing intervention on health outcomes in breast cancer patients undergoing chemotherapy. However, the findings of the study add to the existing expressive writing intervention research, showing that increasing the dosage does not appear to improve the efficacy of expressive writing intervention in breast cancer patients and survivors. Additional research is warranted to determine whether individual differences, the ability to express emotion, and other possible moderators are associated with the efficacy of expressive writing interventions among breast cancer patients undergoing chemotherapy.

Roles played by candidate

The candidate is the first author of the paper and played the role of principle investigator of the study. First, the candidate designed the study and secured funding from the Health Commission of Guangdong Province, China (grant no. A2018090) (100%). Then, the candidate conducted the study, including responsible for the overall project management, applying for ethical approval, registering the trial online, training research assistants in each of the participating hospitals, calculating the sample size of the study, collection and analysis of the data, writing and revising the paper. The candidate's original contributions, verified by the collaborating authors, can be found in Appendix 2 and 3.

Paper 6: Wu, Y., Yang, D., Jian, B., Li, C., Liu, L., Li, W., Li, X., & Zhou, C. (2021). Can emotional expressivity and writing content predict beneficial effects of expressive writing among breast cancer patients receiving chemotherapy? A secondary analysis of randomized controlled trial data from China. *Psychological Medicine*, 1–15. Advance online publication.

Study Overview

This study was a secondary analysis, using data collected initially from the multicenter RCT described above (Y. Wu, Liu, et al., 2021). Using a descriptive, correlational design, the emotional expressivity of patients and the patterns of affective word use in expressive writing texts were analyzed to explore whether emotional expressivity and the patterns of language use could predict the benefits of expressive writing (objective 4).

Specifically, four hypotheses among breast cancer patients receiving chemotherapy were tested: (1) breast cancer patients with higher levels of emotional expressivity tended to report higher levels of positive or negative affect words in texts; (2) those who have higher levels of emotional expressivity would demonstrate greater improvements in health outcomes after the expressive writing intervention compared to those who tend to be less emotionally expressive; (3) those who used more positive or less negative affect words in texts would demonstrate greater improvements in health outcomes after the expressive writing intervention; (4) the patterns of affective word use would mediate emotional expressivity in exerting an impact on health outcomes after expressive writing intervention. The level of emotional expressivity of the breast cancer patients was assessed using the Chinese version of the Emotional Expressivity Scale (EES). In addition, the writing content of breast cancer patients that end up in the Chinese expressive writing texts were first tokenized using the THU Lexical Analyzer for Chinese. Then, LIWC2015 software was used to calculate the percentages of positive affect words (e.g. happy, love) and negative affect words (e.g. sad, hurt) among the total words in each writing text.

The first hypothesis of this study that breast cancer patients with higher levels of emotional expressivity tended to use higher levels of positive and negative affect words in texts was not supported ($r = 0.067$, $p = 0.549$ and $r = 0.559$, respectively).

The level of emotional expressivity has a significant effect on the quality of life, and those who used more positive or fewer negative affective words in texts had a better quality of life (all $p < 0.05$). However, no significant difference was identified in physical and psychological well-being (all $p > 0.05$). Furthermore, the patterns of affective word use during expressive writing did not mediate the effects of emotional expressivity on health outcomes (all $p > 0.05$).

In conclusion, the findings suggest that the level of emotional expressivity and the patterns of affective word use could be factors that moderate the effects of expressive writing on quality of life, which may help clinicians identify the individuals most likely to benefit from such writing exercises in China (objective 4).

Contribution and critique of the Y. Wu, Yang, et al. (2021) study

This study makes a unique contribution to knowledge by first testing the relationship between emotional expressivity and health outcomes in expressive writing in breast cancer patients undergoing chemotherapy and its role in influencing the patterns of affective word use in writing texts. Previous studies have identified the relationship between external constraints (e.g., social constraints) and the level of expressing one's emotions in relation to traumatic events (Martin et al., 2020). According to this view, one could expect internal constraints to have similar consequences as external constraints. Someone may not be naturally inclined to express their emotions through writing or talking with others. Therefore, it is essential to identify stable individual differences in the tendency to express feelings and emotions that could influence the effects of writing interventions. Emotional expressivity has been defined as the extent to which a person outwardly displays emotions regardless of valence or channel (Kring et al., 1994). People with lower levels of emotional expressivity are associated with depression, social anhedonia and other psychological impairments (Leung et al., 2010; D. M. Sloan et al., 2001). Conversely, higher levels of emotional expressivity have been linked to greater pleasure from social interactions (Kring et al., 1994). The importance of individual differences in emotional expressivity in psychology and clinical practice and its possible role in physical and psychological health have long been recognized (Jacobson et al., 2015). To address this significant gap in the

literature, this study first tested whether emotional expressivity could predict benefits from expressive writing intervention in breast cancer patients (objective 4).

In addition, this is also the first study to examine the relationship between the patterns of affective word use and health outcomes in expressive writing in Chinese breast cancer patients, whose culture particularly discourages emotional disclosure (Louie et al., 2013; Ting & George, 2012). Consistent with previous data on other populations, this study also identified correlations between the patterns of affective word use and health outcomes in Chinese breast cancer patients. The present study showed that breast cancer patients who used more negative emotional words reported lower levels of quality of life over time, which is supported by Niles et al. (2016), who identified that negative emotional word use was significantly positively correlated with increased depression. A possible explanation for this is that perhaps participants who overuse negative emotion words are generally higher in negative affect and use the expressive writing intervention as a ruminative process that could inhibit the achievement of closure through the writing intervention (Niles et al., 2016; Pennebaker & Chung, 2007).

Furthermore, the hypothesis that breast cancer patients with higher levels of emotional expressivity tended to report higher levels of positive or negative affect words in texts was not demonstrated in this study. This result was unexpected because previous studies have identified a link between emotional expressivity and psychological and physical symptoms in writing interventions in healthy participants (Niles et al., 2014; Zakowski et al., 2001). Our research and previous evidence also showed that the patterns of language use in texts could predict the intervention effects of expressive writing (Niles et al., 2016; Sullivan et al., 2018). However, our study suggests that breast cancer patients with high levels of emotional expressivity does not mean that they will express more emotions through writing compared to those with low levels of emotional expressivity. Similarly, our study showed that the patterns of affective word use did not mediate the effects of emotional expressivity on health outcomes in expressive writing interventions. This is perhaps because people differ individually in the extent to which they express their emotions (Trierweiler et

al., 2002). Emotions could be expressed in various ways, such as body cues, facial cues, verbal, or expressive writing. Perhaps not all expressive people like to express their feelings in writing. Therefore, it is suggested that matching a person's naturally selected disclosure approach with an assigned intervention is beneficial.

This study has some limitations. First, according to the findings of our previous analysis based on the data of this RCT, there was no significant difference in the quality of life, physical and psychological wellbeing between the prolonged expressive writing group (12 sessions) and the standard expressive writing group (four sessions) at any time point (Y. Wu, Liu, et al., 2021). It was shown that the writing dosage does not moderate the effects of expressive writing. Therefore, subjects in the two groups were not analyzed separately in the current study. Although LIWC2015 calculated the percentages of positive or negative affect words among the total words in each writing text, the information from the prolonged expressive writing group was much richer and possibly more nuanced than that from the standard expressive writing group, which may have produced some biases in the study. Second, the level of emotional expressivity of the breast cancer patients was assessed using the Chinese version of the Emotional Expressivity Scale (EES), which is a 17-item self-report instrument. A higher score indicates that a participant is more likely to display their emotions to others. However, this scale was used to assess the level of emotional expressivity but could not identify the breast cancer patients' naturally selected disclosure approach, which might limit the conclusions of the study. In addition, because this study investigated writing interventions and emotional expression in Chinese breast cancer patients, it is unclear how these findings would generalize to other cultures. However, breast cancer patients in our study were recruited from five large tertiary hospitals from four different cities in China, which could demonstrate the generalization of the findings in Chinese breast cancer patients.

In conclusion, this study is the first to test the relationship between emotional expressivity and health outcomes in expressive writing in breast cancer patients and its role in influencing the patterns of affective word use in writing texts. The findings of the present study support the hypothesis that the level of emotional expressivity

and the pattern of affective word use could be factors that moderate the effects of expressive writing on quality of life of breast cancer patients, which may help clinicians identify the individuals most likely to benefit from writing exercises in China. However, a relationship between emotional expressivity and linguistic changes in expressive writing was not demonstrated and additional research is necessary to identify possible factors that may moderate the patterns of affective word use in expressive writing that could be used to enhance the positive effects of writing interventions.

Roles played by candidate

The candidate is the first author of the paper and played the role of the principle investigator of the study. First, the candidate designed the study and secured funding from the Natural Science Foundation of Guangdong Province, China (grant no. 2020A1515 110894) (15,390 USD, 100%). Then, the candidate conducted the secondary analysis of the study, including proposing the four hypotheses of the study, responsibility for the overall project management, analysis of the data with the supervision of a statistician, writing and revising the paper. The candidate's original contributions, verified by the collaborating authors, can be found in Appendix 2 and 3.

3.3 Critique of the publications by thesis objectives

Objective 1: Explore psychological distress in breast cancer patients receiving chemotherapy.

Two papers in the portfolio of works have explored psychological distress in breast cancer patients undergoing chemotherapy (Liu, Wu, et al., 2021; Zhao et al., 2022). First, Liu, Wu, et al. (2021) conducted a systematic review of qualitative research to get a comprehensive understanding of the breast cancer patients' experience of chemotherapy at an international level. The qualitative research method seeks to understand the complexity of human phenomena and facilitates the analysis of human experience and social phenomena (Ailing, 2003). The systematic review of qualitative research has an essential role in exploring experience through synthesizing the existing high-quality evidence (Lockwood et al., 2015), which could provide

in-depth and explicit evidence of the psychological process and emotional feelings when receiving chemotherapy for breast cancer. **Liu, Wu, et al. (2021)** concluded that although the experience of women with breast cancer undergoing chemotherapy is individualized, the distressing experience related to chemotherapy as a stimulus was viewed as a stressor that requires coping skills or adaptation. Based on the Lazarus stress and coping theory (Lazarus, 1974), the ability of a woman to appraise how chemotherapy changed her life and how she appraises her resources to cope with chemotherapy are essential. The results highlight that pre-chemotherapy care programs, information support systems, social support groups and individual effective coping strategies are helpful in reducing treatment-related distress levels and enhance self-care effects at home.

Other methods of assessing the situation of psychological distress include use of questionnaires (French et al., 2020; Momenimovahed et al., 2021). For example, Chaix et al. (2020) conducted a cross-sectional study and found that 34% of breast cancer patients experienced psychological distress. A survey study in China using the Self-Rating Depression Scale (SDS) and Self-Rating Anxiety Scale (SAS) showed that 67.5% and 74.5% of cancer patients experienced anxiety and depression separately (G. Chen et al., 2020).

Given the advantages of questionnaires to explore patient psychological distress such as collecting data from a large number of respondents and the higher levels of generalizability of the results, **Zhao et al. (2022)** conducted a cross-sectional study to examine patient-caregiver concordances about psychological distress among Chinese patients with breast cancer undergoing chemotherapy and identify factors related to concordance among patients and family caregivers. The survey enrolled 137 dyads of breast cancer patients undergoing chemotherapy and caregivers and the results demonstrated the low concordance between breast cancer patients' reports and caregivers' perceptions of psychological distress, which could compensate for the limitations of qualitative research methodology to explore the situation of psychological distress for the first objective of the portfolio of works.

Additionally, another limitation for the work is that whilst a questionnaire survey

was used to assess psychological distress, it is a cross-sectional study collected data at one point in time rather than a longitudinal survey (Zhao et al., 2022). Numerous studies used longitudinal study to assess the situation of psychological distress (Bagade et al., 2022; Dufour et al., 2022; K. Patel et al., 2022; Skillgate et al., 2021). For example, Y. Liu et al. (2022) used the Hospital Anxiety and Depression Scale (HADS) to assess the trajectory of psychological distress of 192 patients with esophageal cancer at 1, 1.5, and 2 years post-surgery, and the results identified the high prevalence and longitudinal increase of psychological distress of esophageal cancer patients after surgery. Whilst longitudinal surveys can observe changing trends in psychological distress over time, this research method also has some disadvantages such as the long-term research, the high cost, and the unpredictability factors during the research over a long period of time (Weitekamp, 1989). Hence, given the main purpose of the first objective of the work was to provide explicit and in-depth evidence of the psychological experience of breast cancer patients undergoing chemotherapy to guide future research, a longitudinal survey was not used.

Objective 2: Adapt and examine the Emotional Inhibition Scale (EIS) to provide a measure to assess the psychological health status in Chinese patients with cancer.

Given the lack of assessment tools of emotional inhibition in Chinese breast cancer patients, a cross-sectional study was used to adapt the EIS to Chinese conditions and examine the psychometric characteristics of the scale in patients with cancer (Liu, Xu, et al., 2021). This study identified that the EIS demonstrated acceptable reliability and validity for assessing the level of emotional inhibition in Chinese-speaking patients with cancer. The study provides a useful measure to better understand emotional inhibition in Chinese patients with cancer to help healthcare providers develop specialized psychological interventions for cancer patients and can be used in further research studies as an outcome measure.

First, the translation process and cultural adaptation were based on the suggestions of classic Brislin's double translation and back translation guidelines (Cha

et al., 2007). Second, statistical analyses in the study included internal consistency, test-retest reliability, Cronbach's α coefficient, content validity, convergent validity, exploratory factor analyses (EFAs), and confirmatory factor analyses (CFAs), which are commonly factors that used to examine the reliability and validity of a scale (Andresen, 2000; *Cong et al., 2020; Zhao, Wu, et al., 2022; C. Zhou et al., 2019; C. Zhou et al., 2016*). However, this validation study was based on the classic theory test (CTT), and it will be useful to perform item response theory (IRT) in future research to provide additional important information (Ye et al., 2019).

Objective 3: Test the effects of an expressive writing intervention on health outcomes in breast cancer patients.

Zhou et al. (2015) conducted a meta-analysis of RCTs to test the effectiveness of an expressive writing intervention on health outcomes in breast cancer patients for the third objective of the work. This meta-analysis revealed that expressive writing intervention may have a significantly positive impact in breast cancer patients, but the benefit may not last long.

It has been acknowledged that RCT is a gold standard for testing the effects of an intervention to minimize bias through the use of randomization and double blinding in the research (Ahuja, 2019). Then, given there have been numerous RCTs testing effects of expressive writing intervention on health outcomes in breast cancer patients and have provided inconsistent findings and there has been no meta-analysis of these studies so far, a meta-analysis was adopted in the study to review all the data from all the high-quality studies available on this topic to make convincing up-to-date conclusions about expressive writing in breast cancer populations. Although some limitations of meta-analysis have been found such as publication bias and poor homogeneity of included studies, it is still widely acknowledged that meta-analysis is an essential way to combine the effect size of numerous similar trials to improve the power of results to obtain more certainly (Aalaei-Andabili & Alavian, 2012).

Objective 4: Identify the factors that may moderate the effects of expressive writing in breast cancer patients receiving chemotherapy.

Given the non-lasting momentum of expressive writing intervention identified in the meta-analysis (Zhou et al., 2015), two papers in the portfolio of works have conducted to identify the factors that might moderate the effects of expressive writing in breast cancer patients undergoing chemotherapy (Y. Wu, Liu, et al., 2021; Y. Wu, Yang, et al., 2021). First, Y. Wu, Liu, et al. (2021) conducted a multicenter RCT to test whether writing dosage could moderate the effects of expressive writing on breast cancer patients undergoing chemotherapy. This RCT explores the effects of a 3-fold “dosage” of expressive writing intervention (12 sessions) and compares the effects of the classical dose (4 sessions). Then, given the null-finding of the RCT--the writing dosage dose not moderate the effects of expressive writing on breast cancer patients undergoing chemotherapy, Y. Wu, Yang, et al. (2021) conducted a secondary analysis of the RCT continue to propose that whether emotional expressivity and writing content could predict beneficial effects of expressive writing in breast cancer patients receiving chemotherapy.

Currently, RCTs have been widely used to test the moderating effects of an intervention (Lisowski et al., 2022; Nolte et al., 2021; Pasalich et al., 2019; Shapiro et al., 2021). For example, Parker et al. (2020) used a cluster RCT to examine the moderate effects of cancer worry and empathy on quality of life of a survivorship-focused intervention. In addition, Saunders et al. (2019) conducted an RCT and identified that childcare center characteristics may moderate the effectiveness of a physical activity intervention. Based on the existing literature, few other research methods have been used to test the moderate effects of an intervention. This is mainly because RCTs are still widely taken as the gold standard method to reduce and control bias in relation to the outcomes of intervention (Cartwright, 2010).

A limitation of the study is that only writing dosage, emotional expressivity of breast cancer patients, and writing content have been tested in the portfolio of works according to the objectives. Additional research is necessary to identify any other possible moderators associated with the efficacy of expressive writing interventions among breast cancer patients undergoing chemotherapy. However, the results of the work first confirmed the moderate effects of emotional expressivity and its role in

influencing the patterns of affective word use in writing texts, which may help clinicians identify the individuals most likely to benefit from such nurse-led writing exercises in breast cancer patients in China.

3.4 Summary

In this chapter, six published papers in the portfolio of works are presented, individually critiqued, and then examined by thesis objectives.

Collectively, the portfolio of works makes a unique contribution to knowledge by exploring psychological distress in breast cancer patients receiving chemotherapy, and especially in a Chinese context and to evaluate the effects of expressive writing intervention on health outcomes in this population. This was specifically achieved by **Zhao et al. (2022)**, **Y. Wu, Liu, et al. (2021)**, and **Y. Wu, Yang, et al. (2021)**. **Zhao et al. (2022)** first examined patient-caregiver concordances about psychological distress among Chinese patients with breast cancer undergoing chemotherapy and identified factors related to concordance among patients and family caregivers. This paper found that there was relatively low psychological distress concordance between breast cancer patients' reports and caregivers' perceptions. Family caregivers tended to underestimate breast cancer patients' psychological distress. **Y. Wu, Liu, et al. (2021)** contributes to existing knowledge regarding the use of the expressive writing intervention by first identifying that writing dosage does not moderate the effects of expressive writing in breast cancer patients undergoing chemotherapy. Furthermore, **Y. Wu, Yang, et al. (2021)** is also the first to test the relationship between emotional expressivity and health outcomes in expressive writing in breast cancer patients and its role in influencing the patterns of affective word use in writing texts. These results could help clinicians identify the individuals most likely to benefit from expressive writing and also add to our understanding of this writing exercise in breast cancer patients. All these findings make a unique contribution to knowledge.

The next chapter will examine ethical considerations, methodology and limitations, rationale for data collection, and the author's reflections on conducting the studies in the work.

Chapter Four: Ethical considerations, methodological issues, and limitations

This chapter examines ethical considerations, methodology and limitations, rationale for data collection, and the author's reflections on conducting the studies in the work.

4.1 Ethical considerations

Given the importance of protecting human subjects in clinical research, a range of principles and documents have been developed to advocate the duty of researchers to safeguard the rights and well-being of participants, such as the Declaration of Helsinki (World Medical Association, 2013), the Nuremberg Code (Shuster, 1998), and the Patient-Reported Outcomes (PRO) Ethics Guidelines (Cruz Rivera et al., 2022). Although the reporting of ethical considerations in clinical trials has been improved, numerous studies suggested that the transparency of ethical scrutiny and adherence to ethical principles are still lacking (Bonsu et al., 2022; **Y. Wu, Howarth, et al., 2021**). This body of work was carried out in accordance with the principles of the Declaration of Helsinki and several ethical considerations were addressed, including research ethics committees, informed consent, privacy and confidentiality, risks, burdens, and benefits, research registration and publication of results (World Medical Association, 2013).

Ethical approval of all research studies in the portfolio of works had been granted by the Medical Ethics Committee of Nanfang Hospital, and the ethical approval of the multicenter RCT has also been approved by the Ethics Committee of the other four hospitals before the study begins, including Cancer Center of Guangzhou Medical University (reference number: 2018-003), Shenzhen People's Hospital (reference number: 2018-029), Affiliated Hospital of Guangdong Medical University (reference number: PJ2018-029), and The First Affiliated Hospital of Shantou University Medical College (reference number: 2018-039) (Appendix 4) (**Liu, Xu, et al., 2021; Y. Wu, Yang, et al., 2021; Y. Wu, Liu, et al., 2021; Zhao et al., 2022**). Ethical approval was not needed for the review studies (**Liu, Wu, et al.,**

2021; Zhou et al., 2015). In addition, the researcher had provided monitoring information to the Ethics Committee, and a final report had submitted to the committee of each hospital. Participants were also made aware of how to complain if they have any problems or queries about the service or the research.

In addition, written informed consent was obtained from each participant or the legally authorized representative prior to each research study in the portfolio of works (World Medical Association, 2013). To make sure potential research subjects understand the study prior to consenting to participate, written information about the study and checks on understanding were provided during the consent process (Cruz Rivera et al., 2022). For example, in the multicenter RCT, the research was described to the patient by a trained research assistant using a standardized script. Adequate time and opportunity were provided for patients to ask questions about the research and to consider whether to participate. During the consent process, the trained research assistant and the patient could discuss the contents of the informed consent and exchange information to ensure that the patient received and understand the required information. Contact information was provided to potential participants in case additional questions arose. If patients decided to participate, written informed consent and a baseline questionnaire were obtained. The informed consent process continued after the written informed consent was obtained when patients raised additional questions or during the research process (**Y. Wu, Liu, et al., 2021**). Furthermore, participants' rights to be self-governing and autonomous were respected (Shuster, 1998). In these studies, participants were informed that they were free to withdraw from the research at any time without any prejudice. In the consent process, the relationship between the physician and the potential participant was considered. The Declaration of Helsinki state (World Medical Association, 2013):

“When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship” (p.6).

To protect autonomy and minimize burden in the consent process, research assistants were included to recruit participants in the clinical trial of the portfolio of works, which could help to address power imbalances between the healthcare professionals and the research participants (Cruz Rivera et al., 2022). For example, six research assistants were included in the **Y. Wu, Liu, et al. (2021)** and **Y. Wu, Yang, et al. (2021)** studies to seek potential participants' freely-given informed consent in each setting. These research assistants were trained by the principal investigator of the research and an experienced clinical psychologist to ensure that the research assistants understood the research and did not coerce the participants into joining the study during the consent process.

A further ethical consideration is that the privacy of participants and the confidentiality of their personal data and information need to be protected (World Medical Association, 2013). The expressive writing contents and other data of participants were kept confidential according to the Data Protection Act 1998 (DPA) (Redsell & Cheater, 2001). Patients' names were substituted with a sequential number, and a note of the number was made in case patients wanted to withdraw their data from the study. This note also helped researchers to match questionnaires obtained at each follow-up time point with questionnaires obtained at baseline. To protect confidentiality, all writing texts, questionnaires, written informed consent, and other documents collected from patients were stored in a locked filing cabinet. Data collected was coded and was stored in a computer with password protected. The principal researcher had access to this cabinet and the computer.

In addition, the Declaration of Helsinki highlighted that interventions in most medical research involve risks and burdens, and approaches to minimize the risks has to be considered (World Medical Association, 2013). In the portfolio of works, although the benefits and safety of expressive writing, which is a brief emotional expression intervention, have been identified in previous studies (Davis et al., 2020; **Zhou et al., 2015**), the risks of expressive writing intervention in breast cancer patients have been considered. Early explanation of the benefits of expressive writing suggesting that the writing exercise serves a cathartic function, allowing participants

to release and express their traumatic feelings, which in turn improve their psychological or physical wellbeing (Pennebaker & Chung, 2007). Hence, during the expressive writing intervention process, breast cancer patients might experience sadness by expressing their stressful events according to the cancer diagnosis and the long treatment journey. To address this ethical issue, during the writing intervention process of the studies of **Y. Wu, Liu, et al. (2021)** and **Y. Wu, Yang, et al. (2021)**, an experienced psychologist counselor could be consulted upon request from the breast cancer patients. This information was provided in a participant information sheet during the consent process. After the final writing session, each participant was given a form to record any other major diseases or traumatic events over the research period, whether they had participated in other studies, and whether they sought counseling or psychotherapy during this time. Patients with the above conditions were excluded from the analysis. In these studies, no participants sought counseling or psychotherapy during the writing intervention process.

Furthermore, in line with the disciplines of the Declaration of Helsinki (World Medical Association, 2013), the RCT in the portfolio of works has been registered in the Chinese Clinical Trial Registry (ChiCTR) (registration number: ChiCTR1800016278, at <http://www.chictr.org.cn/>). All these studies have been published to disseminate the results and to make publicly available the results of these works on human subjects. Additionally, all negative and positive results of these studies have been published. Funding resources, conflicts of interest, and institutional affiliations have been declared in each publication.

4.2 Methodological limitations

The rationale for the research paradigm and methodology for each paper has been presented in chapter two. In this chapter, limitations of each methodology adopted in the portfolio of works will be discussed.

In the portfolio of works, two systematic reviews were conducted to synthesize existing literature, one for qualitative research (**Liu, Wu, et al., 2021**) and the other for quantitative studies (**Zhou et al., 2015**). **Liu, Wu, et al. (2021)** conducted a

systematic review of qualitative research to understand the experience of women with breast cancer undergoing chemotherapy. Qualitative systematic reviews have an important role in understanding participants experience, investigating the culture of communities, and evaluating activities of health services to inform the delivery of healthcare (Munn et al., 2014). In this paper, qualitative research findings were synthesized based on the process of a meta-aggregative approach (Lockwood et al., 2015). Meta-aggregation is a process that identifies meanings from qualitative studies that may attributed to different methodologies and further abstracts those meanings into categories that are then synthesized (Florczak, 2019). In this review, we chose meta-aggregation as a suitable synthesis methodology to study the experience of chemotherapy among women with breast cancer because it has the advantages listed below. First, because its philosophical foundation is pragmatic and influenced by transcendental phenomenology, a review focusing on qualitative research is philosophically congruent (Lockwood et al., 2015). The purpose of transcendental phenomenology is to generate knowledge in an unbiased way, not influenced by researchers themselves or external factors, but enlightened by the particulars of intentional consciousness of the phenomena of interest (Lockwood & Pearson, 2013). Second, one of the special characteristics of a meta-aggregation is that it tries to provide practical implications for the synthesized findings (Hannes & Lockwood, 2011). Third, meta-aggregation can be used to integrate the results of qualitative studies conducted using different designs (i.e., ethnography, grounded theory, and phenomenology) (Lockwood et al., 2015).

Despite these advantages of meta-aggregation, some limitations of this methodology need to be considered. First, meta-aggregation is an interpretative process in which different teams studying the literature may produce different interpretations (Hannes & Lockwood, 2011). Hence, although the Contextual Model of Lazarus' Stress and Coping Theory has been used to link the experience of chemotherapy and coping strategies, extract data, and synthesize findings from the included qualitative research in the study of **Liu, Wu, et al. (2021)**, it may be a challenge to generate a coherent set of synthesized findings from different researchers

according to the limitations of the meta-aggregation in the literature (Hannes & Lockwood, 2011). In addition, there are other challenges. For example, it is difficult to ensure that the stakeholders engaged in the community of inquiry, such as the research teams and reviewers, are the end users of the synthesized evidence (Lockwood & Pearson, 2013). Various stakeholders will most likely have different definitions of what useful findings are. In this way, either research teams or reviewers who want to initiate ‘lines of action’ that inform decision-making at the policy or clinical level might consider ‘usable findings’ for their own particular context. Hence, whether these ‘lines of action’ are in line with such synthesized findings remains unclear (Hannes & Lockwood, 2011). However, research team members in the meta-aggregation study of **Liu, Wu, et al. (2021)** included clinical nurses in a tertiary hospital, who could consider the integration of evidence from the perspective of clinical care needs for breast cancer patients.

Apart from the limitations of meta-aggregation itself, the process of evidence synthesis by **Liu, Wu, et al. (2021)** needs to be critiqued. First, the search was limited to studies published in the English language. This could produce some publication bias in the study because numerous high-quality non-English studies might have been missed (Cleophas & Zwinderman, 2017). Second, studies focused on women’s experiences of chemotherapy to treat breast cancer will be included in the study; however, some qualitative studies included breast cancer patients in different treatment stages. If the experience of chemotherapy could not be extracted separately, studies were excluded, which might introduce some biases in the synthesized findings. For example, nine studies were excluded in the review because chemotherapy was not the focus. In addition, considering that the majority of breast cancer patients are women and the different experiences of cancer between male and female (Ussher & Sandoval, 2008), this meta-aggregation focused on women’s experiences, which means that the male breast cancer patients’ experience not represented in the study. Furthermore, although grey literature such as OpenSIGLE, Open Grey, and the Grey Literature Report by the New York Academy of Medicine Library were searched to minimize the influence of publication bias, no unpublished studies were included in

the qualitative synthesis.

Zhou et al. (2015) conducted a systematic review and meta-analysis to evaluate the effects of expressive writing intervention on physical and psychological health outcomes in breast cancer patients. For this meta-analysis, apart from the poor homogeneity of the RCTs investigating expressive writing intervention on breast cancer patients and the language limitations that we only included studies written in English, a key area needs to reflect on is the statistical models. Fixed-effect and random-effect models are two popular statistical models for meta-analysis (Borenstein et al., 2010). The selection of the appropriate model is crucial. In this meta-analysis, we selected the statistical model based on the heterogeneity among studies: if statistical heterogeneity (P value ≤ 0.10 and $I^2 \geq 50\%$) was identified, random effects meta-analysis was conducted before the causes of heterogeneity were further investigated by subgroup analysis; if not, a fixed-effect model was used (Higgins & Thompson, 2002). This approach to determine the statistical models in meta-analysis has been widely adopted and reported in other studies (Dragioti et al., 2022; McIntyre et al., 2018).

However, the decision of whether to use fixed-effect and random-effects models for meta-analysis has been a matter of debate, and the selection of statistical models based on statistical heterogeneity has been questioned and critiqued in recent years (Higgins et al., 2022; Tufanaru et al., 2015). The Cochrane Handbook for Systematic Reviews of Interventions (version 6.3) (Higgins et al., 2022) suggested that “*The choice between a fixed-effect and a random-effects meta-analysis should never be made on the basis of a statistical test for heterogeneity*” (see Chapter 10, Section 10.10.4.1). However, the handbook does not provide a universal recommendation on how to determine the statistical model but provides some considerations to take into account in making the choice. For example, numerous researchers have argued that the choice should be made based on an expectation of whether studies included in the meta-analysis share a common intervention effect, preferring the random-effects model if this is unlikely and a fixed-effect model if the effects are truly identical

(Borenstein et al., 2010). Others have argued that in the presence of a statistical heterogeneity, a fixed-effect model could be explained, and that it leads to fewer assumptions compared to a random-effects model of meta-analysis. Then, they called it a ‘fixed-effects’ meta-analysis (Peto et al., 1995; Rice et al., 2018). In addition, it has also been suggested that a pragmatic approach is to conduct both fixed-effect and random-effects models of meta-analysis. If there is no evidence showed the funnel plot asymmetry, the results of a random-effects model could be presented; otherwise, both statistical models are problematic. It may be suitable to perform a sensitivity analysis to exclude small studies or conduct meta-regression directly, or present both results or neither (Higgins et al., 2022). In the meta-analysis of **Zhou et al. (2015)**, although the statistical model was selected based on the statistical significance of heterogeneity among studies, the sensitivity analysis showed that either a fixed-effect or a random-effects analysis showed the same statistical results on the primary and secondary outcomes in the study.

Furthermore, in the portfolio of works, a multi-center, prospective, parallel RCT with a 6-month follow-up carried out at five large tertiary hospitals in China was conducted to test the effects of an expressive writing intervention on breast cancer patients receiving chemotherapy (**Y. Wu, Liu, et al., 2021; Y. Wu, Yang, et al., 2021**). Whilst RCTs are widely considered as the gold standard method to control bias for evaluating the efficacy and safety of a new intervention (Hariton & Locascio, 2018), it has been critiqued that the strict inclusion and exclusion criteria of RCTs may exclude the majority of patients in every-day practice in normal care. Therefore, real-world studies have attracted more attention in recent years (Blonde et al., 2018). Real-world studies might utilize prospective or retrospective data over a long period of time from electronic health databases, from a large heterogeneous population, to provide evidence on the long-term efficacy, safety, and economic outcomes (Blonde et al., 2018). However, real-world studies have numerous limitations. One of the most important limitations in real-world trials is the bias, including selection bias, recall bias, information bias, and detection bias (Roche et al., 2014). A number of biases and confounding factors in real-world trials can affect results, making them either

qualitatively different or overestimated from those obtained in RCTs (Benson & Hartz, 2000; Golder et al., 2011). Hence, despite the advantages of real-world studies, RCTs are still the gold standard for testing the effects of a new intervention (Hariton & Locascio, 2018). Real-world trials could be used to complement data from RCTs to provide more comprehensive information of the advantages and disadvantages of an intervention in practice (Blonde et al., 2018).

Another key area needs to be reflected on about the RCT in the work is that whilst effects of expressive writing intervention could be tested by numerous statistical analyses to determine changes in physical and psychological health outcomes, this is only one way of providing evidence of the effectiveness of an intervention. Evidence-based healthcare could provide more comprehensive information, including the systematic search, synthesis, and implementation of evidence in clinic (Brettell & Grant, 2004). The outcomes of the evidence-based practice might include the experience and views of patients, clinical nurses, psychotherapists, and other experts; the audit outcomes, which could reflect the compliance of the intervention in clinic; and the improvement in clinical practice procedure (Moore et al., 2015; Proctor et al., 2011). Evidence-based practice has been identified as an effective way to improve patient outcomes (Y. Wu et al., 2018; Y. Wu et al., 2020). Hence, expressive writing could also be implemented in clinic as an evidence implementation project to provide more information of the intervention that can complement or even expand the data obtained from the RCT in the work (Y. Wu, Liu, et al., 2021; Y. Wu, Yang, et al., 2021).

Finally, two studies in this portfolio of works adopted a cross-sectional study to examine patient-caregiver concordances about psychological distress in Chinese breast cancer patients undergoing chemotherapy (Zhao et al., 2022) and tested the validity and reliability of the Chinese version of the Emotional Inhibition Scale (EIS) (Liu, Xu, et al., 2021). Some limitations of the cross-sectional study need to be addressed. First, the primary challenge of the cross-sectional study is that it is not possible to generate a temporal relationship between exposure and outcome because the exposure and outcome are assessed at the same time (Solem, 2015). However, the

primary purpose of the two studies is not to establish a true cause and effect relationship, but to explore the situation of psychological distress and tested the validity and reliability of the Chinese version of the Emotional Inhibition Scale through questionnaire survey. Second, the cross-sectional design assessed patients' situation in only a single visit while they were undergoing cancer treatment, but patients' perceptions and experiences will differ at different times across the cancer continuum (Ashing-Giwa et al., 2004; Yahaya et al., 2015). In addition, bias in the cross-sectional study is another key issue that needs to be considered, such as selection bias, recall bias, and response bias (J. W. Creswell, 2014). In the work, both questionnaire survey studies had a high response rate, 91.3% in one study (**Zhao et al., 2022**) as well as 93.45% and 95.28% in another study (**Liu, Xu, et al., 2021**), which could reduce response bias of the two studies in some extent. However, patients in the two questionnaire studies were limited to a tertiary hospital in Guangzhou, and this may generate selection bias. Future studies should recruit more representative samples to replicate and verify the results in other regions and cultures.

4.3 Rationale for data collection

The quantitative studies in the portfolio of works used self-report questionnaires to collect data and measure variables (**Liu, Xu, et al., 2021; Y. Wu, Liu, et al., 2021; Y. Wu, Yang, et al., 2021; Zhao et al., 2022**). In recent years, placing patients at the center of clinical research and outcome evaluation has been increasingly emphasized and advocated (Weldring & Smith, 2013). Patient-reported outcomes (PROs) have been advocated by many bodies. For example, the pharmaceutical industry emphasized the essential of considering PROs to support biomarkers of health improvement (Willke et al., 2004). In addition, the Department of Health and Social Care (2011) in the UK also released guidelines for the mandatory adoption of PROs across the National Health Service. Driven by the UK government, PROs are utilized as a method to collect information on the effects of healthcare intervention from the patient perspective (Black, 2013). Compared with traditional outcomes that focused on the physiological benefits of healthcare intervention, PROs could provide

a more comprehensive assessment and information of the benefits of an intervention, which might include patients' quality of life, satisfaction, as well as emotional and functional status (Black, 2013; Rathert et al., 2011). It has been suggested that PROs could be used as either primary outcomes, such as quality of life, or to complement primary outcomes in clinical pharmacology trials (Higgins et al., 2022). When benefits of the intervention will be mainly reflected through subjective outcomes such as patients' quality of life, PROs can be used as primary outcome measures (Weldring & Smith, 2013). Hence, in the portfolio of works, given the main purpose of the RCT was to explore the benefits of an expressive writing intervention on physical and psychological health outcomes of patients, self-report questionnaires were used to collect data of the trial (**Y. Wu, Liu, et al., 2021; Y. Wu, Yang, et al., 2021**).

Despite these advantages of PROs, some limitations and issues need to be considered. First, the choice of instruments is essential to make sure of the reliability and validity of the outcomes, especially when there are a number of instruments that can be used to measure a particular PRO, such as quality of life (Higgins et al., 2022). To address this issue, questionnaires in the quantitative studies presented in the portfolio were all selected carefully. For example, the quality of life of the breast cancer patients in the RCT (**Y. Wu, Liu, et al., 2021; Y. Wu, Yang, et al., 2021**) was assessed using the Functional Assessment of Cancer Therapy-Breast Cancer Version (FACT-B), which is a 36-item self-report instrument (Brady et al., 1997). The FACT-B has been widely used in expressive writing interventions among breast cancer patients (Craft et al., 2013; Gellaitry et al., 2010; Stanton, 2002), and the validity of the FACT-B in breast cancer patients has been reported to be 92.5% (Craft et al., 2013) and 92% (Stanton, 2002).

Another issue relates to the self-report questionnaires is the bias of the outcomes, especially when blinding cannot be achieved in a clinical trial (J. W. Creswell, 2014). In the RCT presented in this portfolio (**Y. Wu, Liu, et al., 2021; Y. Wu, Yang, et al., 2021**), breast cancer patients and the research assistants were not totally blinded due to the nature of the expressive writing intervention; each participant and researcher had to know the writing tasks and methods, which could introduce some risks of

performance bias. However, to reduce the risk of “patient-reported outcomes,” which might result in performance bias (Gurusamy et al., 2009), the hypothesis of this research was masked, and participants were informed that the research purpose was to “explore in-depth how women adjust to breast cancer” and that they would be randomized to one of two groups that need to write about their experiences with breast cancer. Therefore, the writing assignments of other participants were not revealed. Moreover, to minimize performance bias, research assistants were also not aware of the study hypothesis (Gurusamy et al., 2009).

4.4 Reflections

It is essential for a researcher to be aware of how their values, culture, biases, and personal background such as working and learning experiences, status, and gender shape their internal and external responses in a research (J. W. Creswell, 2014). Reflexivity helps researchers create an honest and open environment to clarify the bias that they might bring to their research (Etherington, 2004). A reflective log was used to journal my professional and personal development and the influence this might have on the studies presented in this portfolio of works.

I have been working as an academic editor for a top peer reviewed Chinese nursing journal for sixteen years after I graduated from university and was recognised and awarded as an excellent academic editor in the Guangdong Province in China in 2019. By reviewing different research design manuscripts during these years of editing work, I have built my research skills and knowledge, critical thinking ability, and academic ethics. My experience as an academic editor made me pay great attention to control the quality of these published studies in this portfolio of works. For example, the RCT in the work (Y. Wu, Liu, et al., 2021; Y. Wu, Yang, et al., 2021) was designed and carried out based on the CONSORT 2010 Statement (Schulz et al., 2010).

In addition, working as an academic editor has also influenced the research paradigm that underpins the approaches taken to the research process. As an editor, I review papers utilising different research designs, and consider the reasonableness of

the research design in solving a particular research question in the nursing field. This experience may have influenced my choice of pragmatic research paradigm in the work, which adopted multiple forms of qualitative and quantitative research data in studies. The pragmatic research paradigm is based on the premise that researchers should utilize the best suitable methodological approach to address real-world problems, allowing the adoption of a wide range of methods to answer research questions (Allemang et al., 2022). Furthermore, my experience as an editor has also improved my understanding of the importance of nursing scientific research in resolving clinical problems and the passion on conducting research. Meanwhile, my understanding of the standardization of reporting a study also helped to publish my research in journals, which has led to being able to submit PhD by published works. To date, I have published 84 academic papers in international or Chinese peer reviewed journals (among them, 35 papers were first author or corresponding author), which focused on breast cancer, evidence implementation, and nursing ethics.

I also work as a research nurse in a tertiary teaching hospital with 5201-beds in Guangdong Province. My first contact with breast cancer patients was due to my participation in the research team of my supervisor when I got my first Master's degree in China. During the process, I felt the heavy physical and mental health problems of breast cancer patients, as well as the burden of long-term treatment. When conducting a literature search, I learned about expressive writing intervention and its possible role in improving health outcomes in breast cancer patients. In the research process of testing the effects of an expressive writing intervention on breast cancer patients, I was shocked by their stories and sad feelings from their writing texts, which could produce a wealth of data on participants' feelings and thoughts. Until today, I still can remember that a young women wrote:

“Since the mastectomy, my husband gave me a lot of cold shoulder, but with two small children, I don't want to die, I don't know what I should do.....”

I read their written texts again and again, and I have a deep sympathy for breast cancer patients. Reflecting on this research experience, it has deeply influenced me. For example, as a researcher, I always told myself that you can do more to alleviate

the suffering of patients, which makes my faith in research stronger. Furthermore, this experience made me feel that it is important to use outcome measures that capture patients' views and feelings such as PROs rather than morbidity and mortality statistics. Hence, I used self-report questionnaires to collect data and measure variables in the quantitative studies that presented in the portfolio of works (**Liu, Xu, et al., 2021; Y. Wu, Liu, et al., 2021; Y. Wu, Yang, et al., 2021; Zhao et al., 2022**).

In addition, under the support of the hospital, I got my second Master's degree at the University of Salford in 2017. Looking back, this learning experience has strengthened my belief in lifelong learning and improved my critical thinking ability. For example, during the MSc Nursing learning journey at the university, I was required to write a reflective essay to critically explore my nursing career. This was the first time I learned about reflective writing and how to look back at something which has happened to reflect what I have learned from it. Telling stories, writing autobiographically, and reflecting on my professional career are closely linked with good nursing practice and also improved my empathy with patients (Corbally & O'Neill, 2014; Howe, 2012; Moon, 2006). Furthermore, I had contact with many teachers, who inspired me to view the gains and losses of life more objectively, so that I could face difficulties and failures more rationally and dialectically when I carried out these studies in the portfolio of works. For example, I still can remember that an esteemed professor once said to a PhD student at the SPARC conference in 2017.

“Life happens! There are ups and downs. Recognise the downs and look forward to the ups! The important thing is that you keep the general ‘mojo’ trend forwards and upwards, recognise your success and learn from your failures. You need to be resilient in life to be successful and that includes when doing your PhD because life doesn’t stop!”

These learning experiences make me more tenacious and critical when conducting research. This could be reflected that when I got a null finding of the RCT (**Y. Wu, Liu, et al., 2021**). I can think about things in a different way and continued to explore other possible factors that might moderate the effects of expressive writing

intervention in breast cancer patients (**Y. Wu, Yang, et al., 2021**). In addition, this experience also influenced me when I guide postgraduate students to conduct research in the university where I work. I always tell them that as a researcher, failures and setbacks are an essential part of life and research, and all of these can make you more resilient.

Studying abroad has given me a deeper understanding of different cultures, which might affect my interpretation and understanding of cultures in the expressive writing intervention research. During the learning experience, I communicated with classmates and other people in different countries such as America, Britain, India, and Syria. Such personal experience was much more profound than that I can learn from books and studies about the cultures of different countries. For example, in the class, Euro-American students appearing to value verbal communication over non-verbal; Asian students, however, are shown to value non-verbal communication over verbal, which in line with studies found major differences in the area of communication among different ethnic groups of breast cancer patients (Kagawa-Singer & Wellisch, 2003). This difference in expression between different cultures could be reflected that Euro-American students are more active in raising their hands to ask or answer questions in the class, while Chinese students are used to keeping silent.

Furthermore, I also work as a champion of evidence-based practice, which has influenced my selection of research methods and my future plans for the results of the portfolio of works. Looking back, the learning experience of evidence-based nursing in the university has enhanced my belief of evidence implementation in nursing practice. After I graduated, I continued to learn evidence-based nursing in the JBI in Australia and became a JBI trainer of evidence-based practice in 2021. With a passion for evidence-based healthcare, I have been elected as the Chair of the Asian Region in the JBI in 2022. These experiences of practicing and learning evidence-based nursing have significantly influenced my research and the dissemination of that research. For instance, in the process of learning meta-analysis, I learned the importance of publishing a negative result in the detecting of publishing bias. Hence, when I got a null finding of the RCT (**Y. Wu, Liu, et al., 2021**), I tried to submit it to the journal

and persuade reviewers of the importance of the negative results of the study. Second, as a champion of evidence-based practice, I realized the importance of evidence dissemination, which might have influenced me to publish my research and share my experiences to others. This can be evidenced by these papers that I have published to being able to submit PhD by published works. Third, advocating evidence-based practice has also influenced my selection of research methods when I did this work. For example, when I wanted to explore the current situation of psychological distress and the effects of expressive writing intervention, I chose the methods of systematic review and meta-analysis to synthesize the current evidence on the topic first to find research gaps in the area. Furthermore, I have significant experience of implementing projects or interventions informed by the evidence base to improve the quality of nursing care and patient outcomes in clinic (*L. Zhang et al., 2021; L. Zhang et al., 2022; Y. Wu et al., 2020; Zhao et al., 2020*). In addition, I always think about how to translate the results of these works into clinic. Currently, for example, expressive writing has been implemented in clinical practice and used as a normal care for breast cancer patients in a tertiary hospital in Guangdong Province in China, more information of the writing exercises in the every-day clinical practice will be collected in the near future to provide more data of the intervention.

4.5 Summary

In this chapter, ethical considerations, methodology and limitations, rationale for data collection, and self-reflections in relation to the studies in this portfolio of works have been examined.

The next chapter will summarize the thesis' key outcomes, whilst also providing recommendations for practice, future research, and policy.

Chapter Five: Key thesis outcomes and recommendations for practice, future research, and policy

This chapter summarizes the key outcomes from this thesis, whilst also providing recommendations for practice, future research, and policy.

5.1 Outcomes

The key objectives were to:

1. Explore psychological distress in breast cancer patients receiving chemotherapy.
2. Adapt and examine the Emotional Inhibition Scale (EIS) to provide a measure to assess the psychological health status in Chinese patients with cancer.
3. Test the effects of an expressive writing intervention on health outcomes in breast cancer patients.
4. Identify the factors that may moderate the effects of expressive writing in breast cancer patients receiving chemotherapy.

The outcomes in terms of meeting the above objectives have been achieved through the portfolio of published works and have been presented in the thesis.

First, to better understand the situation of psychological distress of breast cancer patients undergoing chemotherapy, **Liu, Wu, et al. (2021)** conducted a systematic review of qualitative research to gain a comprehensive understanding of the breast cancer patients' experience of chemotherapy (objective 1). Then, **Zhao et al. (2022)** demonstrated the low concordance between breast cancer patients' reports and caregivers' perceptions of psychological distress, which may help healthcare providers better interpret caregiver assessments (objective 1).

In addition, given the lack of assessment tools of emotional inhibition in Chinese breast cancer patients, **Liu, Xu, et al. (2021)** adapted and validated the Emotional Inhibition Scale (EIS) to provide a useful measure of the level of emotional inhibition

for cancer patients in China (objective 2). This study provides initial evidence for the reliability, construct validity, content validity, and convergent validity of the Chinese version of the EIS in a sample of Chinese patients with cancer.

Furthermore, the effectiveness of an expressive writing intervention on health outcomes in breast cancer patients receiving chemotherapy has been examined in **Zhou et al. (2015)**, who conducted a meta-analysis to reveal that expressive writing intervention may have a significantly positive impact in breast cancer patients, but the benefit may not last long (objective 3). To further explore whether some factors may predict beneficial effects of expressive writing, **Y. Wu, Liu, et al. (2021)** conducted a multicenter RCT and demonstrated that the writing dosage does not moderate the effects of expressive writing on breast cancer patients undergoing chemotherapy (objective 4). Then, **Y. Wu, Yang, et al. (2021)** conducted a secondary analysis of the RCT. The study confirmed the relationship between emotional expressivity and health outcomes in expressive writing in breast cancer patients and its role in influencing the patterns of affective word use in writing texts. The findings of this study may help clinicians identify the individuals most likely to benefit from such nurse-led writing exercises (objective 4).

Through the development and publication of the six focused papers presented in this thesis, a unique contribution to expressive writing intervention on breast cancer patients has been established. This portfolio of works includes the meta-analysis that identified the non-lasting momentum of expressive writing intervention on breast cancer patients. To address this interesting issue of expressive writing, the works continue to explore some potential factors that might moderate the effects of this writing exercise. This portfolio of works includes the first published study confirming that writing dosage does not moderate the effects of expressive writing on breast cancer patients undergoing chemotherapy. Furthermore, this is also the first study to provide evidence that the level of emotional expressivity and the pattern of affective word use could be factors that moderate the effects of expressive writing on quality of life of breast cancer patients. These results could help clinicians identify the individuals most likely to benefit from expressive writing and also add to our

understanding of this writing exercise in breast cancer patients.

5.2 Recommendations for practice, future research, and policy

As a result of the findings from the published papers that form the portfolio of works, the following recommendations for future research are proposed:

- The effects of expressive writing intervention on other stages of breast cancer patients need to be tested in future research.
- Additional research is warranted to determine whether individual differences, and other possible moderators are associated with the efficacy of expressive writing intervention among breast cancer patients undergoing chemotherapy.
- Given the relationship between emotional expressivity and linguistic changes in expressive writing was not demonstrated in the work, future research is necessary to identify possible factors that may moderate the patterns of affective word use in expressive writing intervention that could be used to enhance the positive effects of writing interventions.
- As this portfolio of works largely investigated writing intervention and emotional expression in a Chinese breast cancer context, it may be advantageous to undertake studies to determine how these findings would generalise to other cultures.
- Expressive writing could also be implemented in clinic as an evidence implementation project to provide more information of the intervention that can complement or even expand the data obtained from the RCT in the work. Implementation of expressive writing into normal clinical practice could gain a better understanding of how to deliver and integrate expressive writing within existing health services.
- Future studies should recruit more representative samples to replicate and verify the results in other populations and various regions of China and establish the Chinese norm of the Chinese version of the EIS.
- As this portfolio of works depended exclusively on the self-report data collection method, which may have some bias or inaccurate reporting

(Parahoo, 2014), future research may include other objective approaches to get a more comprehensive understanding of the results, such as behavioral and physiological measures and experimental paradigms.

As a result of the findings from the published papers that form the portfolio of works, the following recommendations for practice are proposed:

- Breast cancer patients with higher levels of emotional expressivity might benefit more from the expressive writing intervention than those who tended to be less emotionally expressive.
- Since the results of this portfolio of works showed that there was no statistical difference in the effect of expressive writing intervention among breast cancer patients with different writing dosage and whether they write continuously, clinical nurses can guide breast cancer patients to choose whether to write on consecutive days or not according to their own needs and conditions.
- The results from our study showed that the patterns of affective word use did not mediate the effects of emotional expressivity on health outcomes in expressive writing interventions. This is perhaps because people differ individually in the extent to which they express their emotions (Trierweiler et al., 2002). Emotions could be expressed in various ways, such as body cues, facial cues, verbal, or expressive writing. Therefore, in clinical practice, it is suggested that matching a person's naturally selected emotional disclosure approach with an assigned intervention may be beneficial.
- Having an awareness of the incongruence between patient and caregiver perceptions of psychological distress may help healthcare providers better interpret caregiver assessments. Healthcare providers should reinforce patient-caregiver dyadic psychosocial education to improve concordance. More psychological care and substantial emotional support should be provided in China for breast cancer patients undergoing chemotherapy by family caregivers and healthcare providers.
- The Chinese version of the Emotional Inhibition Scale could be a useful

measure for assessing the level of emotional inhibition for cancer patients in clinic in China.

As a result of the findings from the published papers that form the portfolio of works, the following recommendations for policy are proposed:

- The systematic review in the portfolio of works concluded that when breast cancer patients experienced various stressful side effects, supportive care to address needs and effective coping strategies are essential to help them adapt to this difficult journey. Generally, we recommend that policy makers increase access to psychological therapies for breast cancer patients, including the need to develop care programs, information support systems, social support groups, and individual effective coping strategies to reduce chemotherapy-related distress levels and enhance self-care at different stages of cancer.
- Specifically, it is suggested that policy makers introduce expressive writing, a convenient adjunctive intervention, to clinical nurses to help improve psychological and health outcomes of breast cancer patients.
- Given the lack of tools to assess emotional inhibition in patient populations, we recommend that policy makers introduce the Chinese version of the Emotional Inhibition Scale for assessing the level of emotional inhibition for cancer patients in clinic in China to remind healthcare professionals to pay more attention to patients' psychological health.

5.3 Conclusions

This thesis has explored psychological distress in breast cancer patients receiving chemotherapy, and especially in a Chinese context, and has evaluated the effects of expressive writing intervention on health outcomes in this population.

The portfolio of works provides a unique contribution to the existing literature by expanding our knowledge on the expressive writing intervention in patients with

cancer using a range of rigorous methods. Given the non-lasting momentum of expressive writing intervention identified in the meta-analysis, we continued to explore if any possible factors would be associated with the intervention effect of expressive writing. To our knowledge, this is the first RCT focused on exploring the moderating effects of writing dosage, emotional expressivity, and writing content on expressive writing interventions in cancer patients. The findings of this work first identified that writing dosage does not moderate the effects of expressive writing on breast cancer patients undergoing chemotherapy. Furthermore, this work also first proposed that the level of emotional expressivity and the pattern of affective word use could be factors that moderate the effects of expressive writing on quality of life of breast cancer patients. These results are a relevant addition to the existing expressive writing intervention research, which could help clinicians identify the individuals most likely to benefit from expressive writing intervention.

Transferring evidence from research into real-world settings is an essential way to bridge the knowledge-to-practice gap (Birken et al., 2017). The author advocates evidence implementation and always thinks about how to translate the results of these works into clinic. Currently, expressive writing, as a convenient adjunctive intervention, is being used within normal clinical practice for breast cancer patients in a tertiary hospital in Guangdong Province in China. More information of the writing exercises when delivered in the existing health services will be collected in the near future to provide more data of the intervention in practice.

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Appendices

Appendix 1: Papers included in the Portfolio of Published Works

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REVIEW



Experience of women with breast cancer undergoing chemotherapy: a systematic review of qualitative research

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Abstract

Purpose Chemotherapy exerts adverse effects on physical, psychological and social functioning in women with breast cancer, which may trigger adaptive activities. For a better understanding of the experience of symptoms associated with chemotherapy and the development of targeted interventions, this study aimed to (a) explore the patient experience of chemotherapy, (b) identify patients' strategies to cope with the side effects and distress and (c) explore the link between their experience and coping strategies.

Methods Qualitative studies were included if they explored the experience or coping strategies of women with breast cancer receiving chemotherapy. Instruments from the Joanna Briggs Institute were used to critically appraise the methodological quality, extract data and aggregate findings from the included studies.

Results Twelve studies presenting findings from 184 women with breast cancer who had received chemotherapy were included in this review. Three synthesized findings were identified from 8 categories based on 91 original findings: (1) Women living with chemotherapy experienced various stressful side effects, and their lives were changed. (2) Supportive care to address needs is essential to help women get through this difficult time. (3) They engaged in numerous types of coping strategies to deal with side effects and adapt to this difficult journey. Moreover, the link between experience of chemotherapy and coping strategies is based on the Lazarus' stress and coping theory.

Conclusions Although the experience of women with breast cancer undergoing chemotherapy is individualized, we concluded that the distressing experience related to chemotherapy as a stimulus was viewed as a stressor that demands coping or adaptation. Based on the Lazarus stress and coping theory, the ability of a woman to appraise how chemotherapy changed her life and how she appraises her resources to cope with chemotherapy are essential. The results highlight that pre-chemotherapy care programmes, information support systems, social support groups and individual effective coping strategies are helpful in reducing treatment-related distress levels and enhance self-care effects at home.

Keywords Breast neoplasms · Drug therapy · Support · Coping strategies · Review

Abbreviations

JBIR-QARI	Joanna Briggs Institute Qualitative Assessment and Review Instrument
JBIR-SUMARI	Joanna Briggs Institute System for the Unified Management Assessment and Review of Information

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Background

The effects of breast cancer and chemotherapy

Breast cancer has the highest incidence of cancer in women worldwide and is the leading cause of cancer-related death. In 2018, 2,090,000 new cases and 626,000 deaths due to breast cancer occurred in women worldwide, accounting for 11.6% and 0.6% of all cancers, respectively [1]. Organized breast cancer screening and advances in adjuvant therapy have helped decrease breast cancer mortality rates and improve survival rates [2, 3]. Currently, the 5-year survival rate is greater than 90%, and the 10-year survival rate is greater than 80%. Clinically, the first five to ten years after breast cancer treatment represent a vulnerable period, during

which some women face a multitude of physical and psychosocial problems [4].

Over half of patients with breast cancer are treated with chemotherapy that comprises chemical agents for both localized and metastatic cancer. For patients who present with localized cancer, the therapeutic goals are tumour eradication and recurrence prevention, while the therapeutic goals for patients who present with metastatic cancer are the prolongation of survival, maintenance of quality of life and palliation of symptoms [5, 6]. Chemotherapy helps reduce the 10-year mortality rate and achieve the greatest survival potential in the first 5 years for women with breast cancer [6, 7]. However, chemotherapy has some side effects, which can be immediate, short term or long term [8, 9]. Several quantitative studies have indicated that women with breast cancer undergoing chemotherapy experienced a cluster of symptoms associated with toxicity and side effects and experienced substantial changes in their psychological status, quality of life and social function [8–10]. According to most studies, women with breast cancer who received chemotherapy reported a poorer quality of life, physical functioning and psychological functioning (or psychological well-being) than women who did not receive chemotherapy [11, 12].

Qualitative systematic reviews on the experience of chemotherapy

Recently, researchers in related fields have shown considerable interest in exploring the adverse effects of chemotherapy, quality of life during chemotherapy and related interventions to cope with chemotherapy. However, the use of quantitative instruments to capture the unique features of individual experiences of patients with breast cancer related to chemotherapy is challenging, and this approach may omit important issues that would be analysed in a qualitative research study [13]. The perspective of patients on chemotherapy was much deeper than what an outsider would describe; thus, the best sources of information about their experience are the patients themselves. Qualitative studies are valuable because they enable patients to describe their experiences during chemotherapy treatment, facilitating a deeper understanding of the adaptive experiences that emerge. Some qualitative studies have described the lived experiences, social support and coping strategies of women receiving chemotherapy. These studies focussed on specific issues, such as different cycles of chemotherapy and diverse samples (e.g. patients with different stages of cancer, chemotherapy regimens, ages and cultures) [14–17].

Meta-aggregation is a process that identifies meanings from qualitative studies that may attributed to different methodologies and further abstracts those meanings into categories that are then synthesized [18]. In this review, we chose meta-aggregation as a suitable synthesis methodology

to study the experience of chemotherapy among women with breast cancer because it has the advantages listed below [19–21]. First, because its philosophical foundation is pragmatic and influenced by transcendental phenomenology, a review focussing on qualitative research is philosophically congruent. Second, one of the special characteristics of a meta-aggregation is that it tries to provide practical implications for the synthesized findings. Third, meta-aggregation can be used to integrate the results of qualitative studies conducted using different designs (i.e. ethnography, grounded theory and phenomenology).

Rationale and objective of the review

An understanding of the current experience and coping strategies of women with breast cancer undergoing chemotherapy may help health-care professionals design self-care programmes or interventions to better prepare and manage the adverse effects of chemotherapy. Previous related qualitative reviews focussed on the symptoms experienced during chemotherapy [22], driving and disabling factors for chemotherapy [23, 24], experience and survivorship of patients with breast cancer [25], or the experience of patients with other types of cancer receiving chemotherapy [26]. Although research on the chemotherapy experience during different periods of cancer and treatment with different drugs and across different regions has increased, no qualitative reviews have focussed on the experience and coping strategies of women with breast cancer. By synthesizing the existing evidence, we hope to provide explicit and in-depth evidence of the experience of this population group while undergoing chemotherapy to guide future research. Therefore, we conducted a review focusing on the specific period of breast cancer treatment to understand women's inner thoughts. Specifically, the objectives of this review were to analyse the following questions:

- (i) What is the experience of women with breast cancer receiving chemotherapy?
- (ii) How do they cope with distress during this process?
- (iii) What is the link between their experience and coping strategies?

Methods

Inclusion criteria and exclusion criteria

Studies were included in this review if they were (1) original research, (2) qualitative studies, (3) studies focussed on the perspectives of women with breast cancer reporting their experiences, (4) studies focussed on the experience of chemotherapy and (5) studies written in English. Studies were excluded if they (1) analysed other types of cancer, (2) were

not focussed on chemotherapy or (3) were mixed-method studies or quantitative studies.

Search strategy

The search strategy (Table 1) aimed to identify published and unpublished qualitative research studies assisted by an evidence-based nursing expert. The search was limited to studies published in the English language. First, an initial unlimited search was performed in PubMed and CINAHL, and an analysis of the title, abstracts and index terms of the resulting articles was then performed. Second, a subsequent search was performed using identified index terms and keywords in the following databases: PubMed (1966–2018), CINAHL (1937–2018), the Cochrane Library (1985–2018), PsycINFO (1887–2018), EBSCO host (1944–2018), Scopus (1823–2018), Embase (1974–2018) and the Web of Science (1900–2018). Third, reference lists of identified articles were searched to find additional studies, including bibliographic searching, reference searching and citation backtracking. Finally, a search for unpublished studies, for example, in OpenSIGLE, Open Grey and the Grey Literature Report by the New York Academy of Medicine Library, was performed

to minimize the influence of publication bias on the findings. The search results and process are illustrated in Fig. 1.

Assessment of methodological quality

Using the Johanna Briggs Institute Qualitative Assessment and Review Instrument (JBI-QARI), two independent raters (LPL and WLC) read and assessed the full texts of the included studies. A study that answered a minimum of six of ten prompt questions positively was included (or vice versa). Any disagreements that arose between the reviewers were decided through discussion or with the third reviewer. All studies included in the review met the inclusion and study quality criteria.

Data extraction

Qualitative data were extracted from studies included in the review by two reviewers (YNW and MYH). The extracted information included the bibliographic details, sample age and size, disease stages, numbered findings, data collection methodology, as well as data analysis methodology. Extracted findings together with “Quotations”, which form

Table 1 Search strategy for pubmed

Search	Query
#1	Search breast neoplasms [MeSH Terms]
#2	Search (breast neoplasm* OR breast malignan* OR breast neoplasm* OR breast cancer* OR breast carcinoma* OR breast adenocarcinoma OR breast tumor* OR breast sarcoma* OR breast lymphedema OR breast dcis OR breast ductal OR breast infiltrating OR breast intraductal OR breast lobular OR breast medullary OR mammary neoplasm* OR mammary malignan* OR mammary neoplasm* OR mammary cancer* OR mammary carcinoma* OR mammary adenocarcinoma OR mammary tumor* OR mammary sarcoma* OR mammary lymphedema OR mammary dcis OR mammary ductal OR mammary infiltrating OR mammary intraductal OR mammary lobular OR mammary medullary)
#3	Search (#1) OR #2
#4	Search drug therapy [MeSH Terms]
#5	Search (therap*, drug OR drug therap* OR chemotherap* OR pharmacotherap* OR chemotherapy* protocol* OR antineoplast* agents OR chemotherapy* agents OR antineoplast* protocol*)
#6	Search (#4) OR #5
#7	Search Psychology, Social [MeSH Terms]
#8	Search (social psychology OR psychologies, social OR social psychologies OR need* OR experienc* OR information OR preference OR surviv* OR life OR depression OR anxiety OR distress OR cognitive OR emotion OR feeling OR Loneliness OR fear OR hope)
#9	Search (#7) OR #8
#10	Search qualitative research [MeSH Terms]
#11	Search (qualitative study OR ethnograph* research OR ethnonursing research OR constant comparative method OR observational method OR qualitative validity OR purposive sample OR field study OR phenomenology OR grounded theory OR ethno* OR focus group* OR narrative analys* OR theoretical sampl* OR interview OR content analy* OR field note* OR fieldnote* OR field record* OR field stud* OR semi-structured OR semistructured OR unstructured categor* OR action research OR audiorecord* OR taperecord* OR videorecord* OR qualitative inquiry OR discourse OR methodology* OR life history research)
#12	Search (#10) OR #11
#13	Search (((#3) AND #6) AND #9) AND #12
#14	Search (((#3) AND #6) AND #9) AND #12 Filters: Humans
#15	Search (((#3) AND #6) AND #9) AND #12 Filters: Humans; English

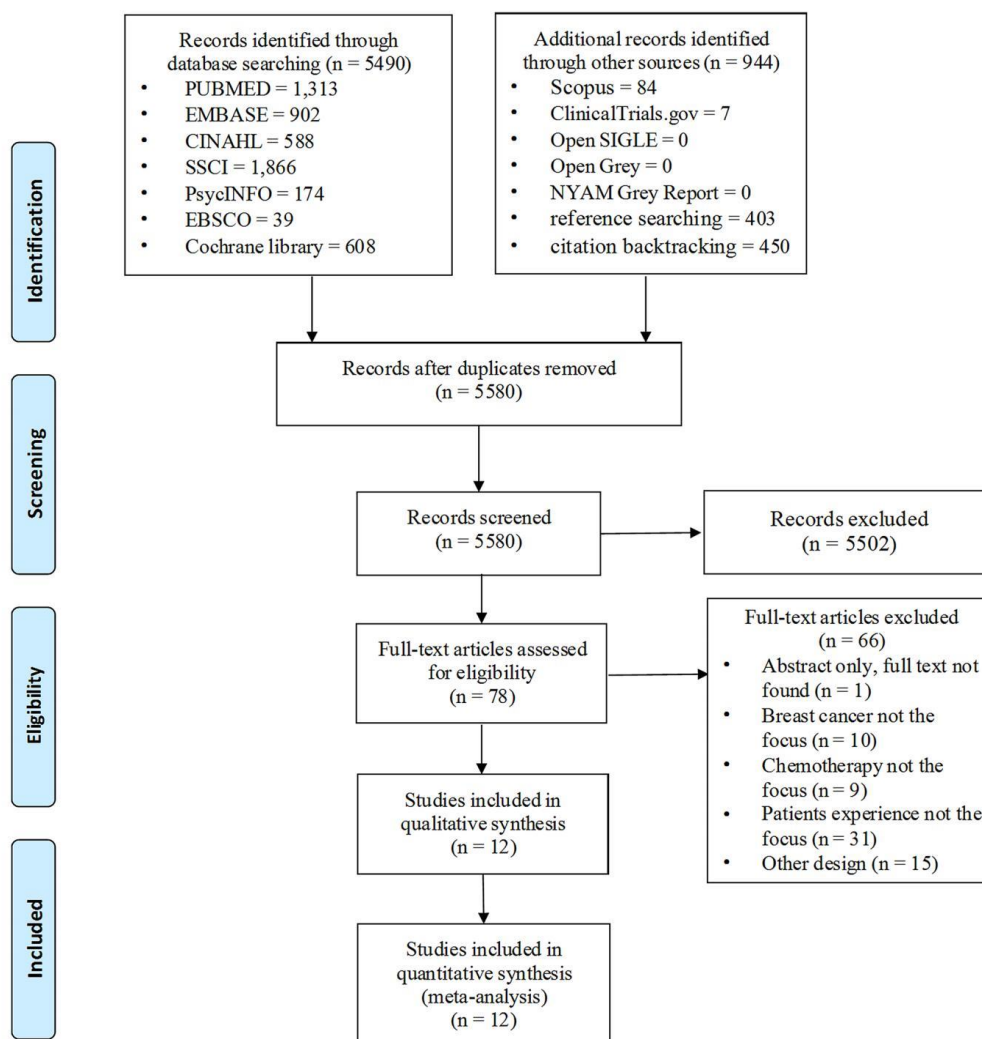


Fig. 1 Flowchart of the article selection process. (Color figure online)

the first of the three-phased meta-aggregation process, are provided in Online Appendix 1.

Data synthesis

Qualitative research findings were summarized using the standardized data extraction tool from the Joanna Briggs Institute System for the Unified Management, Assessment

and Review of Information (JBI-SUMARI). Meta-aggregation involves the synthesis or aggregation of findings to generate a set of statements that represent the aggregation through the assembly of the findings rated according to their quality and categorizing these findings based on similarity in meaning. These categories were then subjected to a meta-aggregation procedure to produce a single comprehensive set of synthesized findings that were used as a basis for evidence-based

practice. These categories were then mapped according to the principles and framework of Lazarus' Psychological Stress and Coping Theory (Fig. 1).

Two independent reviewers assigned a credibility level to each category based on whether the category was accompanied by a direct quote of a participant and how directly the quote(s) were related to the research question [27]. The credibility level was rated as unequivocal, credible, or not supported (see Table 4 footnotes).

Results

Study characteristics

Twelve studies were included in the review [14–17, 28–35]. These included studies were conducted internationally in the USA ($n=2$), the UK ($n=2$), Turkey ($n=2$), Nigeria ($n=1$), China ($n=2$), Pakistan ($n=1$), Sweden ($n=1$), and Syria ($n=1$). The sample size ranged from 7 to 30. The total sample of the studies included 184 women aged 22–70 years. The study settings were diverse because of the different countries and varying socioeconomic backgrounds of both the participants and locations. All studies used interviews ($n=11$) and focus group discussions ($n=1$) for data collection (Table 2).

The quality ratings of 2 studies were 6/10, of 3 studies were 7/10 and of 7 studies were 8/10 (Table 3). No study was excluded from this review.

Results of the synthesis

We included 12 studies in this review, representing 184 participants. Two independent raters identified 91 themes. These themes were clustered into 8 categories and 3 synthesized findings. A summary of each of these themes and associated studies is provided in Table 2. The three synthesized findings are listed below. (1) Women living with chemotherapy experienced various stressful side effects, and their lives were changed. (2) Supportive care to address needs is essential to help women get through this difficult time. (3) They engaged in numerous types of coping strategies to deal with side effects and adapted to this difficult journey.

In addition, the categories rated as having “unequivocal” credibility included physical problems, psychological discomfort, useful information and decision-making and desired social support. Other categories were rated as having “credible” credibility (Table 4).

Synthesized finding 1: women living with chemotherapy experienced various stressful side effects, and their lives were changed

A series of painful side effects accompany chemotherapy. Forty-five extracted findings identified that women

undergoing chemotherapy experienced various distressful side effects and their lives were impaired. This synthesized finding included four categories: physical changes, emotional distress, cognitive changes and life changes (see Table 4 and Online Appendix 1).

Physical changes

Although reactions to symptoms and symptom experiences are very individualized, some common symptoms were reported as distressful by most women in this study [15–17, 30–34]. The long duration of the chemotherapy process may cause multiple symptoms, including chemotherapy-related fatigue, cognitive changes, hair loss, nausea, vomiting, insomnia, bone pain and peripheral neuropathy. Three physical symptoms were predominant in this study: fatigue, cognitive changes and hair loss. Fatigue included a constant sensation of tiredness, a lack of energy, lethargy and weakness that was not alleviated by resting or sleeping. Hair loss was not permanent but constituted a serious detriment to the women's image of themselves. Interestingly, physical symptoms were dynamic; namely, the cycle of illness, recovery and illness as chemotherapy progressed was regarded as having a roller coaster effect.

Emotional distress

Fourteen findings extracted from eight studies indicated that women with breast cancer experienced a myriad of psychological burdens during the chemotherapy period, such as worry, fear, anxiety, anger, depression, uncertainty and isolation [14, 16, 17, 28, 30, 32, 34, 35]. Four psychological symptoms were predominant: fear, anxiety, depression and sadness. Women feared that the disease would be incurable and that they would be permanently separated from their family. They felt anxious about the changes in their bodies, the loss of independence and the possibility of recurrence in the future. Furthermore, they felt depressed and sad when they blamed themselves for not fulfilling their maternal responsibilities because of the adverse effects of chemotherapy. As they experienced strong psychological strain, they felt powerless and desperate, and some women had suicidal ideation or attempted suicide.

Cognitive changes

Although the symptoms were very subtle, the cognitive changes experienced affected their abilities to think clearly. Described as “chemo brain”, cognitive changes manifested as (1) difficulty finding words, (2) problems with memory, (3) difficulty in concentrating and paying attention, (4) difficulty organizing and prioritizing problems, (5) fatigue and

Table 2 Characteristics of the qualitative studies selected for analysis ($N = 12$)

First author, Country, Publication date	Sample Age; size	Disease stages	Purpose	Numbered findings	Data collection methodology	Data analysis methodology
Anarado [28], Nigeria, October 16, 2015	36–66; $N = 20$	Stage II–IV	To explore experiences and nursing support needs of women undergoing outpatient breast cancer chemotherapy in Southeastern Nigeria	Inadequate preparation for chemotherapy Chemotherapy is scary, distressing and financially demanding Hope, faith and courage sustained treatment Self-care actions to “weather the storm” Nursing support desired.	Focus Group discussion	Grounded theory approach
Banning [14], Pakistan, January 5, 2009	22–60; $N = 30$	Unclear	To examine the experience and coping strategies used by patients with breast cancer	Family assurance Coping through prayer Feelings of isolation Financial burden of treatment	Semi-structured interviews	Thematic analysis
Beaver [15], the United Kingdom, June 1, 2015	30–67; $N = 20$	Unclear	To explore the experiences of women who received neo-adjuvant chemotherapy for breast cancer	Coping with the rapid transition from “well” to “ill” Information needs Decision-making Needing support and empathy Impact on family Creating a new “normal”	In-depth interviews	Thematic analysis
Boehmke [29], the United States June 20, 2005	32–66; $N = 20$	Stage II–III	To identify symptoms, symptom experiences and resulting symptom distress encountered by women with breast cancer receiving current chemotherapy protocols	Symptoms with chemotherapy cycles Severe nausea and hair loss Severe bone pain and peripheral neuropathy Affect on their quality of life and functioning Distressed by the cognitive changes experienced	Taped interviews	Phenomenology
Browall [30], Sweden September 12, 2005	55 to 70; $N = 8$	Unclear	To describe the experience of postmenopausal women with breast cancer who undergo adjuvant chemotherapy treatment	Preconceived notions of the treatment Constant worry Physical reminders Psychological reminders Sensory reminders Support from significant others Support from health-care professionals Sharing with others Different values Demands from oneself and others	Interview	Content analysis

Table 2 (continued)

First author, Country, Publication date	Sample Age; size	Disease stages	Purpose	Numbered findings	Data collection methodology	Data analysis methodology
Cebeci [31], Turkey, September 6, 2012	30–47; N = 8	Stage II–III	To explore the experience of women living with breast cancer	The need for spouse and family support The need to worship The need to receive and share information Loss of one's hair Changes in ones normal life Change in self-perception Understanding of the value of health	Semi-structured and in-depth individual interviews	Content analysis
Cowley [32], the United Kingdom, May 13, 1999	33–59; N = 13	Unclear	To explore women's experiences of adjuvant chemotherapy, and of the risks they faced	Greater appreciation for life Information deficiency about chemotherapy Decision-making on chemotherapy Uncertainty and fear to chemotherapy Management strategies Maintain usual roles Concealed their feelings and fears Humour Discount the present The roller coaster effect	Non-standard interview	Grounded theory approach
Gumusen [33], Turkey, May 30, 2013	mean age: 48.84; N = 11	Unclear	To identify the experiences of women with breast cancer and the facilitating coping factors while they receive chemotherapy	Strains factors Coping strategy Social support Positive with treatment Relationships with nurses	Individual semi-structured interviews	Phenomenology
Kanaskie [34], the United States of America, July 20, 2014	42–59; N = 7	Unclear	To explore the meaning and symptoms of cognitive change, how symptoms impact roles in personal and professional lives, and how women cope with these changes	Noticing the difference Experiencing cognitive changes Interacting socially Coping Looking forward Lived space Lived body Lived time Lived human relationships	Two in-depth semi-structured interviews	Interpretive phenomenology

Table 2 (continued)

First author, Country, Publication date	Sample Age; size	Disease stages	Purpose	Numbered findings	Data collection methodology	Data analysis methodology
Lai [35], Hongkong (China), March 1, 2017	38–53; N = 10	Stage I–III	To understand the experiences of patients with breast cancer and their involvement during outpatient-based chemotherapy in Hong Kong	A sense of uncertainty Information desired Preparation for chemotherapy Lack of confidence Normal life is impaired Behaviour engagement Social engagement Cognitive and emotional strategy Psychological status varied Plan to future Seek solution	Individual interviews	Content analysis
Nizamli [17], Syria, August 31, 2011	30–45; N = 17	Stage II–IV	To explore the experiences of Syrian women with breast cancer regarding their chemotherapy	Negative emotion Body image Depressive symptoms Acute consequences of chemotherapy General consequences of chemotherapy Social isolation Lack of marriage opportunities Failure in mother role Failure in sexual relationship	Semi-structured interviews	Content analysis
Chen [16], Taiwan (China) October 13, 2015	39–62; N = 20	Stage I–IV	To explore patients' psychological process when receiving initial chemotherapy for breast cancer	Fear of permanent separation from family Fear of chemotherapy Fear of the disease getting worse Physical suffering Mental torment Fight against the disease Adjustment methods Assistance from support systems Relaxation of body and mind Accepting change in their lives	Semi-structured interviews	Grounded theory approach

Table 3 Assessment of methodological quality using the JBI-QARI appraisal instrument

Studies	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Quality rating
Anarado 2017	N	Y	Y	Y	Y	N	Y	N	Y	Y	7/10
Banning 2009	N	Y	Y	N	Y	Y	N	N	Y	Y	6/10
Beaver 2016	Y	Y	Y	Y	Y	N	Y	Y	N	Y	8/10
Boehmke 2005	Y	Y	Y	Y	Y	N	N	Y	N	Y	7/10
Browall 2006	Y	Y	Y	Y	Y	N	Y	Y	Y	N	8/10
Cebeci 2012	Y	Y	Y	Y	Y	N	N	Y	Y	Y	8/10
Cowley 2000	N	Y	Y	Y	Y	N	N	Y	N	Y	6/10
Gunusen 2013	Y	Y	Y	Y	Y	N	Y	N	Y	Y	8/10
Kanaskie 2015	Y	Y	Y	Y	Y	Y	N	Y	N	Y	8/10
Lai 2017	Y	Y	Y	Y	Y	N	N	Y	Y	Y	8/10
Nizamli 2011	Y	Y	Y	Y	Y	N	N	Y	Y	Y	8/10
Chen 2016	Y	Y	Y	N	Y	Y	Y	N	Y	N	7/10

Y yes; N no; U unclear;

Q1. There is congruity between the stated philosophical perspective and the research methodology

Q2. There is congruity between the research methodology and the research question or objectives

Q3. There is congruity between the research methodology and the methods used to collect data

Q4. There is congruity between the research methodology and the representation and analysis of data

Q5. There is congruity between the research methodology and the interpretation of results

Q6. There is a statement locating the researcher culturally or theoretically

Q7. The influence of the researcher on the research, and vice versa, is addressed

Q8. Participants and their voices are adequately represented

Q9. The research is ethical according to current criteria or, for recent studies, there is evidence of ethical approval by an appropriate body

Q10. Conclusions drawn in the research report do appear to flow from the analysis, or interpretation, of data

(6) sensory changes, which created many daily struggles [29–31, 34].

Life changes

The symptoms of chemotherapy influence daily life and even the survival of these women [14, 15, 17, 29, 31, 32, 34, 35]. First, the side effects reduced the women's abilities to perform daily activities and their activity levels. Second, as a wife, mother and daughter, women are the keepers of the family and maintain family functioning. Therefore, they experienced role failure when faced with the physical and emotional burdens of treatment. Third, after physical changes in body appearance and self-image, they became extremely sensitive and felt isolated, similar to stigmatization.

Synthesized finding 2: supportive care to address needs is essential to help women get through this difficult time

As described above, almost all types of patients undergoing chemotherapy face some similar major problems. Studies have focussed on needs for information and social

support to assist women in overcoming a list of problems that tend to change and reoccur over time. Twenty-one findings were extracted from six studies that identified that supportive care needs are essential for women to go through this difficult time. This synthesized finding included two categories: the need for information and the need for social support (Table 4 and Online Appendix 1).

The need for information

The proactive dissemination of necessary information is important to equip these women with the abilities to better manage their lives, to provide stability and to relieve pressure [15, 28, 31, 32, 35]. The information they indeed needed was related to self-care practices, life-prolonging procedures and disease prognosis and treatment decisions. Most women concluded that the discomfort from chemotherapy was outweighed by the resulting improvement in survival chances, but few of them were allowed to make choices. Moreover, doctors were the major source of information. Other supplementary resources were received from other cancer survivors, books, the internet and friends with similar experiences.

Table 4 Methodology–meta-aggregation

Synthesized statements	Categories	Study findings	Credibility level ^a
Women living with chemotherapy experienced various stressful side effects, and their lives were changed	Physical changes	16. Symptoms with chemotherapy cycles [29] 17. Severe nausea and hair loss [29] 18. Severe bone pain and peripheral neuropathy [29] 23. Physical reminders [30] 34. Loss of one's hair [31] 47. The roller coaster effect [32] 48. Strains factors [32] 59. Lived body [34] 74. Body image [17] 76. Acute consequences of chemotherapy [17] 77. General consequences of chemotherapy [17]	Unequivocal
	Emotional distress	85. Physical suffering [18] Chemotherapy is scary, distressing, and financially demanding [28] Feelings of isolation [14] 22. Constant worry [30] 24. Psychological reminders [30] 41. Uncertainty and fear to chemotherapy [32] 58. Lived space [34] 62. A sense of uncertainty [35] 70. Psychological status varied [35] 73. Negative emotion [17] 75. Depressive symptoms [17] 82. Fear of permanent separation from family [16] 83. Fear of chemotherapy [16] 84. Fear of the disease getting worse [16] 86. Mental torment [16]	Unequivocal
	Cognitive changes	20. Distressed by the cognitive changes experienced [29] 21. Preconceived notions of the treatment [30] 25. Sensory reminders [30] 28. Sharing with others [30] 36. Change in self-perception [31] 53. Noticing the difference [34] 54. Experiencing cognitive changes [34] 61. Lived human relationships [34]	Credible
	Life changes	9. Financial burden of treatment [14] 14. Impact on family [15] 19. Affect on their quality of life and functioning [29] 35. Changes in ones normal life [31] 46. Discount the present [32] 60. Lived time [34] 66. Normal life is impaired [35] 78. Social isolation [17] 79. Lack of marriage opportunities [17] 80. Failure in mother role [17] 81. Failure in sexual relationship [17]	Credible

Table 4 (continued)

Synthesized statements	Categories	Study findings	Credibility level ^a
Supportive care to address needs is essential to help women get through this difficult time	The need for information	1. Inadequate preparation for chemotherapy [28] 11. Information needs [15] 12. Decision-making [15] 33. The need to receive and share information [31] 39. Information deficiency about chemotherapy [32] 40. Decision-making on chemotherapy [32] 63. Information desired [35] 64. Preparation for chemotherapy [35] 65. Lack of confidence [35]	Unequivocal
	The need for social support	5. Nursing support desired [28] 6. Family assurance [14] 13. Needing support and empathy [15] 26. Support from significant others [30] 27. Support from health-care professionals [30] 30. Demands from oneself and others [30] 31. The need for spouse and family support [31] 32. The need to worship [31] 50. Social support [33] 52. Relationships with nurses [33] 55. Interacting socially [34] 89. Assistance from support systems [16]	Unequivocal
They engaged in numerous types of coping strategies to deal with side effects and adapt to this difficult journey	Problem-focussed coping strategies	7. Coping through prayer [14] 42. Management strategies [32] 45. Humour [32] 49. Coping strategy [33] 56. Coping [34] 69. Cognitive and emotional strategy [35] 88. Adjustment methods [16]	Credible
	Behaviour coping strategies	4. Self-care actions to "weather the storm" [28] 10. Coping with the rapid transition from "well" to "ill" [15] 15. Creating a new "normal" [15] 43. Maintain usual roles [32] 67. Behaviour engagement [35] 68. Social engagement [35] 71. Plan to future [35] 72. Seek solution [35] 87. Fight against the disease [16]	Credible
	Emotion- focussed coping strategies	Hope, faith and courage sustained treatment [28] 29. Different values [30] 37. Understanding of the value of health [31] 38. Greater appreciation for life [31] 44. Concealed their feelings and fears [32] 51. Positive with treatment [33] 57. Looking forward [34] 90. Relaxation of body and mind [16] 91. Accepting change in their lives [16]	Credible

^aAs defined by Munn et al [26]: Unequivocal—relates to evidence beyond reasonable doubt which may include findings that are matter of fact, directly reported/observed and not open to challenge; Credible—relates to those findings that are, albeit interpretations, plausible in light of the data and theoretical framework. They can be logically inferred from the data. Because the findings are interpretive they can be challenged; Unsupported—is when the findings are not supported by the data

The need for social support

Twelve of the extracted findings from five studies indicated that social support, particularly from family members and health-care providers, helped women get through this situation with comfort, safety and happiness [14–16, 28, 30, 31, 33, 34]. First, family, such as parents, children, husbands and siblings, played the most important role in their support systems. Families fulfilled all their needs and boosted their morale to overcome challenges. Furthermore, other support was received from health-care professionals, including pre-emptive information and health education on chemotherapy, encouragement to face chemotherapy bravely and with a positive attitude and the provision of regular physical care and emotional support. Finally, any source that improved mental energy might be considered a support system, such as encouragement from friends, shared experiences with other patients and spiritual comfort from religion.

Synthesized finding 3: they engaged in numerous types of coping strategies to deal with side effects and adapt to this difficult journey

Coping strategies often vary from person to person and evolve during chemotherapy. The coping strategies used depend on the patient's personal coping style or nature, personal symptom experience, the need to control symptoms, the way they deal with challenges, how their life was affected by chemotherapy, their knowledge and beliefs, the way they manage their symptoms and their personal goals and different cultural backgrounds. Twenty-eight findings extracted from six studies indicated that women with breast cancer engaged in effective coping strategies to deal with chemotherapy. According to Lazarus' Stress Adaptation Theory, coping is the cognitive and behavioural effort to understand, minimize or endure the inner and outer demands that develop as a result of stressful situations. This synthesized finding included three categories: problem-focussed coping strategies, behavioural coping strategies and emotion-focussed coping strategies. These strategies aimed to reduce distress and increase optimal coping strategies in women with breast cancer undergoing chemotherapy (Table 4 and Online Appendix 1).

Problem-focussed coping strategies

Twelve of the extracted findings from five studies indicated that many women with breast cancer engaged in problem-focussed coping strategies to control and address problems related to the side effects of chemotherapy [32–35]. The process may include identifying distressful events, making assessments, finding solutions and solving problems related to a particular scenario. During the chemotherapy process,

the women identified strategies to prevent, manage, or eliminate side effects. For example, they adjusted their diet and monitored their nutrition and food intake to solve appetite problems.

Behavioural coping strategies

Seven of the extracted findings from six studies identified that behavioural coping strategies were an important part of coping strategies [15, 16, 28, 32, 35]. Behavioural coping strategies aimed to ensure that their mind remained sharp, mobilize them to cope with side effects, and maintain a normal life during the chemotherapy process. First, the abilities to maintain hope and bravely fight the disease helped them accept chemotherapy. Second, religion was an effective self-care strategy to boost physiological, emotional, social, or spiritual well-being in some cultures. Third, women tried to maintain their usual roles, such as a wife, mother and employee.

Emotion-focussed coping strategies

Emotion-focussed coping strategies are effective coping strategies aiming to reduce distress and minimize psychological discomfort from chemotherapy. Eleven of the extracted findings from seven studies showed that women with breast cancer described various emotion-focussed coping strategies during chemotherapy, including crying to release all heavy burdens, focusing on the positive, accepting reality, maintaining a sense of humour, being hopeful and faithful, trying to think less, denial, diverting attention to another thing and concealing their feelings, among others [14, 16, 28, 30, 31, 33, 34]. In addition, as the adverse effects of chemotherapy gradually subsided, the patients began to make an effort to maintain a normal and peaceful life, such as understanding the value of health, enjoying their life, planning for the future and going back to work.

Proposed model: patients' experience of chemotherapy

The proposed model reveals the themes and subthemes arising from the thematic synthesis, as presented in Table 4. The themes that describe the nature of women's experiences during chemotherapy and how these themes are related are shown in Fig. 2. These themes will be elaborated in more detail in the discussion.

Discussion

This study developed three synthesized findings reflecting the experience and coping strategies of women with breast cancer undergoing chemotherapy. The synthesized

findings provide further evidence on the experience of side effects during chemotherapy, coping strategies to address these adverse effects and the need for information and social support to cope with distressful events.

Experience of women with breast cancer receiving chemotherapy

The first synthesized statement more generally overlapped with the stressful experiences of women with breast cancer receiving chemotherapy. The personal symptom experience was complex and dynamic, and each patient experienced different symptoms daily during the new treatment cycle.

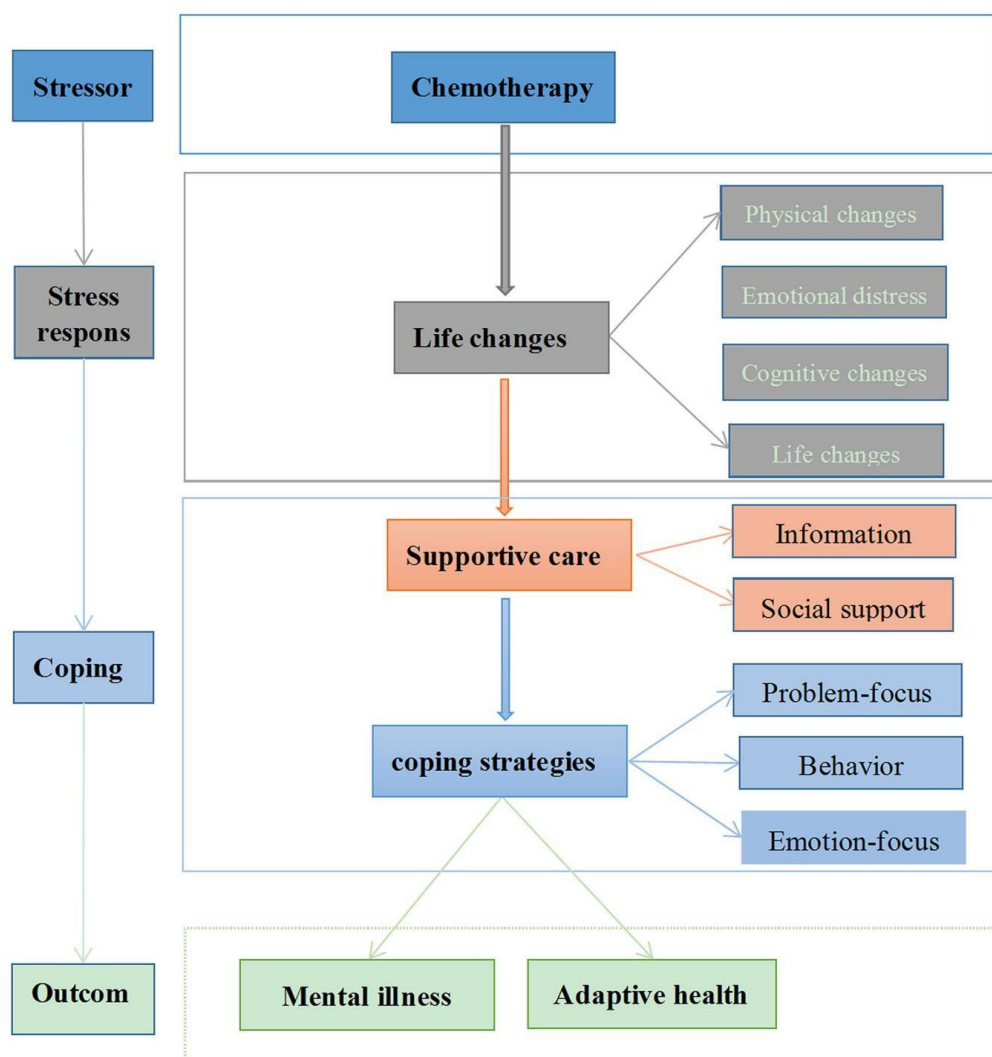


Fig. 2 Principles and framework of Lazarus's psychological and coping theory. (Color figure online)

However, we identified some common symptoms based on our research. In our review, the common physical symptoms were fatigue, cognitive changes, hair loss, nausea, vomiting, insomnia, bone pain and peripheral neuropathy, which were slightly different from common side effects reported in a previous study conducted in a Southeast Asian setting [36]. In that study, the five most prevalent physical symptoms were fatigue, dry mouth, hair loss, drowsiness and a lack of appetite, and the most distressing symptoms were fatigue, loss of appetite and changes in food taste. However, the differences in the two results may be attributed to the analysis of patients from two countries with different stages of the disease, receiving different types of chemotherapy and different ages. A symptom has a range of physical, psychological, family and social effects. Thus, women with breast cancer may experience a series of physical symptoms resulting from chemotherapy. Any symptom may exert multidimensional effects; namely, a physical manifestation of side effects from chemotherapy may exert profound effects on other aspects of health. In addition, the impact of physical symptoms on daily life is not merely determined by the characteristics of the individual and their beliefs, knowledge and expectations of chemotherapy but also by their identity, roles in family and social networks, future perspectives and the support received in this phase [37].

The second synthesized statement showed that a support network is essential for women to better cope with chemotherapy. In this review, the most important types of support were information and social support. In addition, social support is a type of practical support provided by family, friends, health-care professionals, or anyone in society that makes the individual feel safe and loved. Social support plays an important part in decision-making and survival/coping strategies, which exerts beneficial effects on social well-being and the quality of life in stressful situations [38, 39]. These findings are consistent with previous studies reporting that patients who undergo chemotherapy tend to emphasize common interpersonal stressors (e.g. providing and caring for family, and distance from family) and social/structural stressors (e.g. economic problems, and lack of information) [40].

Coping strategies are stated to be effective if they lead to good adaptation and a new pattern of life, while ineffective strategies may lead to health problems. In the present study, problem-focussed coping strategies, behavioural coping strategies and emotion-focussed coping strategies were effective strategies that reduced the severity of symptom-related distress and enabled the patients to gain control of their lives [41–43]. Problem-focussed coping strategies aim to analyse and explore the causes of stressful events, seek relevant information and social support, eliminate or solve problems, set goals and change personal expectations. Emotion-focussed coping strategy responses are not aimed

at solving problems directly but at changing a person's thoughts, such as crying, denial, acceptance, hopeful thinking, a sense of humour, attention diversion and avoidance. Behavioural coping strategies, such as remaining hopeful, understanding and following the instructions for self-care, always checking in with themselves to ensure good health and trying to maintain one's normal role in life, are strategies that may improve patient quality of life and help them cope with adverse symptoms [44].

The link between experience of chemotherapy and coping strategies

This systematic review has highlighted the link between the chemotherapy experience and coping strategies (see Fig. 2). Chemotherapy is an external stressor for women with breast cancer, which leads to various physiological and psychological side effects (fear, stress, anxiety, and depression). This stress motivates individuals to seek coping strategies that will prevent further psychological disorders and maintain psychological well-being. This finding is consistent with the views of previous studies [41, 43, 45]. A quantitative study by Sari [41] showed that adequate social support and effective coping strategies significantly reduce the symptom-related distress of patients undergoing chemotherapy. In addition, another study by Chirico [46] found an inverse relationship between self-efficacy for coping and distress from chemotherapy and a positive relationship between self-efficacy for coping and quality of life.

Moreover, we found that the results of this review matched the Contextual Model of Lazarus' Stress and Coping Theory, which was helpful in describing and organizing the results. This theory is a system for assessing the process of coping with stressful experiences. Stressful encounters are interpreted as individual-environment transactions, which depend on the impact of the external stressor [47, 48]. All individuals have resources and skills known as coping mechanisms that are used to relieve stress. Anything that causes stress endangers life, unless it is met by adequate adaptive responses; conversely, anything that endangers life causes stress and adaptive responses [49]. The application of this theory would allow nurse practitioners to include a plan to relieve patient stress and to incorporate this plan into short-term goals with the aim of ensuring safety. The ability of patients to successfully complete chemotherapy depends on their coping skills, which will decrease stressors and allow the patient to move towards a more positive outlook and lifestyle.

Implications for practice

The synthesized findings from this meta-aggregation the Lazarus stress and coping theory provide some clear

recommendations for intervention development and practice for patients to cope with chemotherapy. First, health-care professionals must scientifically and systematically assess real supportive care needs for woman with breast cancer undergoing chemotherapy and proactively provide specific information about the disease prognosis, chemotherapy regimen and potential side effects. Second, information support system and social support groups integrated in the routine procedures offered by nurses and other health-care providers should be established. For example, continuity of care by breast cancer nurses is needed throughout the duration of chemotherapy. Third, the development of pre-chemotherapy care programmes that include specific and focussed preparatory material to reduce the treatment distress level and increase adaptive coping are needed.

Strengths and limitations of the study

This systematic review and meta-aggregation of qualitative studies is the first to describe the experience and coping strategies of women with breast cancer undergoing chemotherapy. This study developed a comprehensive search strategy and an explicit and clearly reported quality assessment of the included studies and data extraction and synthesis process. The studies included in this review were conducted in eight countries, and these international studies make the results more convincing. In addition, the meta-aggregation also provides valuable insights into the work of nursing researchers and nursing administrators in related areas and identifies many potential areas for the development of further interventions and future research.

However, there are some limitations that should also be noted: First, because of the language limitations, a number of high-quality non-English studies might have been missed. Second, the systematic review protocol used in this study was not registered in Prospero prior to the study. Third, meta-aggregation is an interpretative process in which different teams studying the literature may produce different interpretations. Fourth, the experiences and coping strategies among women of different races and cultures, treated with different chemotherapy regimens and with stages of breast cancer may vary, but we were unable to conduct the analysis separately in this review because of the failure to obtain complete related data from most of the original studies. Therefore, the results from this study are relevant for some but not all patients.

Conclusions

This review is among the first to synthesize the literature of the experience and coping strategies of women with breast cancer undergoing chemotherapy based on the Contextual

Model of Lazarus' Stress and Coping Theory. According to the existing literature, we concluded that when women experienced various stressful side effects, supportive care to address needs and effective coping strategies are essential to help them adapt to this difficult journey. We recognized the need to develop pre-chemotherapy care programmes, information support systems, social support groups and individual effective coping strategies to reduce chemotherapy-related distress levels and enhance self-care at home.

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Data availability Data sharing is not applicable to this article, as no datasets were generated or analysed during the current study.

Compliance with ethical standards

Conflict of interest The authors declared that there is no conflict of interest to disclose.

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Psychological distress among Chinese patients with breast cancer undergoing chemotherapy: Concordance between patient and family caregiver reports

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Abstract

Aims: To examine patient-caregiver concordances about psychological distress among Chinese patients with breast cancer undergoing chemotherapy and identify factors related to concordance among patients and family caregivers.

Design: Cross-sectional study.

Methods: From October 2019 to June 2020, 137 patient-caregiver dyads were enrolled. Sociodemographic information, the distress thermometer (including the problem list), the Distress Disclosure Index and the Family Adaptability and Cohesion Evaluation Scale were used to collect data. Data were analysed using intraclass correlation coefficients (ICC), kappa statistics, two related samples test, chi-square tests and/or Fisher's exact tests and binary logistic regression.

Results: Overall, fair agreement was identified between patients' and caregivers' reports (intraclass correlation coefficients [ICC] = .528). Patients reported significantly higher psychological distress scores than paired caregiver reports. Lower psychological distress concordance was found among patients with comorbidities (odds ratio [OR], 0.352; 95% confidence interval [CI], 0.155–0.798) and lower levels of self-disclosure (OR, 0.402; 95% CI, 0.186–0.868).

Conclusion: There was relatively low concordance between patients' reports and caregivers' perceptions of psychological distress. Family caregivers tended to underestimate patients' psychological distress. A comorbid condition and lower levels of self-disclosure contributed to this bias.

Impact: Having an awareness of the incongruence between patient and caregiver may help healthcare providers better interpret caregiver assessments. Healthcare providers should reinforce patient-caregiver dyadic psychosocial education to improve concordance. More psychological care and substantial emotional support should be provided for Chinese breast cancer patients undergoing chemotherapy by family caregivers and healthcare providers.

KEYWORDS

breast cancer, chemotherapy, concordance, influencing factors, nursing, patient-caregiver dyad, psychological distress, social support

Huihui Zhao and Xiaojin Li contributed equally to this article.

1 | INTRODUCTION

Worldwide, breast cancer remains the most frequent neoplasm diagnosed among females, with about 2.1 million new cases identified in 2018 (Bray et al., 2018). In China, the incidence of breast cancer showed an upward trend in recent years (Feng et al., 2019). Fortunately, various advanced treatment techniques have improved the 5-year survival rate. These include surgery, chemotherapy, radiotherapy, targeted therapy and endocrine therapy (NCCN, 2020a). Nevertheless, the diagnosis and treatment of breast cancer have a tremendous impact on patients' psychological well-being. Evidence shows that psychological distress is more prevalent among women with breast cancer than those without cancer (Maass et al., 2019). Chemotherapy is one of the most stressful features of the breast cancer experience, psychological distress is highly prevalent in patients with breast cancer undergoing chemotherapy, with about 90% of breast cancer patients experiencing some level of distress (Gibbons & Groarke, 2018). The National Comprehensive Cancer Network (NCCN) defined distress as a multifactorial, unpleasant experience of a psychological (e.g. emotional, cognitive), physical, social and spiritual nature (NCCN, 2020b). The NCCN recognized distress as a significant sequela related to cancer diagnosis and treatment (Gibbons & Groarke, 2018) and highlighted the importance of distress assessment and management for patients with cancer (NCCN, 2020b). Psychological distress is a serious concern that requires more attention, leading to lower health-related quality of life and poor treatment compliance (Oh & Cho, 2020; Wu et al., 2018). However, it has been reported that psychological distress in breast cancer patients is often underestimated and under-treated (Sun et al., 2021). Identification of psychological distress during cancer survivorship is challenging (Syrowatka et al., 2017). Although guidelines commonly recommend that healthcare professionals provide distress screening for patients, little is focused on that from family caregivers' perspectives (NCCN, 2020b). Congruence refers to the agreement or similarity in the perceptions of the experience in patients and family caregivers (Martinez et al., 2020). Family caregivers play an essential role in providing first-line emotional and instrumental support to patients (Segrin et al., 2021). It is crucial to understand whether family caregivers have a good understanding of patients' psychological symptoms. Over- or underestimating patients' psychological distress may impede appropriate support to cope with patients' psychological impairments (Silveira et al., 2010). Cancer survivors with lower social support suffered from more psychological symptoms than those with higher levels of support (Perez-Tejada et al., 2019). Given this, for healthcare providers, a comprehensive understanding of patient-caregiver concordances about psychological distress in patients with breast cancer undergoing chemotherapy and its influencing factors is essential to carry out effective interventions to alleviate patients' psychological symptoms and improve their quality of life.

1.1 | Background

Chemotherapy is widely used in breast cancer treatment in China, about 81.4% of patients receive chemotherapy (Zhu et al., 2017).

Despite its high efficiency, chemotherapy may lead to various physical side effects and psychological distress. Psychological distress refers to maladaptive psychological functioning in response to specific stressors or demands, characterized by perceived discomfort that inability to cope and changed in emotional status (Ridner, 2004). Almost all such patients experience distress related to cancer diagnosis, the influence of disease and disease treatments (NCCN, 2020b). In China, approximately 50% of patients reported psychological distress after breast cancer diagnosis (Liu et al., 2014). Patients with breast cancer undergoing chemotherapy may experience psychological problems such as anxiety, depression, worry, fear, anger, uncertainty, isolation and sadness (Liu et al., 2021). Psychological distress may interfere with a patient's ability to obtain essential follow-up care (Montgomery & McCrone, 2010). It also can negatively affect the outcomes of the management of cancer-related and treatment-related symptoms (Badger et al., 2020). Focusing on the distress that patients suffer is essential to improve distress management.

Much of the psychological distress during chemotherapy was associated with the experience of side effects (Gibbons & Groarke, 2018). Side effects caused by chemotherapy include hair loss, anorexia, insomnia, fatigue, cognitive impairments and so on (Zhang et al., 2018). Patients felt sadness and worried about their appearance when they lost their hair (Chen et al., 2016). They also felt depressed that they could not fulfil their responsibilities due to adverse effects of chemotherapy (e.g. weakness and fatigue) (Liu et al., 2021). Moreover, they were anxious because of the physical changes and the loss of independence after receiving chemotherapy (Liu et al., 2021). In turn, psychological distress contributes to developing chemotherapy side effects and even increasing the risk of cancer-related morbidity and mortality (Chirico et al., 2020; Kamen et al., 2017). Psychological distress played a role in suppressing immune function (Lee & Singh, 2021). It may trigger the development of chemotherapy-induced nausea, thereby resulting in poor adherence to chemotherapy (Grassi et al., 2015). Additionally, psychological distress may lead to objective and subjective cognitive dysfunction because the stress results from chemotherapy can impact cognitive functioning (Kaiser et al., 2019). Psychological distress negatively impacts mortality with health-risk behaviours, socioeconomic disadvantages or reduced access to healthcare (Lee & Singh, 2021). Concerning physiological mechanisms, psychological distress is associated with high cancer mortality by promoting the spread of cancer cells from the primary tumour to other sites (Lee & Singh, 2021). All these negatively influence patients' quality of life, suggesting that more attention should be paid to psychological distress among breast cancer patients undergoing chemotherapy.

Psychological care for breast cancer patients undergoing chemotherapy is important. Numerous psychological care strategies, including refocusing attention, emotional expression and seeking support, were influential in coping with psychological distress for breast cancer patients undergoing chemotherapy (Gibbons & Groarke, 2018). Although psychological care for cancer patients has aroused more concern in recent years, not every breast cancer patient who suffered from distress received such care. It has been

reported that only 31%–37% of cancer patients talked about their psychosocial needs with others and they rarely receive supportive treatments for their psychological distress (Rao et al., 2019). Expressive suppression and stigma related to disease or psychological problems are barriers to distress assessment and management (Lu et al., 2018; NCCN, 2020b). These patients may be reluctant to express their emotional problems to others, including their families. Social support, especially from family, has proven vital for breast cancer patients (Segrin et al., 2021). If family caregivers recognized patients' distress, more emotional support might be provided. Furthermore, family caregivers are important communication links between patients and healthcare providers (Yeşilbalkan & Okgün, 2010), contributing to better distress assessment by healthcare providers. For these reasons, it is necessary to know about whether caregivers' understanding of patients' negative emotions keeps consistent with patients' self-reports.

A substantial body of evidence focused on the concordances between patient and caregiver/partner reports of the perceptions about symptom, cancer-related concerns and social support (Hou et al., 2018; Martinez et al., 2020; Silveira et al., 2010). A study showed that breast cancer patients' partners often tend to overestimate patients' self-reported levels of psychological distress (Carlson et al., 2001), indicating a lack of a shared understanding of patient distress. Another study of chronic pain patients and their partners found that couple concordance in pain severity perceptions significantly predicted partners' reports and partners who overestimated the patients' self-reported pain levels provided more social support (Junghaenel et al., 2018). However, another study demonstrated that husbands' over- or under-estimation of breast cancer patients' adjustment to breast cancer negatively influenced the patients' moods (Romero et al., 2008). High levels of congruence have proven to be associated with lower caregiver burden (Higginson & Gao, 2008). All these studies indicated that maintaining concordances between patient and family caregiver reports is essential. Emotional support is particularly important for cancer patients (Carlson et al., 2001). Evidence suggests that breast cancer patients who received support from family and healthcare providers had a better psychological adjustment and quality of life (Al-Ghabeesh et al., 2019). Understanding patient-caregiver dyads concordances in psychological distress perceptions may help raise caregivers' awareness of psychological care and provide more substantial emotional support to alleviate psychological impairments.

In addition to understanding the degree of patient-caregiver dyad concordances, it is essential to consider those factors that may be associated with it. Demographic factors predict psychological distress (Kagee et al., 2018). Participants' demographic characteristics influenced the agreement between patient-family proxy assessments on patient symptom experiences (Silveira et al., 2010). Agreements of psychological distress may differ among patients and family caregivers. Emotional self-disclosure refers to how individuals express themselves and show their emotions and feelings (Kahn et al., 2012). Greater self-disclosure of concerns was associated with greater intimacy for patient and partner (Perndorfer et al., 2019).

If patients do not share their concerns, family caregivers may assume that the patient's feelings and thoughts are similar to their own feelings and thoughts, resulting in a bias inference. Family cohesion refers to the emotional bond (e.g. feelings of intimacy and bonding) among family members, and adaptability refers to the ability to change the rules of family structure in response to events that arise during the life cycle (Park et al., 2018). It has been suggested that high family functioning and adaptive problem-solving patterns can decrease anxiety and depressive disorders in breast cancer patients (Lueboonthavatchai, 2007). The levels of family cohesion and adaptability also impact family caregiver's perceptions of emotions (Park et al., 2018). Under these circumstances, it might be expected to affect the patient-caregiver dyad concordances of psychological distress.

Contrary to the straightforward and open communication ways in western countries, China has a unique cultural context (Williamson et al., 2012). Chinese cancer patients often expect their family caregivers to 'mind-read' their thoughts and needs (Hou et al., 2018). To the best of our knowledge, little is known about the patient-caregiver dyad concordances in psychological distress perceptions among Chinese breast cancer patients undergoing chemotherapy and their family caregivers. Therefore, the specific aims of this study were (1) to investigate the concordance between patients' reports and caregivers' perceptions of psychological distress and (2) to identify the factors that contribute to the concordances, namely, whether participants' characteristics, individual levels of distress disclosure and adaptability and cohesion of families may affect the concordances.

2 | STUDY

2.1 | Aims

This study aimed to examine patient-caregiver concordances about psychological distress in patients with breast cancer undergoing chemotherapy in China and identify factors related to concordance among patients and their family caregivers.

2.2 | Design

This was a cross-sectional study.

2.3 | Participants

Participants were recruited from the breast surgery department of a 3000-bed tertiary hospital in Guangzhou, China, between October 2019 and June 2020, using a convenience sampling method. Inclusion criteria of patients were as follows: (1) pathologically diagnosed breast cancer and having undergone surgery, (2) at least 18 years of age, (3) currently receiving postoperative chemotherapy,

(4) voluntary participation with informed written consent. Family caregivers were included if (1) they lived with the patients, (2) were at least 18 years old, (3) voluntarily participated and provided informed written consent. Patients and family caregivers were excluded if they had psychiatric conditions or linguistic/intellectual difficulties. According to the Kendall sample estimation method, the sample size should be approximately 5–10 times the number of the explanatory variables (Lu & Fang, 2003). It was estimated that there were 26 explanatory variables in this study, therefore a sample size of a minimum 130 (26×5) was calculated.

2.4 | Instruments

The paper-based questionnaires used in this study consisted of four parts: a self-designed questionnaire about demographic and medical information, the distress thermometer (DT) and problem list, the Distress Disclosure Index (DDI) and the Family Adaptability and Cohesion Evaluation Scale (FACES II).

2.4.1 | Demographic and medical information

Demographic information (age, gender, marital status, employment status, income level, education level and the relationship between patient and family caregiver) were obtained from participants. Patients' medical information (body mass index, disease staging, comorbidity, type of surgery, surgical side and the number of chemotherapy cycles) were recorded from medical records.

2.4.2 | Chinese version of the distress thermometer and problem list

The DT, as a distress screening tool, is recommended by the NCCN (NCCN, 2020b). It is a self-reported instrument that consists of a 0–10 rating scale (0 = 'no distress' to 10 = 'extreme distress'). A cut-off score of four represents clinically significant distress and warrants further screening (NCCN, 2020b). A supplemental list named 'problem list' contains the NCCN Distress Management Panel developed 39 items was used to identify the sources of distress. It was divided into five groups: practical, family, emotional, physical and spiritual/religious. The validity of the Chinese version of the DT and the problem list was confirmed in a previous study (Tang et al., 2011). The Chinese version of the problem list includes 40 items, with an added item named 'relationship with healthcare providers' (Tang et al., 2011).

2.4.3 | Chinese version of the Distress Disclosure Index

The DDI is a widely used instrument to measure individual levels of distress disclosure (Kahn & Hessling, 2001). The self-report scale

comprises 12 items on a 5-point scale, ranging from 1 (strongly disagree) to 5 (strongly agree). A higher score corresponds to a higher willingness to disclose distress. The Chinese version of DDI has satisfactory validity and reliability properties (Li, 2009). The Cronbach's α was .866 in this study.

2.4.4 | Chinese version of the Family Adaptability and Cohesion Evaluation Scale

The FACES II is a self-report tool assessing the adaptability and cohesion of families (Olson et al., 1985). It contains 30 items on a 5-point scale, ranging from 1 (never or hardly ever) to 5 (always or almost always). A higher score represents better adaptability and cohesion of families. The instrument has shown an acceptable internal consistency coefficient in the Chinese version of FACES II, with Cronbach's α higher than 0.6 (Lipeng et al., 1991).

2.5 | Data collection

Research staff identified potentially eligible participants through medical records. All patients and their caregivers who agreed to participate were informed of the study objectives and procedures and signed informed consent forms. The patients and their caregivers were asked to fill out the questionnaire separately and independently in a quiet room. The research staff assisted the participants in answering the questionnaire using standard instructions if necessary. After completing the questionnaire, the research staff checked the questionnaire to ensure that no data were missing. Approximately 15–20 min were required to complete the questionnaire.

2.6 | Ethical considerations

The Ethics Committees of Medical Ethics Committee of Nanfang Hospital approved all study procedures (no: NFEC-2018-049). Written informed consent was obtained from each participant before the investigation.

2.7 | Data analysis

Data analysis was performed using SPSS version 20.0 (IBM Corp). Descriptive statistics were generated for participants' characteristics and were summarized as median (25%–75% percentiles) and frequency. Intraclass correlation coefficients (ICCs) between patient-reported and caregiver-reported DT scores were calculated to evaluate the extent of agreement between patient and caregiver reports. ICC values were considered poor if lower than 0.40, fair if ranging from 0.40 to 0.59, good if ranging from 0.60 to 0.74 and excellent if greater than 0.75 (Cicchetti, 1994). Kappa tests were used to assess the consistency between patient and caregiver

reports related to the problem list. Kappa values were interpreted as follow: poor (<0.00), slight (0.0–0.20), fair (0.21–0.40), moderate (0.41–0.60), substantial (0.61–0.80) and almost perfect (0.81–1.00) (Landis & Koch, 1977). Two related samples test was performed to determine whether patients' reports of psychological distress and caregivers' perceptions differed significantly. Chi-squared tests or Fisher's exact tests were employed to examine which variables were related to the concordance between patient and caregiver reports. Predictors of concordance were identified using binary logistic regression, and a difference DT scores (calculated as patient DT score minus caregiver DT score) was the outcome variable. If the difference of DT scores were in the range –1 to +1, it would be considered concordant (Silveira et al., 2010). With the median score as the cut-off, DDI and FACES II scores were dichotomized as 1 (lower group) and 2 (higher group). *p*-values lower than .05 were considered statistically significant.

2.8 | Validity and reliability

Both instruments used in the current study have been widely validated in the previous study. Before the investigation, two researchers, who are nursing postgraduates, received structured training about the key points of data collection. After data collection, all data were entered into SPSS independently by two researchers. Before data analysis, researchers checked the missing data and outliers to ensure the accuracy of the data.

3 | RESULTS

3.1 | Characteristics of the participants

A total of 150 dyads of patients with breast cancer undergoing chemotherapy and caregivers met the inclusion criteria, among which 13 dyads refused to participate. Thus, a total of 137 dyads participated (91.3% response rate). All patients were females and ranged in age from 22 to 66 years. Most patients were married and underwent a modified radical mastectomy with axillary lymph node dissection. Of the total 137 caregivers, 68.6% were male and 89.1% were married. The caregivers' ages ranged from 23 to 80 years and 62.8% were the patients' spouses. Table 1 shows detailed information of participants' demographic and medical information.

3.2 | Patient and caregiver responses

For DT scores, the patients' median (P_{25} , P_{75}) score was 4 (2–5). Caregivers reported lower DT scores than patients, with a median (P_{25} , P_{75}) score of 3 (2–5). Higher scores on DT (≥ 4) were found in 42.3% of the patients' reports and 29.2% of the caregivers' reports ($\chi^2 = 5.147$, $p = .023$). A visual comparison of DT scores by patients' reports and caregivers' reports is presented in Figure 1.

For the problem list, the source of distress that was reported most often in patients' and caregivers' reports was physical problems, followed by emotional problems, practical problems, interpersonal relation problems, other problems and spiritual problems. The five most frequently reported problems by patients were: restricted in physical activity ($n = 79$, 57.7%), fatigue ($n = 77$, 56.2%), appearance ($n = 72$, 52.6%), worry ($n = 64$, 46.7%) and sleep ($n = 62$, 45.3%). Among caregiver reports, the five most frequently reported problems were: restricted in physical activity ($n = 50$, 36.6%), nausea ($n = 45$, 32.8%), appearance ($n = 45$, 32.8%), nervousness ($n = 35$, 25.5%) and depression (34, 24.8%).

3.3 | Patient-caregiver concordance on psychological distress

Two related samples test for matched pairs revealed a significant discrepancy between patients' reports and caregivers' perceptions of psychological distress ($Z = -3.538$, $p < .001$). The ICC value indicated a fair agreement between patient and caregiver reports for DT scores (ICC = 0.528; 95% confidence interval [CI]: 0.396–0.639, $p < .001$).

Among all patient-caregiver dyads, the median kappa score was 0.318. Agreement between patient and caregiver was highest for mouth sores and sex (kappa = 1.00, $p < .001$), whereas the least agreed-on concern was skin dry/itchy (kappa = –0.069, $p = .413$). Slight agreement was found for worry (kappa = 0.153, $p = .041$) and memory/concentration (kappa = 0.186, $p = .011$) (Table 2). Approximately 41% of the kappa values ranged from 0.21 to 0.40, suggesting fair agreement between patients and caregivers reports for the problem list. The average levels of agreement among patient-caregiver dyad are shown in Figure 2.

3.4 | Factors related to concordance

Table 3 summarizes the results of univariate analyses (χ^2 tests or Fisher's exact tests) which assessed factors related to the concordance between patient and caregiver reports. The concordance between patient and caregiver reports was significantly different for comorbid conditions, DDI scores and FACES II scores ($p < .05$). All remaining tests on patients characteristic (age, marital status, employment status, monthly household income, disease staging, type of surgery, surgical side and cycle of chemotherapy) and caregiver characteristics (gender, age, marital status, education level and caregivers' relationship with patients) were associated with p -values $>.05$.

3.5 | Predictors of concordance

Binary logistic regression was carried out to confirm the predictive effect of the significant variables from the univariate analyses.

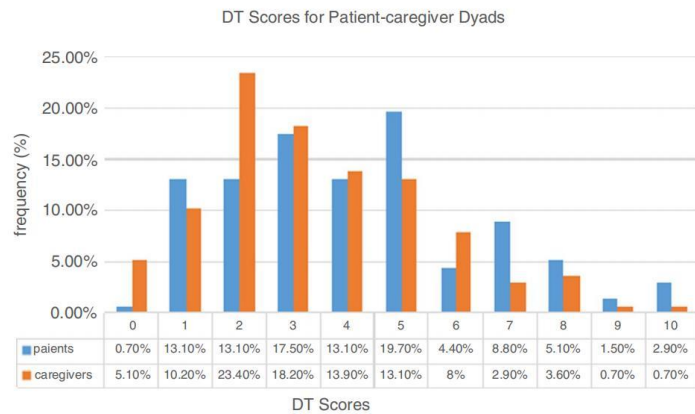
TABLE 1 Characteristics of the participants (N = 274)^a

Variables	Category	Patients (N = 137)	Caregivers (N = 137)
BMI, kg/m ² , median (25%–75%)	—	22.66 (20.80–24.03)	—
		n (%)	n (%)
Gender	Male	0 (0.0)	94 (68.6)
	Female	137 (100.0)	43 (31.4)
Age	≤29	6 (4.4)	15 (10.9)
	30–39	30 (21.9)	36 (26.3)
	40–49	65 (47.4)	52 (38.0)
	50–59	27 (19.7)	28 (20.4)
	≥60	9 (6.6)	6 (4.4)
Marital status	Married	125 (91.2)	122 (89.1)
	Single/divorced/widowed	12 (8.8)	15 (10.9)
Education level	Primary school	28 (20.4)	4 (2.9)
	Middle school	43 (31.4)	40 (29.2)
	High school	34 (24.8)	40 (29.2)
	College or above	32 (23.4)	53 (38.7)
Employment status	Employed	76 (55.5)	—
	Unemployed	61 (44.5)	—
Monthly household income (RMB)	<3000	21 (15.3)	—
	3000–5000	50 (36.5)	—
	>5000	66 (48.2)	—
Disease staging	I	51 (37.2)	—
	II	71 (51.8)	—
	III	15 (10.9)	—
Comorbidity	Yes	40 (29.2)	—
	No	97 (70.8)	—
Type of surgery	Modified radical mastectomy	127 (92.7)	—
	Surgery of the prosthesis implantation	4 (2.9)	—
	Breast-conserving surgery	6 (4.4)	—
Surgical side	Left	69 (50.4)	—
	Right	67 (48.9)	—
	Bilateral	1 (0.7)	—
The number of chemotherapy cycle	1	44 (32.1)	—
	2	15 (10.9)	—
	3	22 (16.1)	—
	4	20 (14.6)	—
	5	6 (4.4)	—
	6	9 (6.6)	—
	7	4 (2.9)	—
	8	17 (12.4)	—
Caregivers' relationship with patients	Spouse	—	86 (62.8)
	Daughter/son	—	29 (21.2)
	Brother/sister	—	18 (13.1)
	Parent	—	4 (2.9)

Abbreviation: BMI, body mass index.

^aData are presented as median (25%–75%), or frequency (percentage).

FIGURE 1 Comparison of distress thermometer (DT) scores for patient-caregiver dyads



As an indicator of agreement, the response variable was coded as 0 = 'concordant' and 1 = 'discordant'. Although the variable 'caregivers' relationship with patients' did not show statistical significance, it was considered clinically relevant to the concordance because Chinese patients were very cultural sensitive and caregivers' relationship with patients was associated with the closeness between patients and caregivers. Therefore, variables including comorbidity, DDI scores, FACES II scores and caregivers' relationship with patients were entered into the model. The final model had a statistical significance with the chi-square test of $p = .000$. The results (Table 4) demonstrated that comorbidity (odds ratio [OR], 0.352; 95% CI, 0.155–0.798) and DDI scores (OR, 0.402; 95% CI, 0.186–0.868) were significant predictors of the concordance between patient and caregiver reports (all $p < .05$).

4 | DISCUSSION

Psychological distress in breast cancer patients undergoing chemotherapy is prevalent. This study was conducted to explore the congruence of psychological distress between patients with breast cancer undergoing chemotherapy and their family caregivers and identify the factors that may influence the congruence.

We found fair agreement between the patient and caregiver ratings in DT and problem list assessment results, and patients reported significantly higher DT scores than caregivers. These results suggest that there were individual differences between patients' and caregivers' perceptions of psychological distress. Caregivers tended to underestimate the psychological distress that patients experienced. This underestimation of psychological distress is similar to the previous studies finding that caregivers were poor evaluators of patients' distress levels (Silveira et al., 2010; Yeşilbalkan & Okgün, 2010). Female patients were found to be more probably to be distressed (Hagedoorn et al., 2008). Emotional problems, which are subjective, are often overlooked among cancer patients (Suzuki et al., 2011). In comparison with psychological distress, healthcare

providers or family caregivers tend to pay more attention to the physical symptoms of cancer patients (Madden, 2006; Silveira et al., 2010). Psychological distress negatively impacts cancer patients and their family caregivers because of their interdependence (Segrin et al., 2020). Caregivers experienced the same or greater levels of distress than cancer patients themselves (Segrin et al., 2020). Caregivers also needed a psychological adjustment process, so that they might ignore the patients' psychological problems and did not recognize that they should take actions to relieve patients' negative emotions. In addition, social conformity and collectivism are important in Chinese culture. Chinese breast cancer patients often inhibit the expression of negative emotions or thoughts to avoid burdening their family caregivers and maintain relationship harmony (Ho et al., 2016; Hou et al., 2018). Therefore, caregivers might do not know that their loved ones are experiencing severe distress.

Identifying the number of distressing factors and specific items is crucial to the process of assessing distress. Concerning the sources that contributed to distress, physical and emotional problems (restricted in physical activity, nausea, appearance, nervousness and depression) were the five most frequent problems reported by caregivers, which were partially congruent with patients' reports (restricted in physical activity, fatigue, appearance, worry and sleep). Our study indicates that caregivers believed that the objectifiable and observable symptoms such as nausea and appearance influenced patients more than fatigue. Fatigue is one of the distressing side effects of cancer treatments that may affect patients' quality of life for a lifetime, and the highest prevalence of fatigue was found among patients undergoing chemotherapy (Reinertsen et al., 2017). However, most patients did not report their fatigue because they considered it inevitable or untreatable (Shun et al., 2009). Our findings suggest that fatigue received little attention from patients and caregivers. Patient and caregiver education is needed to heighten fatigue awareness, to alleviate negative impacts on emotion further.

Consistent with another study (Tang & McCorkle, 2002), we found poorer agreement with patients who had comorbid conditions, suggesting that patients' health status may affect caregivers'

TABLE 2 The results of concordance between patient and family caregiver reports of the sources of distress

	Patient (N = 137)		Caregiver (N = 137)			
Variable	Yes	No	Yes	No	Kappa (95% CI)	p
Practical problems						
Child care	16 (11.7)	121 (88.3)	22 (16.1)	115 (83.9)	0.452 (0.240–0.664)	<.001
Housing	40 (29.2)	97 (70.8)	15 (10.9)	122 (89.1)	0.243 (0.078–0.408)	.001
Insurance/financial	37 (27.0)	100 (73.0)	18 (13.1)	119 (86.8)	0.404 (0.230–0.578)	<.001
Transportation	7 (5.1)	130 (94.9)	11 (8.0)	126 (92.0)	0.289 (0.001–0.580)	<.001
Work/school	44 (32.1)	93 (67.9)	24 (17.5)	113 (82.5)	0.277 (0.110–0.44 4)	<.001
Surroundings	1 (0.7)	136 (99.3)	8 (5.8)	129 (94.2)	–0.013 (–0.037–0.011)	.803
Interpersonal relation problems						
Dealing with children	8 (5.8)	129 (94.2)	2 (1.5)	135 (98.5)	0.386 (0.006–0.767)	<.001
Dealing with partner	5 (3.6)	132 (96.4)	3 (2.2)	134 (97.8)	–0.028 [–0.050–(–0.006)]	.773
Dealing with relatives and friends	8 (5.8)	129 (94.2)	4 (2.9)	133 (97.1)	0.133 (–0.157–0.423)	.097
Dealing with healthcare providers	3 (2.2)	134 (97.8)	1 (0.7)	136 (99.3)	–0.011 (–0.027–0.004)	.881
Emotional problems						
Depression	34 (24.8)	103 (75.2)	34 (24.8)	103 (75.2)	0.252 (0.068–0.436)	.003
Fears	34 (24.8)	103 (75.2)	21 (15.3)	116 (84.7)	0.305 (0.121–0.489)	<.001
Loneliness	12 (8.8)	125 (91.2)	5 (3.6)	132 (96.4)	0.318 (0.024–0.612)	<.001
Nervousness	35 (25.5)	102 (74.5)	35 (25.5)	102 (74.5)	0.309(0.131–0.487)	<.001
Sadness	48 (35.0)	89 (65.0)	25 (18.2)	112 (81.8)	0.333 (0.172–0.493)	<.001
Worry	64 (46.7)	73 (53.3)	32 (23.4)	105 (76.6)	0.153 (0.006–0.300)	.041
Loss of interest in usual activities	5 (3.6)	132 (96.4)	1 (0.7)	136 (99.3)	–0.012 (–0.316–0.0076)	.845
Sleep	62 (45.3)	75 (54.7)	32 (23.4)	105 (76.6)	0.385 (0.244–0.526)	<.001
Memory/concentration	34 (24.8)	103 (75.2)	13 (9.5)	124 (90.5)	0.186 (0.012–0.360)	.011
Physical problems						
Appearance	72 (52.6)	65 (47.4)	45 (32.8)	92 (67.2)	0.412 (0.273–0.551)	<.001
Bathing/dressing	22 (16.1)	115 (83.9)	16 (11.7)	121 (88.3)	0.452 (0.240–0.663)	<.001
Breathing	7 (5.1)	130 (94.9)	3 (2.2)	134 (97.8)	–0.032 [–0.057–(0.007)]	.648
Changes in urination	4 (2.9)	133 (97.1)	4 (2.9)	133 (97.1)	0.742 (0.399–1.085)	<.001
Constipation	16 (11.7)	121 (88.3)	13 (9.5)	124 (90.5)	0.268 (0.029–0.507)	.002
Diarrhoea	10 (7.3)	127 (92.7)	5 (3.6)	132 (96.4)	0.509 (0.197–0.821)	<.001
Eating	40 (29.2)	97 (70.8)	31 (22.6)	106 (77.4)	0.225 (0.049–0.401)	.008
Fatigue	77 (56.2)	60 (43.8)	33 (24.1)	104 (75.9)	0.369 (0.249–0.488)	<.001
Feeling swollen	5 (3.6)	132 (96.4)	4 (2.9)	133 (97.1)	0.655 (0.290–1.020)	<.001
Fevers	6 (4.4)	131 (95.6)	5 (3.6)	132 (96.4)	0.905 (0.721–1.089)	<.001
Getting around	38 (27.7)	99 (72.3)	17 (12.4)	120 (87.6)	0.451 (0.282–0.620)	<.001
Indigestion	4 (2.9)	133 (97.1)	0 (0.0)	137 (100.0)	–	–
Mouth sores	3 (2.2)	134 (97.8)	3 (2.2)	134 (97.8)	1 (0.000–1.000)	<.001
Nausea	59 (43.1)	78 (56.9)	45 (32.8)	92 (67.2)	0.571 (0.433–0.709)	<.001
Nose dry/congested	4 (2.9)	133 (97.1)	6 (4.4)	131 (95.6)	0.585 (0.218–0.952)	<.001
Pain	26 (19.0)	111 (81.0)	25 (18.2)	112 (81.8)	0.398 (0.204–0.592)	<.001
Sexual	1 (0.7)	136 (99.3)	1 (0.7)	136 (99.3)	1 (0.000–1.000)	<.001

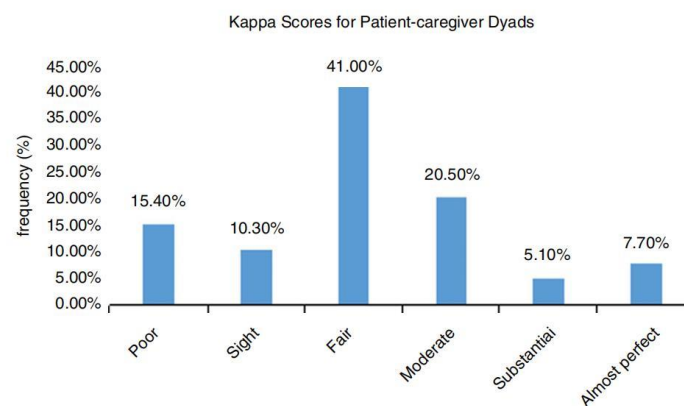
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TABLE 2 (Continued)

Variable	Patient (N = 137)		Caregiver (N = 137)		Kappa (95% CI)	p
	Yes	No	Yes	No		
Skin dry/itchy	8 (5.8)	129 (94.2)	10 (7.3)	127 (92.7)	-0.069 [-0.102-(-0.036)]	.413
Tingling in hands/feet	12 (8.8)	125 (91.2)	8 (5.8)	129 (94.2)	0.140 (-0.105-0.385)	.094
Restricted in physical activity	79 (57.7)	58 (42.3)	50 (36.6)	87 (63.5)	0.369 (0.230-0.508)	<.001
Spiritual/religious concerns						
Spiritual/religious concerns	0 (0.0)	137 (100.0)	0 (0.0)	137 (100.0)	—	—
Other problems						
Irritable	13 (9.5)	124 (90.5)	5 (3.6)	132 (96.4)	0.296 (0.014-0.578)	<.001
PICC catheter	8 (5.8)	129 (94.2)	0 (0.0)	137 (100.0)	—	—

Abbreviation: CI, confidence interval.

FIGURE 2 Kappa scores for patient-caregiver dyads



perception of psychological distress and the accuracy of proxy rating declines with disease progression. Comorbidities are prevalent among breast cancer patients undergoing chemotherapy (Wu et al., 2019). Compared with others, patients with comorbidities are more probably to have more symptoms and poorer quality of life. Evidence has shown that the number of comorbidities was significantly correlated with the symptoms such as pain, sleep quality and worse functioning (Wu et al., 2019). It is possible that patients' health status may decline because of comorbidities, and caregivers cannot evaluate and report patients' emotional conditions.

Emotional expression can influence patients' psychological adaptation, which is beneficial to relieving their psychological distress (Brandão et al., 2016). The current study shows that better agreement was more probably to occur among patients with higher distress disclosure, which was in line with a previous finding that satisfaction with partner support for breast cancer patients was relevant to high patient disclosure (Carlson et al., 2001). Patients who have high levels of self-disclosure engage in more frequent disclosure of their distress levels and seek psychological help (Kahn et al., 2012). Caregivers therefore can have a better understanding

of patients' negative emotions, contributing to the higher concordance in patients' and caregivers' reports of distress. The findings of this study also suggest that disclosure communication plays a fundamental role in the agreement between patients' and caregivers' reports. Positive emotional communication between cancer patients and caregivers helps share the thoughts and feelings and regulating dyad coping mechanisms, thereby improving surrogate accuracy (Li et al., 2020). However, many Chinese breast cancer patients were reluctant to share their distressing feelings with their family caregivers (Ji et al., 2019). Furthermore, they did not want to burden their family caregivers, and some patients felt psychological distress was untreatable. They felt they could not benefit from talking about their distressing problems with caregivers, or they were ashamed to disclose their negative emotions because of disease stigma (Tsai et al., 2019). Family caregivers need to perform caregiving tasks and balance obligations at work (Yeung et al., 2020). If caregivers are busy with their work, it is difficult for patients to have emotional communication with them. These findings suggest that much remains to be done to improve the psychological care for breast cancer patients undergoing chemotherapy in China.

TABLE 3 Factors associated with patient-caregiver dyads concordances

Variable	Category	Agreement, n (%)	Disagreement, n (%)	χ^2	p
Patient characteristics					
Age	≤29	4 (66.7)	2 (33.3)	1.954	.756
	30–39	14 (46.7)	16 (53.3)		
	40–49	32 (49.2)	33 (50.8)		
	50–59	15 (55.6)	12 (44.4)		
	≥60	6 (66.7)	3 (33.3)		
Marital status	Married	65 (52.0)	60 (48.0)	0.018	1
	Single/divorced/widowed	6 (50.0)	6 (50.0)		
Education level	Primary school	17 (60.7)	11 (39.3)	2.100	.572
	Middle school	21 (48.8)	22 (51.2)		
	High school	19 (55.9)	15 (44.1)		
	College or above	14 (43.8)	18 (56.3)		
Employment status	Employed	38 (50.0)	38 (50.0)	0.228	.731
	Unemployed	33 (54.1)	28 (45.9)		
Monthly household income (RMB)	<3000	11 (52.4)	10 (47.6)	0.491	.782
	3000–5000	24 (48.0)	26 (52.0)		
	>5000	36 (54.5)	30 (45.5)		
Disease staging	I	28 (54.9)	23 (45.1)	1.036	.606
	II	37 (52.1)	34 (47.9)		
	III	6 (40.0)	9 (60.0)		
Comorbidity	Yes	14 (35.0)	26 (65.0)	6.405	.014
	No	57 (58.8)	40 (41.2)		
Type of surgery	Modified radical mastectomy	66 (52.0)	61 (48.0)	0.014	1.00
	Surgery of the prosthesis implantation	2 (50.0)	2 (50.0)		
	Breast-conserving surgery	3 (50.0)	3 (50.0)		
Surgical side	Left	31 (44.9)	38 (55.1)	3.255	.125
	Right	39 (58.2)	28 (41.8)		
	Bilateral	1 (100.0)	0 (0.0)		
Number of chemotherapy	1	21 (47.7)	23 (52.3)	10.034	.178
	2	10 (66.7)	5 (33.3)		
	3	12 (54.5)	10 (45.5)		
	4	11 (55.0)	9 (45.0)		
	5	2 (33.3)	4 (66.7)		
	6	7 (77.8)	2 (22.2)		
	7	2 (50.0)	2 (50.0)		
	8	6 (35.3)	11 (64.7)		
Distress Disclosure Scores	Lower	26 (40.0)	39 (60.0)	6.927	.008
	Higher	45 (62.5)	27 (37.5)		
Caregiver characteristics					
Gender	Male	50 (53.2)	44 (46.8)	0.224	.7141
	Female	21 (48.8)	22 (51.2)		

(Continues)

TABLE 3 (Continued)

Variable	Category	Agreement, n (%)	Disagreement, n (%)	χ^2	p
Age	≤29	10 (66.7)	5 (33.3)	3.323	.518
	30–39	20 (55.6)	16 (44.4)		
	40–49	27 (51.9)	25 (48.1)		
	50–59	11 (39.3)	17 (60.7)		
	≥60	3 (50.0)	3 (50.0)		
Marital status	Married	61 (50.0)	61 (50.0)	1.486	.279
	Single/divorced/widowed	10 (66.7)	5 (33.3)		
Education level	Primary school	1 (25.0)	3 (75.0)	1.389	.738
	Middle school	20 (50.0)	20 (50.0)		
	High school	22 (55.0)	18 (45.0)		
	College or above	28 (52.8)	25 (47.2)		
Caregivers' relationship with patients	Spouse	44 (51.2)	42 (48.8)	4.671	.196
	Daughter/son	17 (58.6)	12 (41.4)		
	Brother/sister	10 (55.6)	8 (44.4)		
	Parent	0	4 (100.0)		
Family Adaptability and Cohesion Scores	Lower	28 (42.4)	38 (57.6)	4.508	.034
	Higher	43 (60.6)	28 (39.4)		

TABLE 4 Binary logistic regression analysis to identify variables associated with patient-caregiver dyads concordances

Model	B	SE	Wald χ^2	p	Exp (B)	95% CI Exp (B)
Comorbidity	−1.043	0.417	6.253	.012	0.352	0.155–0.798
Distress Disclosure	−0.912	0.393	5.385	.020	0.402	0.186–0.868
Cox and Snell R^2 /Nagelkerke $R = 0.163/0.217$	—	—	—	—	—	—

Abbreviations: B, regression coefficient; CI, confidence interval; SE, standard error.

4.1 | Implications for clinical practice

Congruency in psychological distress may provide crucial information about how patients and caregivers cope with the psychological impacts of cancer. This study demonstrated that the caregivers of breast cancer patients undergoing chemotherapy tended to underestimate the patients' psychological distress. We found that the level of concordance between patients' and caregivers' psychological distress reports was associated with the patient's comorbid conditions and the level of self-disclosure. Our findings increase the awareness of the importance of the caregivers' understanding of patients' psychological distress and indicate the directions of dyadic psychosocial education among patients with breast cancer undergoing chemotherapy and their caregivers. Patient education should encourage them to share their distressing thoughts and feelings and take advantage of emotional support (especially family-based support). Furthermore, healthcare providers should educate caregivers to improve their perceptions of patients' psychological distress and

adjust their emotional support strategies to promote patients' recovery further physically and psychologically. Distress assessment and management for patients with breast cancer undergoing chemotherapy are highly recommended in the Chinese context.

4.2 | Limitations

This study has certain limitations. First, all participants were recruited from one hospital, and this may generate selection bias. Second, as the study was done with female patients with breast cancer undergoing chemotherapy, the results may not be generalizable to other cancer diagnoses or males. Third, whether the concordances in patients' and caregivers' perception of psychological distress positively or negatively affect patients' or caregivers' health outcomes was not explored. We recommend future multicentre studies including patients with different genders and examination of the effects of concordances.

5 | CONCLUSIONS

The concordance between patients' reports of psychological distress and caregivers' perceptions is relatively low. Comorbid conditions and a lower level of self-disclosure contribute to this bias. Patient and caregiver education should be implemented to improve this concordance. More psychological care and substantial emotional support should be provided for Chinese breast cancer patients undergoing chemotherapy by caregivers and healthcare providers to alleviate their distress and improve their quality of life.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

AUTHOR CONTRIBUTIONS

Huihui Zhao: conceptualization, methodology, software, data curation, formal analysis, writing—original draft. Xiaojin Li: conceptualization, methodology, writing—review & editing. Chunlan Zhou: supervision, funding acquisition, writing—review & editing. Yanni Wu: formal analysis, data curation. Wenji Li: investigation. Liling Chen: investigation.

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Cross-Cultural Adaptation and Validation of the Emotional Inhibition Scale in a Chinese Cancer Sample

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The Emotional Inhibition Scale (EIS) is a brief measure based on a four-factor model with documented validity in a mood disorder sample that may be useful for assessing emotional inhibition in patient populations, such as individuals with cancer. The present study adapted the EIS to Chinese conditions and examined the psychometric characteristics of the EIS in patients with cancer. The recruited participants comprised a sample of 100 patients (sample 1) and a sample of 202 patients (sample 2) with cancer. The two samples (sample 1 and sample 2) with cancer completed surveys including the EIS. The Toronto Alexithymia Scale-20 was completed by the two sample groups to assess criterion validity. Statistical analyses included internal consistency (sample 1), exploratory factor analyses (EFAs; sample 1), and confirmatory factor analyses (CFAs; sample 2). The results showed that EFA and CFA confirmed the four-factor solution proposed by the original authors (verbal inhibition, self-control, disguise of feelings, and timidity). The internal consistency and test-retest reliability of the EIS were satisfactory. In conclusion, the EIS demonstrated acceptable reliability and validity for assessing emotional inhibition in Chinese-speaking patients with cancer and may be a useful measure for assessing the level of emotional inhibition and the effect of emotional disclosure interventions.

Keywords: cancer, reliability, validity, emotional inhibition, Chinese, confirmatory factor analysis

INTRODUCTION

Emotional inhibition (EI) refers to the tendency to consciously inhibit emotional expressions while emotionally aroused (Coggins and Fox, 2009; Ellis and Cromby, 2012; Traue et al., 2016). Overt EI is characterized by unemotional language, reduced expressiveness, and shyness, all of which are linked to dysfunctional bodily reactions and may be adaptive in a short-term social stress situation. EI in the long term is considered an underlying cause of psychopathology and may adversely impact psychological and health outcomes (Traue et al., 2016). However, little is known about the correlates and potential causes of EI. EI has been linked to the adaptation and well-being of patients. Recent studies strongly related EI to anxiety disorders (Zimmermann et al., 2015; Peh et al., 2017), depression (Langner et al., 2012; Li et al., 2015), substance misuse (Marceau et al., 2018), eating disorders (Ferrer et al., 2017), paranoia (Nittel et al., 2018), and borderline personality disorder (Popolo et al., 2014; Salvatore et al., 2016).

Patients with cancer who reported the use of generally less adaptive strategies to regulate or express their emotions (e.g., suppression or inhibition) also reported more emotional distress

and lower well-being (Peh et al., 2016, 2017). A wide range of self-report measures have been developed to assess the emotional regulation and related constructs (e.g., the Emotion Regulation Questionnaire; the Cognitive Emotion Regulation Questionnaire; and the Emotional Expressivity Scale). However, decisions regarding which measure to use are challenging given the diverse conceptualizations and elements of emotional regulation (Brandão et al., 2016). Most instruments focus on tendencies to suppress the expression of negative emotions and include a wide range of specific strategies, including conscious suppression and increasing defensive strategies, which help individuals to eliminate negative affect (Brandão et al., 2016). The results are used to identify patients who might be at risk for emotional disorders and might benefit from supportive interventions. However, these assessments mostly focus on general measures to assess the ability of coping strategies to regulate emotions or emotional expression, which indirectly assess the inhibition of emotions (Brandão et al., 2016). Few assessments have directly examined the trait qualities of EI. In summary, the lack of assessment tools has limited the development of EI research in China.

Robert Kellner developed the Emotional Inhibition Scale (EIS) in 1986 as a self-rating instrument based on clinometric principles that are used to evaluate the beliefs of a person in suppressing feelings and emotions (Kellner, 1986; Grandi et al., 2011). The EIS is the only reliable instrument that explains the behavior and intrinsic features of EI. In recent studies, the EIS has been administered to cardiac recipients, hirsute women, patients with hypochondriacal attitudes, patients with personality disorders, patients with somatic concerns, and patients with panic disorders (Fava et al., 1989; Grandi et al., 2011; Salvatore et al., 2016; Dimaggio et al., 2018). The EI plays an important role in the onset, evolution, and outcome of psychological difficulties (Soto et al., 2011; Ellis and Cromby, 2012). The psychometric attribute of the EIS should be tested to further develop its incremental validity for EI and its sensitivity to change after treatments designed to increase emotional disclosure.

The present study was undertaken to fill the gap mentioned above. This study was designed to (1) translate the EIS into simplified Chinese and provide cross-cultural adaptation in China, (2) evaluate the validity and reliability of the Chinese version of the EIS (C-EIS) in a sample of Chinese-speaking patients with cancer, and (3) determine the demographics affecting the EI of patients with cancer. The current findings contribute to a better understanding of EI in Chinese patients with cancer to help medical staff develop specialized psychological interventions for these patients in the future. This scale may be a useful measure to assess the level of EI and the effects of emotional disclosure interventions.

MATERIALS AND METHODS

Translation and Modification Procedure

The permission to translate and use the EIS was obtained via email correspondence with the author of the original version (Kellner, 1986). The translation process and cultural adaptation were based on the suggestions of classic Brislin's

double translation and back translation guidelines (Cha et al., 2007). Using the same setup as the original English language version, two researchers with knowledge in psychology and extensive experience in translating psychological tests and measures translated the EIS from English to Chinese, and two bilingual research assistants translated it back to English. A panel of six experts was convened to discuss the appropriateness of the translations item by item and determine the cultural equivalence of the C-EIS. A pilot test consisting of 30 patients with cancer was implemented with the prefinal version of the C-EIS, and further alterations to phrasing were performed according to the feedback from participants on the scale. For example, item 9 "Do you speak up for your rights?" was revised to "Do you stick to your rights." Item 15, "Would you like to tell someone how you feel but are too inhibited to do so," was revised to "Would you like to tell someone how you feel but it is too hard for you to do so." After that, all the items were rediscussed and adjusted by the expert panel until there were no substantial differences, and the final version of the C-EIS was formed.

Participants and Procedures

A cross-sectional study design was used to assess the psychometric properties of the C-EIS. The data were collected at a tertiary grade A comprehensive hospital in Guangzhou, China, between January and April 2019. Using convenience sampling, we invited patients to participate in the study if they (1) had a confirmed pathological cancer diagnosis, (2) were over 18 years old, (3) could answer the questionnaire independently, and (4) provided written informed consent. Patients were excluded if they had a diagnosed psychiatric disorder. To better represent the cancer population, this study adopted sampling of participants with cancer, and the incidence rates ranked in the top 10 according to the latest global cancer data of 2018, which are listed as follows: lung cancer, breast cancer, prostate cancer, colon cancer, nasopharyngeal cancer, gastric cancer, liver cancer, rectal cancer, esophageal cancer, and uterine cervical cancer.

A sample size should be 5–10 times larger than the number of items in the scale based on the Kendall sample estimation method (Zou, 2012). A minimum sample size of 80 was determined because the number of items in the EIS was 16. This survey was performed as a two-phase process. First, 100 patients took the survey, which exceeded the required sample size mentioned above. However, because the factors determined by exploratory factor analysis (EFA) were slightly different from the original English version, we involved another group of subjects for confirmatory factor analysis (CFA) because the data for EFA could not be used repeatedly for CFA. Another group of 202 patients was involved in the second phase, which exceeded the suggested minimum sample size of 200 for a CFA (Marsh et al., 1998). Finally, 30 patients who were randomly selected from the two samples completed the C-EIS again after a 3-week interval to evaluate test–retest reliability.

This study was performed based on the principles outlined in the Declaration of Helsinki 2013 (Mastroiolo, 2016), and approval was obtained from the Medical Ethics Committee of the case hospital (NFEC-2018-049). Informed consent was signed by all participants, and the survey questionnaires were

completed voluntarily. It was emphasized that the privacy of participants was kept strictly confidential throughout the whole study process.

Measurements

Sociodemographic and Clinical Characteristics

Sociodemographic data, including age, sex, marital status, faith, family income, education, and profession, were collected. Clinical characteristics data on diagnosis, disease information, medical expenses payment method, and recent treatment were also collected.

Emotional Inhibition Scale

The EIS was developed by Robert Kellner (Kellner, 1986) to measure the belief of a person in suppressing the feelings and emotions found in psychosomatic investigations. The EIS includes four subscales: timidity, verbal inhibition, self-control, and disguise of feelings. It is a 16-item instrument rated on a 5-point Likert-type scale (no = 0, always = 4). The sum of the 16 items is the total EI score, which ranges from 0 to 64. Higher scores demonstrate a higher degree of introversion, emotional restriction, and timidity. The EIS has good construct validity and internal reliability (Grandi et al., 2011). The Cronbach's α coefficient for the scale was 0.95, and the coefficients for the four subscales ranged from 0.77 to 0.95. The CFA results showed acceptable global goodness of fit [comparative fit index (CFI) = 0.925].

Toronto Alexithymia Scale-20

The Toronto Alexithymia Scale (TAS)-20 was conceived by Bagby et al. (1994) to measure the difficulty of a person in identifying, describing, and communicating one's feelings to others. The concept of alexithymia is related to EI. The TAS-20 is a 20-item instrument rated on a 5-point Likert-type scale (1 = strongly disagree, 5 = strongly agree). This instrument is composed of three subscales: externally oriented thinking, difficulty in describing feelings, and difficulty in identifying feelings. The Chinese version of the TAS-20 was used in this study, and it has good construct validity and internal reliability (Ling et al., 2016). The Cronbach's α coefficient for the scale was 0.87, the coefficients for the four subscales ranged from 0.47 to 0.84, and the CFA results showed acceptable global goodness of fit [CFI = 0.92, goodness-of-fit index (GFI) = 0.94].

Statistical Procedures

Statistical Package for the Social Sciences (SPSS) 17.0 software was used to perform EFA and descriptive statistics that summarized the sociodemographic and clinical characteristics of all the participants. Automated Meteorological Observation Station (AMOS) 24.0 software was used to perform CFA. $P < 0.05$ was considered statistically significant.

Three types of coefficients were used to test the reliability of the C-EIS. Cronbach's α coefficient was calculated to examine internal consistency reliability, where α coefficients > 0.7 indicated that the reliability coefficient was acceptable. The Spearman-Brown coefficient was used to test the split-half reliability of the scale, and the Pearson correlation

TABLE 1 | Sociodemographic and clinical characteristics.

Characteristics	Value	
	Sample 1	Sample 2
Age	58.1 $\pm$ 10.9 (<i>n</i> = 100)	51.7 $\pm$ 12.5 (<i>n</i> = 202)
Gender (%)		
Male	73 (73.0)	105 (52.0)
Female	27 (27.0)	97 (48.0)
Religious belief (%)		
Yes	28 (28.0)	40 (19.8)
No	72 (72.0)	162 (80.2)
Place of residence		
Town	54 (54.0)	102 (50.5)
Countryside	46 (46.0)	100 (49.5)
Profession		
Civil servant	16 (16.0)	32 (15.8)
Housewife	6 (16.0)	36 (17.8)
Businessman	9 (9.0)	14 (6.9)
Farmer	29 (29.0)	57 (38.2)
Worker	22 (22.0)	24 (11.9)
Other	18 (18.0)	39 (19.3)
Marital status (%)		
Married	93 (93.0)	186 (92.1)
Single/divorced/widowed	7 (7.0)	16 (7.9)
Education level (%)		
Primary or under	27 (27.0)	42 (20.8)
Junior high school	33 (33.0)	72 (35.6)
Senior high school	18 (18.0)	40 (19.8)
College or above	22 (22.0)	48 (23.8)
Medical expenses payment method		
New rural medical insurance	39 (39.0)	79 (39.1)
Social security	57 (57.0)	115 (56.9)
Self-pay	4 (4.0)	8 (4.0)
Household monthly income (Chinese Yuan) (%)		
<3,500	44 (44.0)	120 (59.4)
3,500–5,000	28 (28.0)	69 (34.2)
>5,000	28 (28.0)	13 (6.4)
Duration of disease (years) (%)		
<1	77 (77.0)	139 (68.8)
1–3	13 (13.0)	44 (21.8)
<3–5	5 (5.0)	11 (5.4)
>5	5 (5.0)	8 (4.0)
Types of cancer		
Lung cancer	14 (14.0)	42 (20.8)
Breast cancer	5 (5.0)	51 (25.2)
Prostate cancer	5 (5.0)	11 (5.4)
Colon cancer	13 (13.0)	16 (7.9)
Nasopharyngeal cancer	26 (26.0)	17 (8.4)
Gastric cancer	13 (13.0)	16 (7.9)
Liver cancer	4 (4.0)	19 (9.4)
Rectal cancer	11 (11.0)	8 (4.0)
Esophagus cancer	9 (9.0)	7 (3.5)

(Continued)

TABLE 1 | Continued

Characteristics	Value	
	Sample 1	Sample 2
Uterine cervical cancer	0 (0.0)	15 (7.4)
Whether to transfer		
Yes	39 (39.0)	70 (34.7)
No	61 (61.0)	132 (65.3)
Whether recurrence		
Yes	13 (13.0)	26 (12.9)
No	87 (87.0)	176 (87.1)
Disease staging		
I stage	3 (3.0)	7 (3.5)
II stage	47 (47.0)	90 (44.6)
III stage	10 (10.0)	35 (17.3)
IV stage	40 (40.0)	70 (34.7)
Recent treatment		
Surgery	50 (50.0)	57 (28.2)
Chemotherapy	39 (39.0)	88 (43.6)
Radiotherapy	2 (2.0)	6 (3.0)
Targeted therapy	0 (0.0)	31 (15.3)
Nutritional treatment	1 (1.0)	8 (4.0)
Other	8 (8.0)	12 (5.9)

coefficient r between the scores of the test-retests was used to explore the total test-retest reliability ($r > 0.8$ showed good test-retest reliability). The intraclass correlation coefficient (ICC) is also a good indication for test-retest reliability. A recent study provided ICC values that ranged from fair agreement (<0.40) to almost perfect agreement (>0.80). The corrected item-total correlation was used as a type of item analysis, with a value >0.30 , as recommended (Andresen, 2000).

Content validity for the scale may be measured by using the content validity index (CVI). An expert panel (four clinical nursing specialists, one nursing magazine editor, and one nursing educator) was formed to assess the CVI of the C-EIS. An evaluation scale was distributed to the expert panelists. The experts were asked to correspondingly rate the relevance and clarity of each item using 4-point Likert scales ranging from 1 (very unclear and needs full revisions) to 4 (very clear and does not need to be revised). The CVI was calculated for the scale level (S-CVI) and each item level (I-CVI), with a minimum acceptable value of 0.78, as recommended (Lynn, 1986).

Construct validity was estimated using item analysis, EFA, and CFA. EFA was used for dimension reduction and identification of the factor structure (principal components with varimax rotation). The following criteria were used for item retention and factor extraction: (a) each factor had three items loading or above; (b) factor loading >0.40 ; (c) eigenvalue >1.0 ; and (d) no cross-loading items on two factors or above (Fang, 2001). The EFA-derived structure was investigated using Velicer's minimum average partial (MAP) test combined with parallel

analysis to corroborate the number of EIS factors (Ye et al., 2018).

The factorial structure of the C-EIS was tested using the CFA model identified in the exploratory study. The parameter estimates (factor loadings and covariances) and model fit indices were used to test the model goodness of fit. The following criteria of model fit were used: standardized root mean square residual (SRMR) < 0.08 ; GFI > 0.9 ; ratio of the chi-square statistic to degrees of freedom (χ^2/df) < 3 ; Tucker-Lewis index (TLI) > 0.9 ; root mean square error of approximation (RMSEA) < 0.08 , and CFI > 0.9 (Marsh et al., 1998).

Construct validity was also assessed by comparisons of contrasted groups based on the expected hypotheses of differences in C-EIS scores for groups split by different disease staging, type of cancer, and time since diagnosis. The following hypotheses were proposed: (1) Patients who have more severe cancer will have higher scores because pain from cancer may aggravate the inhibition of emotion (Cardenal et al., 2012), (2) The type and site of cancer may impact the emotional expression of patients because various cancers may have entirely different psychosocial factors associated with them (Batty et al., 2017), and (3) Patients who have been living with cancer for a longer time may have higher EI scores. The diagnosis and treatment of cancer is a source of distress, and EI may be more obvious with more time to understand the situation (Chapman et al., 2013).

Convergent validity was assessed using the correlation between the scores of the C-EIS and those of the TAS-20. Normality analysis was performed before Pearson analysis. This study considered 0.30 as the minimum acceptable Pearson correlation value (Heinl et al., 2016).

RESULTS

In the first phase of the 107 survey questionnaires distributed to the participants, two were missed and five were excluded due to incomplete items. Therefore, a total of 100 participants were included, with a valid response rate of 93.45%. In the second phase of the 212 survey questionnaires distributed to the participants, four were missed and six were excluded due to incomplete items. Finally, a total of 202 participants were included, with a valid response rate of 95.28%. The response rate of test-retest was 100%.

Sociodemographic and Clinical Characteristics

A total of 302 patients were involved in the two-phase process. Sample 1 was comprised of 27 women and 73 men (mean age, 58.1; SD, 10.9 years; range 22–77 years), and sample 2 was comprised of 97 women and 105 men (mean age, 51.7; SD, 12.5 years; range 20–81 years). Nearly one-quarter of the sample 1 group had nasopharyngeal cancer, and one-quarter of the sample 2 group had breast cancer. There were some common characteristics of the two samples. Nearly half of the diseases were stage II, and most treatments were surgery and chemotherapy. Nearly half of the household monthly income was $\leq 3,500$ Chinese yuan, and medical expenses were paid through

TABLE 2 | Mean, SD, item analysis, and reliability analysis of C-EIS ($n = 100$).

Item number	Mean	SD	Corrected item-total correlation	α if item deleted	α
Verbal inhibition					0.882
EIS2	1.99	1.096	0.738	0.863	
EIS4	1.91	1.102	0.776	0.829	
EIS5	1.77	1.024	0.803	0.807	
Self-control					0.749
EIS1	2.17	1.295	0.505	0.715	
EIS8	2.35	1.184	0.615	0.651	
EIS10	2.61	1.081	0.645	0.642	
EIS14	1.89	1.238	0.434	0.752	
Timidity					0.602
EIS3	1.92	1.316	0.389	0.533	
EIS6	1.63	1.315	0.453	0.436	
EIS7	2.07	1.281	0.389	0.532	
Disguise of feeling					0.784
EIS12	1.68	1.18	0.561	0.747	
EIS13	1.66	1.139	0.593	0.73	
EIS15	1.72	1.198	0.6	0.727	
EIS16	1.84	1.07	0.612	0.722	

TABLE 3 | Reliability analysis of the C-EIS.

Subscale	Mean (SD)	Cronbach alpha	Range ICC	Subscale ICC	Test mean (SD)	Retest mean (SD)
Verbal inhibition	5.67 (2.90)	0.882	0.30–0.86	0.62	9.52 (2.62)	9.20 (3.19)
Self-control	9.02 (3.63)	0.749	0.46–0.94	0.811	12.73 (3.11)	13.67 (3.74)
Timidity	5.62 (2.92)	0.602	0.69–0.88	0.944	6.74 (3.00)	6.93 (2.92)
Disguise of feeling	6.90 (3.58)	0.784	0.10–0.62	0.477	10.40 (2.59)	11.07 (3.22)

C-EIS, Chinese version of Emotional Inhibition Scale; ICC, intraclass correlation coefficient.

social security. Nearly 70% of the time since diagnosis was <1 year (Table 1). For the significance level of demographic factors on the EIS, only three significant variables were identified in the multivariate analysis (Supplement 1): sex ($\beta = 0.115$, adjusted $R^2 = 0.033$, $p = 0.048$), place of residence ($\beta = 0.118$, adjusted $R^2 = 0.057$, and $p = 0.039$), and disease stage ($\beta = 0.358$, adjusted $R^2 = 0.040$, and $p = 0.046$).

Psychometric and Validation Testing

Reliability

Item analysis and reliability results are listed in Table 2. The Cronbach's α coefficient of the EIS was 0.717 for the total scale and 0.602–0.882 for the four subscales. For split-half reliability, the Spearman–Brown coefficient was 0.755 ($P < 0.05$). The total test–retest reliability was 0.855, which indicates great consistency between the two testing times. Table 3 lists the ICC values for the four domains. The item–total correlations ranged from 0.389 to 0.802.

Content Validity

The S-CVI value was 0.915, and the I-CVI value was not less than 0.83, which indicated good content validity of the C-EIS. The

expert panel reduced the risk of errors from inherent differences in the language structure between Chinese and English and helped identify the most accurate and easily understood terms for the C-EIS.

Exploratory Factor Analysis

EFA of the 14 items revealed a Kaiser–Meyer–Olkin value of 0.717, and the Bartlett spherical test value was 485.45 ($\chi^2 = 485.5$, $df = 91$, and $p < 0.001$), which indicated that it was adequate for EFA. First, five common factors, with an eigenvalue of 1.0 or greater, were confirmed by an EFA of the 16 items. The factor loading of item 9 (0.378) was too low to be retained. Item 11 was deleted because only one item loaded on one extra factor. Finally, a four-factor structure was extracted. The first four eigenvalues from the actual dataset of the EIS scores in the parallel analysis were 3.06, 1.86, 1.52, and 1.08. The corresponding first four 95th-percentile random-data eigenvalues were 1.46, 1.34, 1.27, and 1.21, respectively, which indicates that four factors were the best option for the structure of the EIS (Supplement 2). The MAP test showed that when the root was 3 or 4, we obtained the smallest average 4th-power partial correlation of 0.00375. A total of 65.6% of the variance in the data were explained, of which

TABLE 4 | The exploratory factor analysis results of the C-EIS ($n = 100$).

Item number and description	Factors			
	1	2	3	4
Verbal inhibition				
(5). Do you tell people exactly what you think?	0.896	0.045	−0.153	0.031
(4). Do you show how you feel?	0.891	0.001	−0.08	−0.183
(2). Do you find it easy to talk about your feelings?	0.856	0.121	−0.187	−0.03
Disguise of feeling				
(16). Do you let your friends see what your mood is?	0.172	0.789	−0.092	−0.014
(12). Do you stop yourself from saying something because it might hurt another person?	0.111	0.776	−0.01	−0.138
(15). Would you like to tell someone how you feel but are too inhibited to do so?	−0.004	0.768	0.147	0.073
(13). Do you feel that you let people take advantage of you?	−0.12	0.765	0.16	0.185
Self-control				
(10). Do you try to appear calm when you are anxious and worried?	−0.119	0.023	0.831	0.021
(8). When you are angry, do you try to control yourself?	−0.13	0.016	0.817	−0.013
(1). Do you try to be polite even when people are rude to you?	−0.231	0.16	0.681	−0.079
(14). Do you pretend to be cheerful even when you feel sad?	0.023	0.007	0.646	0.304
Timidity				
(6). Do you find it difficult to insist on your rights?	0.019	0.202	0.04	0.752
(3). Do you find it difficult to speak up when you feel that you are being wronged?	0.02	−0.021	−0.015	0.724
(7). Do you find it difficult to talk about your true feelings even with close friends?	−0.237	−0.101	0.117	0.708
% of the variance	18.05	17.81	17	12.75
Cumulative variance	18.05	35.86	52.83	65.58

Factor loadings with an absolute value >0.400 are displayed in bold.

factor 1, 2, 3, and 4 explained 18.1, 17.8, 17.0, and 12.7% of the variance, respectively. The factor loadings for the 14 items ranged from 0.602 to 0.882, which satisfied the criterion of 0.4 or above (Table 4). The four factors were named based on the nature of the items loading on the corresponding factor: verbal inhibition (factor 1), self-control (factor 2), timidity (factor 3), and disguise of feeling (factor 4).

Confirmatory Factor Analysis

The SEM confirmed the EFA-derived four-factor structure, and some of the results of the goodness of fit indices were $\chi^2/df = 1.438$ ($=p < 0.001$), RMSEA = 0.061, TLI = 0.861, and IFI = 0.911, which indicates that a satisfactory model fit the data in four-factor CFA (Table 5). The factor loading ranged from 0.32 to 0.83. Based on the modification indices, several paths of covariance between error and items were added to achieve an improved fitting model. The paths between observed variables, latent variables, and residuals are shown in Figure 1.

The contrasting group comparisons showed that the hypothesis of expected differences for patients with esophageal cancer and more advanced cancer stage had higher scores for the C-EIS. However, there was no significant difference for time since cancer diagnosis (Table 6).

Convergent Validity

Although the strength of associations was relatively small, the score of the C-EIS was significantly associated with the TAS ($r = 0.322$, $P < 0.01$), which provides further evidence supporting the

TABLE 5 | Goodness-of-fit indices for the four-factor model in CFA ($n = 202$).

	χ^2/df	RMSEA	SRMR	CFI	TLI	IFI	GFI
Result	1.741	0.061	0.086	0.905	0.861	0.911	0.929

convergent validity. For the subscales, the details of convergent validity and discriminative validity are shown in Supplement 3.

DISCUSSION

The present study provides initial evidence for the reliability, construct validity, content validity, and convergent validity of the C-EIS in a sample of Chinese patients with cancer. The EIS is brief and may be completed within 10 min. The EIS is easy to perform because of the lack of complex sentences and calculations. Therefore, nurses and psychologists can use the EIS to assess the level of EI and the effect of emotional disclosure interventions.

The sample 2 group ($n = 202$) was recruited to evaluate the psychometric properties of the C-EIS. Based on the findings of the exploratory study, the C-EIS was modified to construct a Chinese version with four subscales: timidity, verbal inhibition, self-control, and disguise of feelings. The results of the factorial structure of the C-EIS of EFA were identical to the results of CFA. Factor analysis revealed four factors that fit easily into the four-dimensional model. This result is similar to the English version

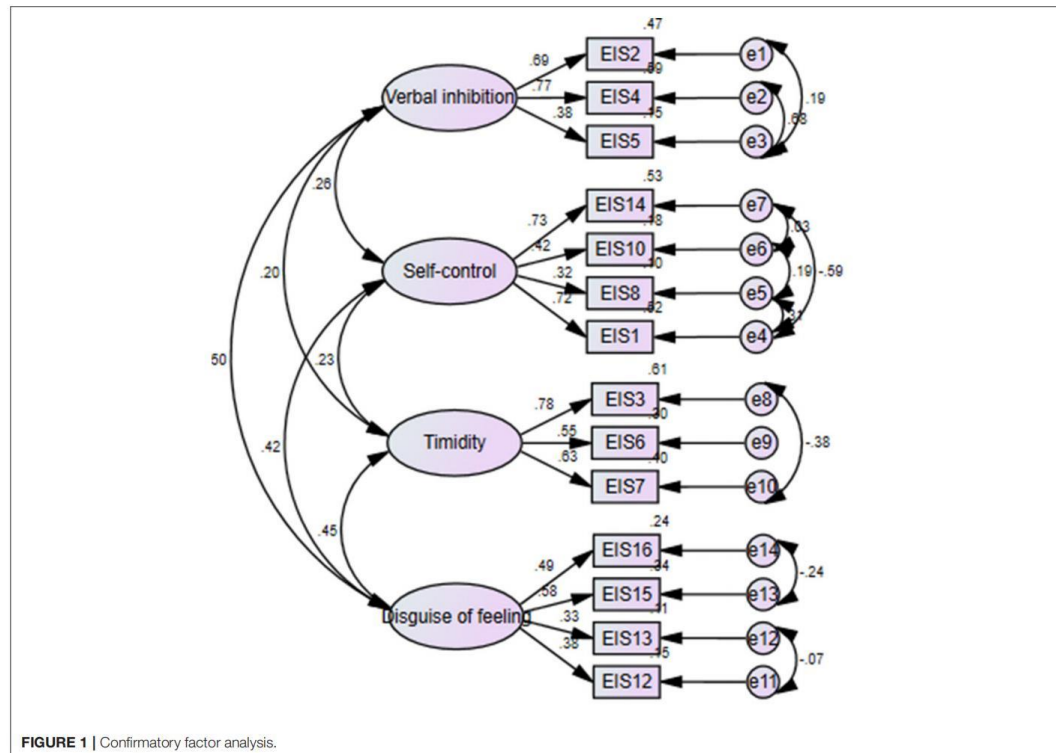


FIGURE 1 | Confirmatory factor analysis.

of the EIS, which also extracted four factors, although not every item in the principal component was the same. Item 9 (“Do you speak up for your rights?”) was problematic, with a low factor loading (<0.40), and item 11 (“Do you speak your mind even if it is bad for you?”) was deleted because of only one item in a different domain of content. The results from the validation sample indicate that the C-EIS had high validity, reliability, and a four-factor structure, which is the same as the original structure. The data provide further evidence of the multidimensional nature of EI. The shift of these items compared to the original EIS may be due to the potential differences in culture, samples, race, ethnicity, and/or some social factors between American and Chinese patients. The differences in the sample type of disease, sample size, age of participants, sex distribution, and disease condition between previous studies and the present study may result in differences in the items retained in the model.

The known-group comparison showed the construct validity to some extent. Two of the three hypotheses were confirmed, which means that the C-EIS distinguished between low and high known groups in patient disease characteristics that affected their expression of emotion. The expected hypothesis based on time since cancer diagnosis was not supported, which might indicate that patients with cancer adjust themselves

and adapt to the cancer diagnosis and treatment (Peh et al., 2016). The results from the known-group comparison in this study showed that patients with higher stages of cancer had higher levels of EI, which reminds health-care professionals to pay more attention to patients with more malignant cancer.

Although the C-EIS score in this study was significantly associated with the TAS score, the association was relatively small, which is consistent with a previous study (Kessler et al., 2010; Grandi et al., 2011). Grandi et al. (2011) reported that EI was a concept similar to alexithymia. To some extent, alexithymia positively correlated with the subscale “verbal inhibition” in the EIS, although it was basically independent from the “self-control,” “timidity,” and “disguise of feelings” subscales in the EIS.

Clinical Implications

The EIS might be useful in studies of the physiology of EI and influencing factors in patients with cancer. Of course, this simple assessment may be used in clinical practice with emotional disclosure intervention. The EIS identified high levels of EI in patients and assessed their response to the intervention. We also found that two variables affected EI levels of patients:

TABLE 6 | Contrasted group comparisons ($n = 302$).

Subgroups comparisons	Statistic value	Adjusted <i>P</i>
Cancer staging	4.221	0.004*
I–II stage	78.87	0.035
I–III stage	82.64	0.040
I–IV stage	99.82	0.003
II–III stage	3.77	1.00
II–III stage	20.95	0.362
II–IV stage	17.18	1.00
Types of cancer	1,838.87	<0.01*
Time since cancer diagnose (year)	2.285	0.319*

* χ^2 -value; *rank sum test.*P* value <0.05 are displayed in bold.

cancer stage and type of cancer. The EIS serves as a reminder to health-care professionals to provide ongoing evaluation and intervention in patients with different types and stages of cancer.

Limitations and Future Research

There are some limitations in this study. First, the current sample was relatively small. The patients from this study were limited to those with cancer at a tertiary grade A hospital in Guangzhou, so it is less persuasive to generalize these results to other populations and regions in China. Future studies should recruit more representative samples to replicate and verify the results in other populations and various regions of China and establish the Chinese norm of the C-EIS. It is also necessary to evaluate the minimum clinically important difference in future research before we use the EIS as a primary or secondary outcome in randomized controlled clinical trials (RCTs). Second, this study depended exclusively on the self-report data collection method, which may have some serious issues, such as bias or inaccurate reporting. Future research may include another objective approach to assess the influence of EI and its consequences, such as behavioral and physiological measures and experimental paradigms. Third, this validation

study was based on the classic theory test (CTT), and it will be useful to perform item response theory (IRT) in future research to provide additional important information (Ye et al., 2019, 2020).

CONCLUSIONS

The present study provided reliability and validity evidence of the C-EIS for assessing emotional characteristics in patients with cancer. Our findings confirmed four factors in the C-EIS, including verbal inhibition, self-control, disguise of feelings, and timidity. The C-EIS can be readily used to assess emotional care of patients with cancer in China, the level of EI, and the effect of emotional disclosure interventions.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Medical Ethics Committee of Nanfang Hospital. Written informed consent to participate in this study was provided by the participants' legal guardian/next of kin.

AUTHOR CONTRIBUTIONS

LL collected and analyzed the data, interpreted the results, and wrote the manuscript. YX prepared the submission materials and collected the data. YW performed the analyses and revised the manuscript. XL designed the study and wrote the manuscript. CZ revised the manuscript critically. All authors contributed to the article and approved the submitted version.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpsyg.2021.654777/full#supplementary-material>

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RESEARCH ARTICLE

Effect of Expressive Writing Intervention on Health Outcomes in Breast Cancer Patients: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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Abstract

Background

Numerous randomized controlled trials (RCTs) have arrived at conflicting conclusions on expressive writing (EW) as an intervention for breast cancer (BC) patients, but there has been no meta-analysis of these studies to assess the effectiveness of EW in BC population.

Methods

PubMed, Web of Science, The Cochrane Library, EMBASE, and CINAHL and the www.clinicaltrials.gov database on ongoing clinical trials were searched to identify all the RCTs investigating efficacy of EW on the physical and psychological health in BC patients. The risk of bias of the original studies was assessed using the Cochrane Collaboration's tool. Our primary outcomes for physical and psychological health were respectively negative somatic symptoms and negative mood which were stratified by emotional, benefit-finding and multiple prompts in sub-group analyses. The data were analyzed using Review Manager 5.2 and Stata version 12.0 statistical software.

Results

Of the 5,232 titles screened, we identified 11 RCTs with a total of 1,178 participants. The pooled results showed a significant effect of EW using either an emotional prompt or a benefit-finding prompt on reducing negative somatic symptoms in BC patients in the ≤ 3 -month follow-up group [Mean Difference (MD), -13.03, 95% CI, -19.23 to -6.83, $P < 0.0001$; MD, -9.18, 95% CI, -15.57 to -2.79, $P = 0.005$]. There was no significant effect of EW on physical health in the > 3 -month follow-up group. There were no significant differences regarding psychological health indexes between EW intervention and control groups at any of the follow-up time-points ($P > 0.05$).

Conclusion

This systematic review and meta-analysis reveals that EW intervention may have a significantly positive impact on the physical health but not the psychological health in BC patients, but this benefit may not last long. However, further high-quality studies with more homogeneity are needed to confirm the current findings.

Introduction

Emotional expression, as a psychological or medical intervention, has been studied for many years, demonstrating favorable impacts on physical and mental health [1–7]. Expressive writing (EW) as a form of emotional expression was first implemented in college students in 1986 by Pennebaker and Beall, who instructed respondents to write about their deepest emotions and thoughts regarding traumatic/upsetting experiences for approximately 20 minutes over four consecutive days [8]. Afterwards, work on EW as a potential intervention for physical and psychosocial adjustment was extended to clinical and medical populations, including non-patients [9–12] as well as patients with rheumatoid arthritis [13,14], asthma [15], HIV [16], cardiovascular disease [17] or renal cell carcinoma [18]. Since Walker explored the feasibility of using EW in a breast cancer (BC) cohort [19], there have been numerous randomized controlled trials (RCTs) testing effectiveness of EW in BC patients [20–29]. These studies have been performed for reasons like: BC remains the second most frequently diagnosed type of cancer in women [30], many BC patients report feeling emotionally inhibited which has been linked with worse psychological functioning [1,31,32], and physical problems are still highly prevalent in BC population [33–38].

Although EW was generally considered beneficial, some researchers questioned its utility in light of failures to replicate the original findings [15,39]. Some studies reached a negative conclusion on the benefits of EW [40–44] while others demonstrated positive effects of EW on the physical and psychological health in various populations, mostly patients [13,16,45–49]. Systematic reviews of the studies on the efficacy of EW in healthy and unhealthy populations also led to various conclusions [50–55]. Diversified concerns, inclusion of different populations, measurement of different variables and different methodology may have been significant reasons for their inconsistent findings. Harris and Mogk concluded that EW had little effect on the subjects tested [53,54], Frisina and Frattaroli found EW was effective [50,52], but Boinon and Merz could not make a definite conclusion about EW in cancer patients [51,55]. Similarly, studies on EW in BC patients also arrived at conflicting conclusions. Some studies failed to confirm the benefit of EW [19,22,23,26], but others found positive effects of EW on the physical or psychological health of this particular population [20,21,24,25,27–29].

Our concern focuses on the benefits of EW on the physical and psychological health of BC population. Firstly, EW is a low-cost, convenient and self-administered intervention that can be routinely used in clinic if its therapeutic benefits can be confirmed. Secondly, BC victims are overwhelmingly females who have to brave particular physical and psychological challenges that may impact their therapeutic outcomes after diagnosis and treatment of BC [56–63]. There is a great demand to develop all kinds of interventions which may help them cope with their specific physical and psychological challenges on their way to combat BC. Moreover, yearly increase of more than 1.3 million new cases has made BC the most frequently diagnosed cancer in women worldwide [64]. However, numerous studies on EW in BC patients have provided inconsistent findings and there has been no meta-analysis of these studies so far.

According to the literature published, although Boinon and Merz both conducted a systematic review [51,55] of the effectiveness of EW in cancer patients, they did not focus their concern specifically on BC population and did not perform meta-analysis. Therefore, it is necessary to perform a meta-analysis to review all the data from all the high-quality studies available on this topic to make convincing up-to-date conclusions about EW in BC population. This study aimed to test the hypothesis that EW might be a promising clinical intervention to improve the physical and psychological health in BC patients by determining whether EW was beneficial for BC patients, what were the benefits, and how effective was EW in relieving physical and psychological symptoms.

Methods

Search methods

We searched the following databases to identify relevant studies for this meta-analysis and adapted different search strategies according to the query requirements of the individual databases. We limited our search by the time after the year 1986 when the first EW study using Pennebaker's prompt was published. We did not restrict our search by language. The following databases were queried: PubMed (from 1986 to June 2014), Web of Science (from 1986 to June 2014), The Cochrane Library (from 1986 to June 2014), EMBASE (from 1986 to June 2014), and CINAHL (from 1986 to June 2014) (S1 Appendix). We searched the database of ongoing trials, www.clinicaltrial.gov. We also screened the references of included studies to identify additional articles. We did not handsearch journals or conference proceedings, due to limited time and resources.

Inclusion criteria

To ensure homogeneity across studies, we included studies that met the following criteria: (1) a randomized controlled trial (RCT) with an experimental design that included an EW group (expressive writing for at least a single 20-minute session using the Pennebaker and Beall paradigm [8]) and a control group for comparison; (2) women participants with a BC diagnosis, irrespective of their age, BC stage, treatment modality or treatment setting (including inpatient, outpatient and primary care); (3) outcome measures that assessed factors relative to the physical and psychological health of BC patients. We excluded review articles or studies the complete data of which were unavailable.

Assessment of methodological quality

The quality of included studies was assessed using the Cochrane Collaboration's risk of bias tool. Each study was assessed for random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and any other potential sources of bias. Each factor would be rated as "low risk" of bias (e.g., random sequence generation was computer generated), "high risk" of bias (e.g., outcome assessment was not blinded) or "unclear risk" of bias (e.g., did not provide specific information as to whether allocation concealment was used). Disagreements would be resolved by consensus.

Data extraction

Two authors (YNW and XJL) independently extracted the data from each trial using a standardized data extraction form that included general information (author, title, source, contact

address, and year of publication), the trial characteristics (randomization method, blinding, duration of intervention period, length of follow-up, and method for handling missing data), the patient characteristics (sample size, stage of disease, race, age, level of education, average time since diagnosis, and inclusion criteria), the intervention (detailed description of the controlled intervention, mode, and duration) and outcomes (outcome measures and scoring range). When data were missing, one author (YNW) contacted the authors to request additional information. If further information could not be obtained, we coded the variables in question as “NR”.

Data analysis

We used Review Manager 5.2 (Cochrane Collaboration, Oxford, UK) and Stata version 12.0 (Stata Corp, College Station, Texas, USA) for data analysis. Two investigators (YNW and SLA) were involved in the statistical analysis. Measurement of outcomes was considered in terms of original data at each follow-up time point (baseline scores not included). The mean difference (MD) and 95% CI were calculated based on fixed-effect model for continuous variables. The z-test was used to obtain the combined P-values of the included studies with a significance level of $P = 0.05$. The statistical significance of heterogeneity among studies was assessed by calculating the chi-square test (a P-value of 0.10 was regarded as statistically significant). The I^2 was used to quantify the effects of heterogeneity. If statistical heterogeneity (P value ≤ 0.10 and $I^2 \geq 50\%$) was identified, random effects meta-analysis was conducted before the causes of heterogeneity was further investigated by subgroup analysis; if not, a fixed-effects model was used [65]. Egger's test and funnel plot were conducted to investigate the potential publication bias influencing the analysis. To determine whether significant differences would exist between specific variables regarding the effectiveness of EW, subgroup analyses were carried out by sorting the same specific variables reported in the RCTs.

Results

Description of the studies

Search results. We conducted the electronic searches in June 2014. A total of 5232 titles and abstracts were screened, and 1622 duplicates were identified. Of the 3610 screened titles and abstracts, 3587 were excluded. After we read the remaining 23 full-text articles, 12 full-text articles were excluded [66–77] and 11 studies included. No additional studies were identified by searching the reference lists. There were no ongoing studies that we were aware of. The study flow diagram is illustrated in Fig 1.

Included studies. Eleven studies examining the effectiveness of EW as an intervention on the health outcomes in BC patients were included in this meta-analysis [19–29]. Descriptions of the studies and samples are presented in Table 1.

In all the 11 RCTs, the participants had been randomly divided into an EW group and a control group. The intervention methods in the EW groups included EW with an emotional prompt (cancer or any trauma), a benefit-finding prompt (cancer) or multiple prompts (emotional, benefit-finding, cognitive appraisal and coping strategies), and those in the control groups included neutral writing or no writing (usual care or non-cancer attention).

In total, 1178 BC patients were involved, with 613 in the EW intervention groups and 565 in the control groups. The BC stages ranged from 0 to 4. Six studies reported racial distribution of the participants, with the Caucasian race accounting for more than 60% in three studies and greater than 90% in the other three. Age distribution was provided in 10 studies, with an average age of approximately 50 years. Educational background of the subjects was reported in seven studies, in six of which from 40% to 87% of the subjects had a university or higher degree

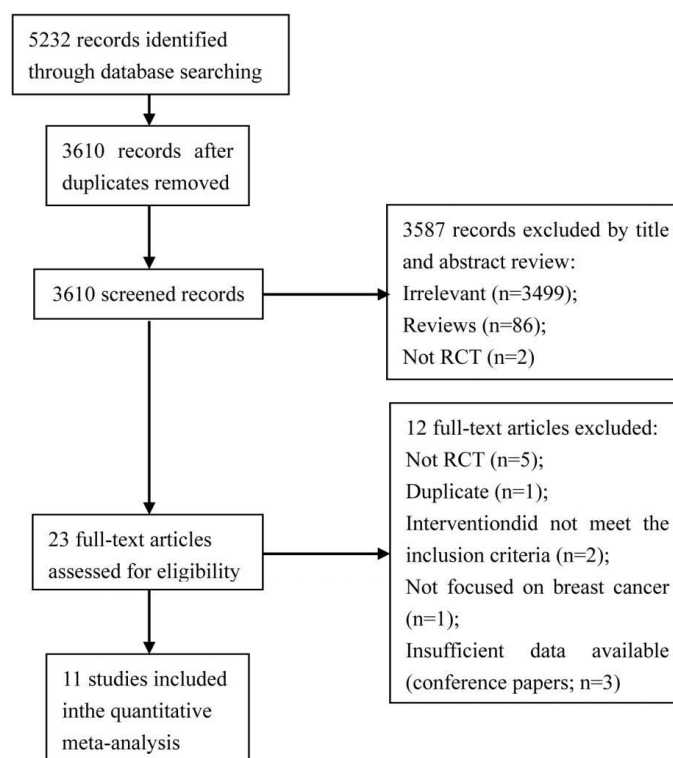


Fig 1. Study flow diagram.

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and in one of which only the average years of education (15.20 ± 2.48) were provided. Five studies reported the time between diagnosis of BC and enrollment of the subjects was between 28.4 weeks and 1.9 years; one study included subjects who were enrolled 4 years after a stage-4 BC diagnosis; one study involved subjects enrolled 151 ± 55 days after operation; the remaining four studies provided no specific time.

The EW intervention in the 11 studies was based on the Pennebaker and Beall [8] paradigm. The number of EW sessions ranged from 1–6 with a minimum of 20 continuous minutes of writing per session. Overall, most of the 11 studies had more than 3 writing sessions. The follow-up time ranged from 1 week to 9 months after the EW intervention, with 3-month follow-up implemented in six studies.

The effect of EW intervention on physical health was evaluated using 11 indexes by eight studies [20–22,24–26,28,29], three of which measured negative somatic symptoms using the negative somatic symptoms scale [78] (Table 1). The effect of EW on psychological health was evaluated using 18 indexes by all the 11 RCTs [19–29], five of which observed negative mood using Profile of Mood States (POMS). Therefore, this meta-analysis decided to take negative somatic symptoms as the primary outcome for physical health and negative mood as the

primary outcome for psychological health. The remaining indexes were regarded as the secondary outcomes for either physical health or psychological health, respectively.

Risk of bias in the included studies. The risk of bias in the 11 studies was assessed using the Cochrane Collaboration's tool. The results are summarized in Fig 2.

Table 1. Characteristics of the included studies

Reference (year)	Sample	Breast cancer stages	Race	Mean age (years)	College educated	Average time since diagnosis	Task	Follow-up	Outcomes
Craft et al. (2013)	97	0–3	92.8% Caucasian	56±10.5	NR	13 months	EW: EMO (<i>n</i> = 26), EMO* (<i>n</i> = 19); Control: NW _c (<i>n</i> = 22), USUAL (<i>n</i> = 30); Four sessions, consecutive days	1 and 6 months	Aspects of psychological health measured using: 1. Functional Assessment of Cancer Therapy-Breast Cancer Version (FACT-B)
De Moor et al. (2008)	49	2–3	63% Caucasian	53.5 ±10.4	78.5%	NR (had finished neoadjuvant chemotherapy)	EW: EMO (<i>n</i> = 24); Control: NW _b (<i>n</i> = 25); Four sessions over 7 days, 3 weeks prior to surgery	3 days pre-surgery and 2 weeks post-surgery	Aspects of physical health measured using: 1. Brief Pain Inventory (BPI), 2. Pittsburgh Sleep Quality Index (PSQI); Aspects of psychological health measured using: 1. Brief Symptom Inventory 18 (BSI-18), 2. Perceived Stress Scale (PSS)
Gellaitry et al. (2010)	80	1–2	NR	57.9 ±9.9	NR	NR (had received radiotherapy treatment)	EW: MULTIPLE (<i>n</i> = 38); Control: USUAL (<i>n</i> = 42); Four sessions, consecutive days (different prompt each day)	1, 3, and 6 months	Aspects of physical health measured using: 1. Healthcare utilization; Aspects of psychological health measured using: 1. Profile of Mood States (POMS), 2. Functional Assessment of Cancer Therapy-Breast Cancer Version (FACT-B)
Henry et al. (2010)	80	1–4	NR	58.9 ±NR	NR	18 months	EW: BEN (<i>n</i> = 40); Control: USUAL (<i>n</i> = 40); One session	3 and 9 months	Aspects of physical health measured using: 1. Physical health measure (included 18 physical symptoms); Aspects of psychological health measured using: 1. Center for Epidemiologic Studies-Depression Scale (CES-D), 2. Profile of Mood States (POMS)
Jensen-Johansen et al. (2012)	507	1–2	NR	53.6 ±9.1	40%	NR (days since surgery 151±55)	EW: EMO* (<i>n</i> = 253); Control: NW (<i>n</i> = 254); Three sessions over 3 weeks	3 and 9 months	Aspects of psychological health measured using: 1. Impact of Events Scale (IES), 2. Beck Depression Inventory-Short Form (BDI-SF), 3. Profile of Mood States (POMS), 4. Passive Positive Mood Scale (PPMS)
Low et al. (2010)	62	4	87% Caucasian	53.8 ±10.3	74%	7.9 years	EW: EMO (<i>n</i> = 31); Control: NW _c (<i>n</i> = 31); Four sessions over 3 weeks	3 months	Aspects of physical health measured using: 1. Negative somatic symptoms scale (developed by Pennebaker, includes 9 somatic symptoms), 2. Pittsburgh Sleep Quality Index (PSQI); Aspects of psychological health measured using: 1. Center for Epidemiologic Studies-Depression Scale (CES-D), 2. Impact of Events Scale (IES)

(Continued)

Table 1. (Continued)

Reference (year)	Sample	Breast cancer stages	Race	Mean age (years)	College educated	Average time since diagnosis	Task	Follow-up	Outcomes
Low et al. (2006)	60	1–2	NR	NR	NR	NR (had completed primary medical treatments)	EW: EMO ($n = 21$), BEN ($n = 21$); Control: NW _c ($n = 18$); Four sessions over 3 weeks	3 months	Aspects of physical health measured using: 1. Negative somatic symptoms scale (developed by Pennebaker, includes 9 somatic symptoms), 2. Medical appointments for cancer-related morbidities; Aspects of psychological health measured using: 1. Profile of Mood States (POMS)
Mosher et al. (2012)	86	4	81% Caucasian	57.9 $\pm$ 12.1	87%	Average time since diagnosis of stage 4 breast cancer: 4 years	EW: EMO ($n = 44$); Control: NW ($n = 42$); Four sessions over 4–7 weeks	8 weeks	Aspects of physical health measured using: 1. The Functional Assessment of Chronic Illness Therapy Fatigue subscale (FACIT-F), 2. Pittsburgh Sleep Quality Index (PSQI); Aspects of psychological health measured using: 1. The Functional Assessment of Chronic Illness Therapy–Spiritual Well-being scale (FACIT-Sp), 2. Distress Thermometer (DT), 3. Center for Epidemiologic Studies–Depression Scale (CES-D), 4. Anxiety: Hospital Anxiety and Depression Scale (HADS-A)
Park et al. (2012)	58	2–3	NR	48.2 $\pm$ 7.5	57%	23 months	EW: EMO ($n = 29$); Control: USUAL ($n = 29$); Six sessions over 6 weeks	4 weeks	Aspects of physical health measured using: 1. Pennebaker's Inventory of Limbic Languidness (PILL), 2. M. D. Anderson Symptom Inventory (MDASI); Aspects of psychological health measured using: 1. Hospital Anxiety and Depression Scale (HADS), 2. Cancer-Quality of Life (C-QOL)
Stanton et al. (2002)	60	1–2	93% Caucasian	49.5 $\pm$ 12.2	NR (average education level: 15.20 $\pm$ 2.48 years)	28.4 weeks	EW: EMO ($n = 21$), BEN ($n = 21$); Control: NW _c ($n = 18$); Four sessions over 3 weeks	1 and 3 months	Aspects of physical health measured using: 1. Negative somatic symptoms scale (developed by Pennebaker, includes 9 somatic symptoms), 2. Medical appointments for cancer-related morbidities; Aspects of psychological health measured using: 1. Functional Assessment of Cancer Therapy (FACT), 2. Profile of Moods State (POMS)
Walker et al. (1999)	39	1–2	95% Caucasian	53.6	79%	NR (were completing RT for stage 1 or 2 breast cancer)	EW: 1 session EMO ($n = 11$), 3 sessions EMO ($n = 14$); Control: ATT ($n = 14$); One or three sessions over 1–4 days	1, 4–6, 16, and 28 weeks	Aspects of psychological health measured using: 1. Positive and Negative Affect Scale (PANAS), 2. Impact of Events Scale (IES)

EMO, emotional (cancer) prompt; EMO⁺, emotional (any trauma) prompt; BEN, benefit-finding (cancer) prompt; MULTIPLE, emotional, benefit-finding, cognitive-appraisal, and coping prompts; NW, neutral writing (trivial); NW_b, neutral writing (health behavior); NW_c, neutral writing (cancer); USUAL, usual care; ATT, non-cancer attention; NR, not reported. The above format is cited in Merz [51].

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The selection bias was considered low in six studies because a random serial grouping program was used. Three of them were rated as completely low-risk because they employed a computer-aided serial grouping program [22,25,28]; the random programs in the other three studies were limited in most occasions, thus enhancing the predictability of grouping for the researchers [21,23,26]. Three studies were considered as high-risk of bias because sequential assignment [19,27] or matched controls [24] was utilized. The remaining two studies that did not describe details of their randomization were rated as unclear risk of bias [20,29].

Three RCTs were identified as low selection bias because they used sequentially numbered envelopes to conceal allocation of participants from the researcher or research assistants [22,28,29]. Three RCTs were identified as high selection bias because they did not use condition allocation concealment of participants [19,24,27]. The remaining five studies did not provide specific information as to whether allocation concealment was used.

In the EW intervention, it was difficult to perform a fully blinded study because each researcher and subject had to be informed of the writing requirements and methods. Therefore, the bias risk was high in the 11 studies regarding the blinding of the participants and personnel.

As for blinding of outcome assessment, three studies were considered low-risk because they made efforts to mask the research purposes and writing tasks from research assistants and participants [23,27,28]. One study was considered high-risk because the nurse in charge of the baseline interview and assessment did not use a blinded method for allocation [24]. It was unclear whether a blinded method was implemented in the outcome assessment for the remaining seven studies.

Ten studies that stated the reason why and the time when a subject dropped out exhibited low risk of attrition bias. Notably, Craft [27] used an intent-to-treat analysis to reduce the possibility of data bias. The remaining one study was regarded as unclear risk because no reason was provided for a subject dropping out of the study [23].

All the 11 studies appeared to have reported on all measured outcomes, showing low risk of reporting bias. No other potential sources of bias were noted in the included studies.

Effects of the interventions

To determine how long the effect of EW intervention would last in BC patients, we divided the pooled outcome measures of physical health and of psychological health respectively into a ≤ 3 -month follow-up group and a > 3 -month follow-up group. In studies that provided outcome measures of more than one follow-up that met the criteria of grouping, the follow-up data at one time point that satisfied the grouping criteria the most were included while the other data were excluded. Specifically, the data of 3 days pre-surgery [26], 1 week [19] and 1 month [25,28] were excluded from the ≤ 3 -month group while the follow-up results of 16 weeks [19] were excluded from the > 3 -month follow-up group.

Furthermore, to determine whether different means of EW intervention might have an impact on the effectiveness of EW intervention we stratified the negative somatic symptoms for physical health and negative mood for psychological health, which were primary outcomes for our meta-analysis, by emotional prompt, benefit-finding prompt and multiple prompts. However, since only one study [25] utilized multiple prompts but did not evaluate negative somatic symptoms, actually it was only feasible for us to stratify negative somatic symptoms by emotional prompt and benefit-finding prompt (Fig 3).

Expressive writing intervention and physical health. As shown in Table 2, seven studies in the ≤ 3 -month follow-up group employed a fixed-effect model to analyze the combined effect of EW on the physical health indexes. The results showed a significant effect of EW using

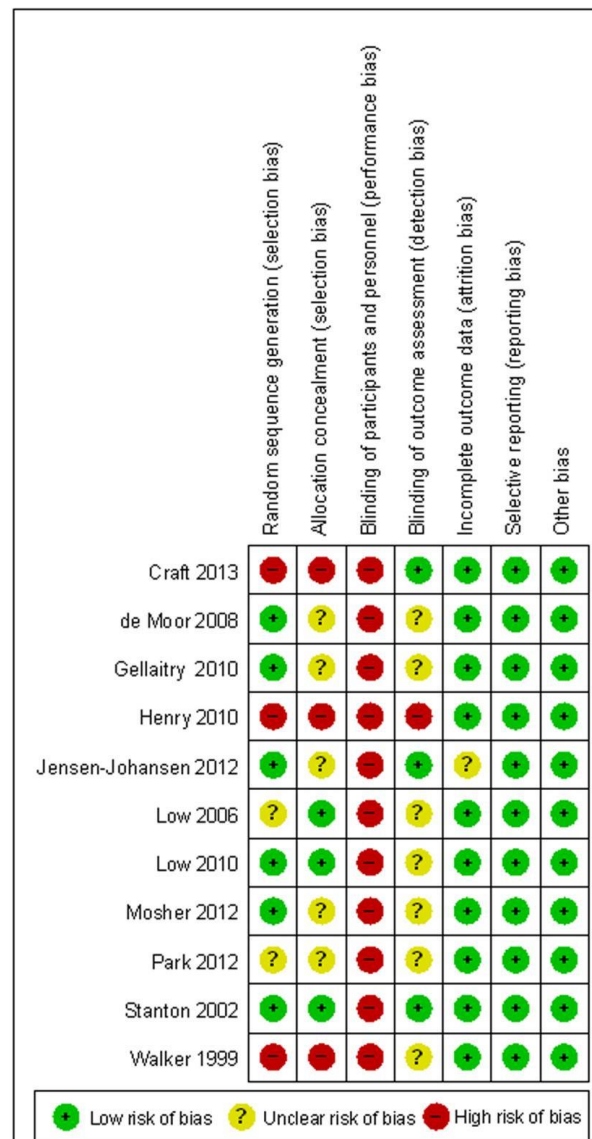


Fig 2. Risk of bias for the included studies.

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either an emotional prompt or a benefit-finding prompt on reducing negative somatic symptoms in BC patients in the ≤ 3 -month follow-up group [Mean Difference (MD), -13.03, 95%

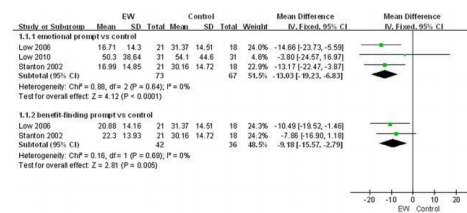


Fig 3. EW intervention and physical health in ≤3-month follow-up group: negative somatic symptoms.

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CI, -19.23 to -6.83, $P < 0.0001$; MD, -9.18, 95% CI, -15.57 to -2.79, $P = 0.005$] compared with the control group (Fig 3). A publication bias analysis using a funnel plot was performed on the studies involving these indexes, and the results exhibited a symmetric distribution, indicating a low publication bias (Fig 4). Furthermore, Egger's test also indicated a low publication bias ($P = 0.372$).

As for secondary outcomes in the 22643-month follow-up group, medical appointments for cancer-related morbidities (MD, -1.69, 95% CI, -2.30 to -1.08, $P < 0.00001$), worst pain (MD, 1.76, 95% CI, 0.27 to 3.25, $P = 0.02$) and physical symptoms (MD, -0.26, 95% CI, -0.51 to -0.01, $P = 0.04$) showed a significantly beneficial effect on physical health. However, no significant effects were observed in the following outcomes: least pain, average pain, pain interference, sleep quality and fatigue. In the >3-month follow-up group, there was only one study with a 9-month follow-up (Table 3). Analysis of the combined effect of EW on the physical symptoms

Table 2. EW intervention and physical health in ≤3-month follow-up group.

Outcome	Number of		Effect size			Heterogeneity		
	Comparison	participants	MD	95% CI	P value	χ^2	P value	I^2 (%)
1 Negative somatic symptoms scale, 4 sessions	5			Subtotals only			Subtotals only	
1.1 emotional prompt vs control	3	140	-13.03	-19.23, -6.83	<0.0001	0.88	0.64	0
1.2 benefit-finding prompt vs control	2	78	-9.18	-15.57, -2.79	0.005	0.16	0.69	0
2 Medical appointments for cancer-related morbidities, 4 sessions	4	156	-1.69	-2.30, -1.08	<0.00001	0.99	0.80	0
3 Worst pain: Brief Pain Inventory, 4 sessions	1	49	1.76	0.27, 3.25	0.02	NA	NA	NA
4 Least pain: Brief Pain Inventory, 4 sessions	1	49	0.82	-0.22, 1.86	0.12	NA	NA	NA
5 Average pain: Brief Pain Inventory, 4 sessions	1	49	0.82	-0.34, 1.98	0.16	NA	NA	NA
6 Pain interference: Brief Pain Inventory (BPI), 4 sessions	1	49	1.28	-0.05, 2.61	0.06	NA	NA	NA
7 Pittsburgh Sleep Quality Index (PSQI), 4 sessions	3	199	0.65	-0.15, 1.46	0.11	0.42	0.81	0
8 The Functional Assessment of Chronic Illness Therapy Fatigue subscale (FACIT-F), 4 sessions	1	86	-2.20	-5.49, 1.09	0.19	NA	NA	NA
9 M.D. Anderson Symptom Inventory (MDASI), 6 sessions	1	58	-11.17	-29.30, 6.96	0.23	NA	NA	NA
10 Pennebaker's Inventory of Limbic Languidness (PILL), 6 sessions	1	58	-6.76	-21.35, 7.83	0.36	NA	NA	NA
11 Physical health measure, 1 session	1	80	-0.26	-0.51, -0.01	0.04	NA	NA	NA

NA, not applicable.

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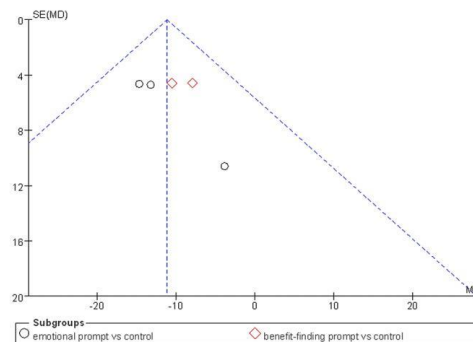


Fig 4. Funnel plot for EW intervention and physical health in ≤ 3 -month follow-up group: negative somatic symptoms.

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using a fixed-effect model demonstrated no significant impact of EW on the physical symptoms in BC patients ($P > 0.05$).

Expressive writing intervention and psychological health outcomes. The influence of EW on the psychological health of BC patients in all the 11 studies [19–29] was analyzed using a fixed-effect model. Our meta-analysis showed no significant effect of EW on the negative mood, our primary outcome for psychological health, in the ≤ 3 -month follow-up group though one study showed that EW with a benefit-finding prompt significantly reduced the negative mood level in BC patients compared with the control group ($P = 0.02$; Fig 5). A publication bias analysis of the studies involving these indexes was performed via a funnel plot, and the results followed a symmetric distribution, indicating a low publication bias (Fig 6). Furthermore, Egger's test also showed a low publication bias ($P = 0.975$). The secondary outcomes, such as positive mood, stress, depression, intrusive thoughts, avoidance, anxiety and quality of life, in the ≤ 3 -month follow-up group showed insignificant effects on the psychological health ($P > 0.05$) (Table 4). In the > 3 -month follow-up group of five studies (Table 5), a fixed-effect model was used to analyze the combined effect of EW on the psychological health. Their results showed no significant effect of EW on the psychological health ($P > 0.05$).

Discussion

In this systematic review of 11 RCTs exploring the influence of EW on the health outcomes of BC patients, we tried to determine specific efficacy of EW as a potential therapeutic aid. Based on the physical health indexes, we found that the negative somatic symptoms of BC patients (measured by the *Negative Somatic Symptoms Scale*) were significantly relieved after EW intervention for ≤ 3 months using either an emotional prompt or a benefit-finding prompt

Table 3. EW intervention and physical health in > 3 -month follow-up group.

Outcome	Number of		Effect size			Heterogeneity		
	comparisons	participants	MD	95% CI	P value	χ^2	P value	I^2 (%)
11 Physical health measure, 1 session	1	80	-0.02	-0.26, 0.22	0.87	NA	NA	NA

NA, not applicable.

doi:10.1371/journal.pone.0131802.t003

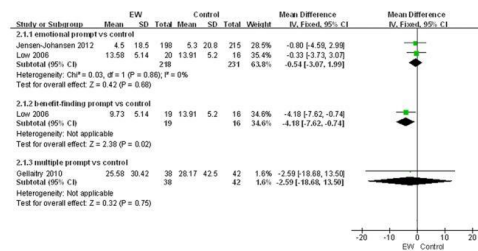


Fig 5. EW intervention and psychological health in ≤3-month follow-up group: negative mood based on POMS.

doi:10.1371/journal.pone.0131802.g005

compared with the control group. This study also identified a significant effect of EW on medical appointments for cancer-related morbidities, worst pain (measured by *Brief Pain Inventory*) and physical symptoms (measured by instrument *Physical Health Measure*) (Table 2). Although negative somatic symptoms, medical appointments for cancer-related morbidities, worst pain and physical symptoms are different indexes adopted by different assessment instruments, they have, in fact, much in common. They all assess status of physical health in BC patients from different points of view or with different focuses or using different terms. Taken together, the RCTs that evaluated these indexes supported the efficacy of EW on relieving negative physical symptoms in BC patients. Consequently, we can safely conclude that EW intervention may benefit the physical health of BC patients. However, we found that this benefit became insignificant >3 months after EW intervention, which means the positive effect of current EW intervention may not last long. This is in agreement with one of Mogk's conclusions about health effects of EW [54]. However, we believe that the duration of effectiveness of EW intervention is an important issue that needs further investigation. It is associated with intervention methods or dosages or an inborn limitation of EW itself? As for the psychological health for BC patients, we found no significant effectiveness of EW intervention in either >3-month follow-up group or ≤3-month follow-up group except that only one study reported that EW with a benefit-finding prompt for ≤3 months significantly reduced the negative mood

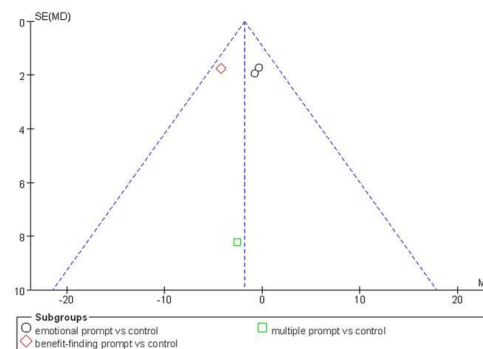


Fig 6. Funnel plot for EW intervention and psychological health in ≤3-month follow-up group: negative mood based on POMS.

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Table 4. EW intervention and psychological health in ≤ 3 -month follow-up group.

Outcome	Number of		Effect size			Heterogeneity		
	comparisons	participants	MD	95% CI	P value	χ^2	P value	I^2 (%)
1 Negative mood: Profile of Mood States (POMS), 3–4 sessions	4			Subtotals only			Subtotals only	
1.1 emotional prompt vs control	2	449	-0.54	-3.07, 1.99	0.68	0.03	0.86	0
1.2 benefit-finding prompt vs control	1	35	-4.18	-7.62, -0.74	0.02	NA	NA	NA
1.3 multiple prompt vs control	1	80	-2.59	-18.68, 13.50	0.75	NA	NA	NA
2 Positive mood: Profile of Mood States (POMS), 4 sessions	2	71	0.16	-0.95, 1.26	0.78	0.24	0.62	0
3 Passive Positive Mood Scale (PPMS), 3 sessions	1	413	-0.40	-1.75, 0.95	0.56	NA	NA	NA
4 Brief Symptom Inventory 18 (BSI-18), 4 sessions	1	49	0.03	-3.20, 3.26	0.99	NA	NA	NA
5 Perceived Stress Scale (PSS), 4 sessions	1	49	0.84	-2.08, 3.76	0.57	NA	NA	NA
6 Beck Depression Inventory-Short Form (BDI-SF), 3 sessions	1	418	-0.50	-1.32, 0.32	0.23	NA	NA	NA
7 Intrusive thoughts: Impact of Event Scale (IES), 3–4 sessions	4	536	-0.50	-6.8, 0.68	0.40	1.18	0.76	0
8 Avoidance: Impact of Event Scale (IES), 3 sessions	3	474	-1.09	-2.59, 0.41	0.15	2.42	0.30	17
9 Meaning/ peace: The Functional Assessment of Chronic Illness Therapy-Spiritual Well-being scale (FACIT-Sp), 4 sessions	1	86	-0.98	-2.63, 0.67	0.24	NA	NA	NA
10 Demoralization: The Functional Assessment of Chronic Illness Therapy-Spiritual Well-being scale (FACIT-Sp), 4 sessions	1	86	1.57	-3.05, 6.19	0.51	NA	NA	NA
11 Distress Thermometer (DT), 4 sessions	1	86	0.16	-0.85, 1.17	0.76	NA	NA	NA
12 Anxiety: Hospital Anxiety and Depression Scale (HADS-A), 4 sessions	2	144	-0.59	-1.72, 0.54	0.31	0.12	0.73	0
13 Depression: Hospital Anxiety and Depression Scale (HADS), 6 sessions	1	58	2.48	-1.09, 6.05	0.97	NA	NA	NA
14 Center for Epidemiologic Studies-Depression Scale (CES-D), 1–4 sessions	3	228	-0.23	-0.48, 0.03	0.08	0.04	0.98	0
15 Positive affect: Positive and Negative Affect Scale (PANAS), 1–3 sessions	2	53	2.48	-1.09, 6.05	0.17	0.04	0.85	0
16 Negative affect: Positive and Negative Affect Scale (PANAS), 1–3 sessions	2	53	2.14	-0.65, 4.92	0.13	0.18	0.67	0
17 Cancer-Quality of Life (C-QOL), 6 sessions	1	58	1.31	-4.71, 7.33	0.67	NA	NA	NA
18 Functional Assessment of Cancer Therapy-Breast Cancer Version (FACT-B), 4 sessions	3	229	-0.67	-5.01, 3.66	0.76	0.63	0.73	0

NA, not applicable.

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level in BC patients. This finding was rather surprising, because as a means of psychological adjustment EW was expected to exert a positive effect on psychological health.

There have been only four meta-analyses available currently on the EW intervention. The above findings are basically consistent with the meta-analysis by Frisina [52] who determined that written emotional disclosure had a significant effect on the physical but not the psychological health of various clinical populations, and with that by Frattaroli [50] who found EW was effective in both healthy and unhealthy people. However, Harris [53] found EW was effective in healthy people but not in samples defined by medical diagnosis or psychological criteria. Our findings are inconsistent with the meta-analysis by Mogk [54] who concluded that EW had minor or no effects on the healthy or unhealthy subjects in their study. Obviously, the diversity of the populations included and the heterogeneity of the meta-analyses are likely a

Table 5. EW intervention and psychological health in >3-month follow-up group.

Outcome	Number of		Effect size			Heterogeneity		
	comparisons	participants	MD	95% CI	P value	χ^2	P value	I^2 (%)
1 Negative mood: Profile of Mood States (POMS), 3–4 sessions	2	511	-2.19	-5.93, 1.55	0.25	0.03	0.85	0
2 Passive Positive Mood Scale (PPMS), 3 sessions	1	431	0.10	-1.19, 1.39	0.88	NA	NA	NA
3 Intrusive thoughts: Impact of Event Scale (IES), 3–4 sessions	3	483	0.56	-0.78, 1.90	0.41	2.41	0.30	17
4 Avoidance: Impact of Event Scale (IES), 3 sessions	3	483	-0.57	-2.07, 0.94	0.46	0.35	0.84	0
5 Positive affect: Positive and Negative Affect Scale (PANAS)	2	53	2.84	-0.64, 6.31	0.11	0.58	0.45	0
6 Negative affect: Positive and Negative Affect Scale (PANAS),	2	53	3.00	-0.33, 6.33	0.08	0.00	1.00	0
7 Center for Epidemiologic Studies-Depression Scale (CES-D), 1 session	1	80	-0.08	-0.35, 0.19	0.56	NA	NA	NA
8 Beck Depression Inventory-Short Form (BDI-SF), 3 sessions	1	435	-0.30	-1.14, 0.54	0.48	NA	NA	NA
9 Functional Assessment of Cancer Therapy-Breast Cancer Version (FACT-B), 4 sessions	3	229	2.26	-1.85, 6.37	0.28	1.58	0.45	0

NA, not applicable.

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major reason for the inconsistency in the conclusions on the EW intervention. This was also the reason why we decided to conduct a meta-analysis on EW intervention specifically in BC population.

The poor homogeneity of the limited number of current meta-analyses on EW intervention, including ours, reflects a fact that the researches on EW as an adjuvant therapy for patients are still diversified. The assessment instruments, indexes, outcome measures, samples included, indications, intervention methods, and conclusions are all various. Notably, EW has been tested or used chiefly in Caucasians rather than in oriental races. There is a long way to go before EW can be used as a well-developed intervention in clinic.

The poor homogeneity of the RCTs investigating EW intervention also led to the chief limitations of our meta-analysis. Firstly, because of inconsistent outcome measures by different instruments and incomplete data, the majority of the indexes were unable to be pooled for meta-analysis, leading to inclusion of $N = 1$ tests in the results. For example, of the 11 studies included in this meta-analysis, only five addressed negative mood as an index of psychological health using the same instrument POMS with emotional prompt, benefit-finding prompt or multiple prompts. Of the five studies, only three provided detailed data we were able to retrieve for sub-group analysis of whether different prompts in EW intervention might have an effect on the intervention outcomes (Fig 5). Other studies measured the effects of EW on psychological health using other instruments or other indexes (Table 4). In addition, the limited number of studies available made it very difficult for us to investigate the potential publication bias influencing the analysis. The power of Egger's test is too low to distinguish chance from real asymmetry. Secondly, inconsistent factors or indexes, such as characteristics of the subjects and writing prompt and cycle of EW intervention, might have caused biases in results. Thirdly, it was infeasible for us to determine more specific efficacy of EW by further sub-group analyses according to age, education or BC staging because the data were lacking or because the sample

size was very limited. Moreover, we did not perform manual retrievals due to time and condition limitations. In addition, three studies failed to provide complete data for five observation indexes even after consultation with the authors [24,25,28], and the full text and data of three conference papers were unavailable even after we tried to contact their authors. All these might have missed some important data on EW as an intervention in BC patients, leading to possible biases in our results.

In summary, this meta-analysis has found that EW intervention may have a positive effect on the physical health rather than the psychological health of BC patients. It proves to chiefly relieve negative physical symptoms in a short term rather than in a long term. The non-lasting momentum of EW intervention is an interesting issue to explore. As a convenient adjunctive intervention for BC patients, EW has much more to be clarified. To determine if personality, race, age, education, BC stage, intervention time since diagnosis and other possible factors would be associated with the intervention effect of EW, it is necessary to do more research in large populations of BC patients to develop EW as an established intervention.

Supporting Information

S1 Checklist. PRISMA 2009 checklist in this meta-analysis.doc.
(DOC)

S1 Appendix. Search strategy.doc.
(DOC)

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Author Contributions

Conceived and designed the experiments: CLZ YNW SLA. Performed the experiments: CLZ YNW SLA XJL. Analyzed the data: YNW SLA. Contributed reagents/materials/analysis tools: YNW SLA XJL. Wrote the paper: CLZ YNW SLA XJL. Designed the search strategy and performed and updated the search: YNW XJL. Screened the reference files and extracted the data: CLZ YNW XJL. Contacted the authors: YNW.

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Effect of prolonged expressive writing on health outcomes in breast cancer patients receiving chemotherapy: a multicenter randomized controlled trial

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Abstract

Purpose This study aims to evaluate the effects of prolonged expressive writing on health outcomes in breast cancer patients undergoing chemotherapy to help understand how the dosage of an expressive writing intervention might moderate its effects.

Methods A total of 112 breast cancer patients undergoing chemotherapy were randomly allocated to the expressive writing group ($n = 56$) or the prolonged expressive writing group ($n = 56$). The expressive writing group received the standard expressive writing intervention based on Pennebaker's prompt to write for at least 20 min over four consecutive days (4 sessions). The prolonged expressive writing group used a modified prompt: write for at least 20 min 3 times a week over a 4-week period (12 sessions); patients could choose whether to write on consecutive days or not. All participants were required to write about their stressor-related upsetting or traumatic feelings about breast cancer. Outcomes were assessed and compared at baseline, as well as 1 month, 3 months, and 6 months postintervention.

Results There was no significant difference in the patients' quality of life, or physical and psychological wellbeing between the expressive writing group and the prolonged expressive writing group at any time point (all $p > .05$). The quality of life of breast cancer patients significantly decreased in the two groups over time ($F = 40.64$, $p < .001$).

Conclusion Our findings suggest that the writing dosage does not moderate the effects of expressive writing on breast cancer patients undergoing chemotherapy.

Trial registration ChiCTR1800016278

Keywords Breast cancer · Chemotherapy · Expressive writing · Quality of life · Nursing practice

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Introduction

Breast cancer (BC) remains the most commonly diagnosed cancer in women [1]. Emotional suppression and psychological distress are still commonly reported in BC patients, and these symptoms do not significantly decrease over time [2]. Moreover, physical problems are also prevalent among BC patients [3]. These symptoms are particularly pertinent in BC patients undergoing chemotherapy [4]. The side effects of chemotherapy include increased mental and physical symptoms such as anxiety, nausea, constipation, and anemia; these side effects can have serious adverse effects on treatment [5, 6]. In addition, it has been demonstrated that emotional suppression could significantly predict high reports of somatic symptoms and psychological problems during chemotherapy for BC [7]. However, Lally and Kupzyk [8] indicated that fewer than 30% of distressed BC patients receive psychosocial

care. Therefore, BC patients undergoing chemotherapy not only have medical problems but also have personal problems, as they have serious physical and psychological symptoms that require various treatment approaches.

Expressive writing (EW), which is a brief emotional disclosure intervention, was first used with college students in 1986 by Pennebaker. The standard Pennebaker paradigm for EW interventions encourages participants to write about their stressor-related upsetting or traumatic feelings for approximately 20 min over four consecutive days [9]. Findings from the original research by Pennebaker and Beall (1986) suggest that EW is a potentially effective intervention that was extended to various kinds of groups of people, including clinical patients [10, 11] and healthy young adults [12]. Since Walker [13] first explored the potential effectiveness of EW in BC patients, numerous randomized controlled trials (RCTs) have been conducted based on Pennebaker's prompt to test the feasibility of EW in BC patients due to the unmet needs of this group [14–17].

Although EW interventions have generally been considered beneficial, results from several meta-analyses have not shown any substantial main effects in cancer patients and survivors. Three meta-analyses testing the effects of EW interventions were published in 2006. Of those meta-analyses, the results of Mogk and Otte [18] and Harris [19] both indicated that EW interventions have minor or no effects on patients' health and wellbeing, but it appears that they only included one and two studies with cancer patients, respectively. Frattaroli [20] found positive and significant effects of EW, but most of the studies included in that meta-analysis were focused on college students, and only one study included cancer patients. More recently, a meta-analysis conducted by Zachariae and O' Toole [21] and published in 2015 synthesized the effects of 16 EW intervention studies with cancer patients and survivors, and the findings indicated that cancer patients do not experience benefits from EW interventions conducted in accordance with the classical Pennebaker paradigm. This is also the case for the 8 studies of BC patients ($ES = 0.001$, $p = .992$). Furthermore, in 2015, Zhou [22] examined 11 studies of BC patients and concluded that EW had statistically significant effects on some physical health-related outcomes in very small subsets of studies. Furthermore, in this meta-analysis, the authors appear to have included studies that are overlapping and thus not independent; they also included a study with only one EW intervention session, which is clearly not in accordance with the Pennebaker paradigm.

Taken together, the available evidence showed that EW interventions conducted in accordance with the classical Pennebaker paradigm do not improve psychological or physical health in cancer patients in general or BC patients specifically. However, given the convenience, low cost, and self-administered interventions that could be routinely used in the clinic, it is important to conduct studies to test the factors that

may moderate the effects of EW. It is unknown whether the null finding is related to the dose of writing, the intervention approach, or a limitation of EW itself. Therefore, the primary goal of this study was to compare the usual 4-session Pennebaker paradigm-based EW intervention with an increased dosage 12-session EW intervention among BC patients. Because physical and psychological wellbeing are usually decreased during chemotherapy [23, 24], the current study aims to test the hypothesis that increasing the dosage could improve the efficacy of EW interventions in BC patients undergoing chemotherapy.

Methods

Study design

This study was a multicenter, prospective, parallel RCT with a 6-month follow-up and was carried out at five large tertiary hospitals in Guangdong Province in China. The study was registered in the Chinese Clinical Trial Registry (ChiCTR) (registration number: ChiCTR1800016278, at <http://www.chictr.org.cn/>).

Setting and participants

BC patients receiving chemotherapy from five tertiary hospitals in Guangdong Province in China were randomly selected. To reduce the influence of the hospital site, five hospitals distributed across four cities in Guangdong Province were recruited in the research (two hospitals in Guangzhou city with nearly 3000 beds and 1000 beds, one hospital in Zhanjiang city with nearly 1200 beds, one hospital in Shantou city with nearly 2000 beds, and one hospital in Shenzhen city with nearly 3000 beds).

The inclusion criteria of participants were as follows: (1) BC patients diagnosed by pathology, (2) patients undergoing chemotherapy with chemotherapy cycles continuing for more than 1 month, (3) patients who were able to write Chinese and physically able to write by hand for more than 20 min at a time, (4) patients with Chinese fluency and a primary education and above, (5) female patients with an age older than 18 years, (6) patients who were expected to survive for more than 6 months, and (7) patients who provided signed informed consent. Furthermore, patients were excluded if they (1) had psychosis, (2) had other cancers or other major diseases, or (3) had been involved in other studies that could influence the results of this research.

Sample size

The estimated effect size of the Functional Assessment of Cancer Therapy-Breast Cancer Version (FACT-B), which is

the primary outcome in the research, is $d = 0.58$ according to previous articles [16, 25–27]. Based on the effect size with an alpha of 0.05 (two-tailed test), with a power of 0.80 [28], and considering an expected dropout rate of 20%, it was determined that each group needed at least 56 patients based on sample size calculations (<https://www.sample-size.net/sample-size-means/>).

Randomization

Eligible patients were randomly allocated to the EW group or the prolonged EW group on a 1:1 basis. Randomization was assigned centrally using a computer-based random number generator by an independent statistician who was blinded to the purpose of the study to avoid selection bias [29]. Participants were randomly assigned, using sequential numbering, once written informed consent and baseline data were obtained by the trained research assistant in each setting. Once randomization was conducted, no change was allowed.

Data collection

Six research assistants were included in the study and trained by an experienced clinical psychologist and the principal investigator (PI) of the research. The research was described to the patient by a trained research assistant using a standardized script, and if patients decided to participate, written informed consent and a baseline questionnaire were obtained.

After completing the baseline assessment, participants were randomized to the EW group ($n = 56$) or the prolonged EW group ($n = 56$). Participants in the EW group were required to write based on Pennebaker's prompt [9], which asked participants to write for at least 20 min over four consecutive days (4 sessions). The prolonged EW group used a modified prompt: write for at least 20 min 3 times a week over a 4-week period (12 sessions); patients could choose whether to write on consecutive days or not. The number of writing sessions in the prolonged EW group was increased based on the procedure of Mosher and Duhamel [15], who required participants to write across four sessions over 4–7 weeks. The instructions for each of the writing sessions were the same. Participants in the two groups were all required to write about their stressor-related upsetting or traumatic feelings about BC in accordance with standard instructions from Pennebaker and Beall [9]. They could write about the same topic or different topics each time.

Participants were instructed by research assistants to write at home or at the research office at their convenience, and the anonymity and confidentiality of the writings were emphasized. To improve participant adherence, each morning, the research assistants sent a message through WeChat to remind the participants to write for the day. Furthermore, participants were asked to use WeChat each day to report to the research

assistants whether they had written that day, and if so, the research assistants asked for detailed information including the writing time and whether they had been disturbed by other people during writing. The research assistants took notes. The instructions for the writing conditions were derived from Pennebaker and Beall [9], who suggested that participants write at a quiet time and in a private place where they would not be disturbed and write continuously without worrying about grammar mistakes, sentence structure, erasing, or crossing things out.

After the final writing session, each participant was given a form on which to record any other major diseases or traumatic events over the research period, whether they had participated in other studies, and whether they sought counseling or psychotherapy during this time. All participants were required to hand in their writing assignments through express. A research assistant phoned the participants to determine whether they had finished the writing tasks if the assignments were not received in 1 week. Given that Chinese people are less likely to disclose their inner emotion to outsiders [17], a random number was used instead of patients' names on their writing assignments to maintain anonymity. Furthermore, the content of patients' emotional disclosure essays was checked by a research assistant. Patients who did not adhere to the research instructions were excluded from the analysis.

All included participants were required to complete the follow-up questionnaires at 1, 3, and 6 months after the intervention. A trained research assistant collected the questionnaires by sending a link to an online survey platform (www.wjx.cn) to each participant via WeChat. A single reminder was sent if these questionnaires had not been completed in 1 week. For the elderly or those with severe physical conditions who were not able to complete the questionnaires by themselves through WeChat, the trained research assistant completed the questionnaires by conducting phone interviews with the participant. The following measures were used at baseline and 1, 3, and 6 months after the final writing session. Quality of life was the primary outcome of the study, and the secondary outcomes included negative somatic symptoms and psychological wellbeing.

Quality of life The quality of life (QOL) of the BC patients was assessed using FACT-B [30], which is a 36-item self-report instrument. It was designed to investigate the multidimensional health-related quality of life of patients with various stages of BC. This instrument has been proven to have high reliability and validity. The FACT-B contains 27 general items (Functional Assessment of Cancer Therapy–General, FACT-G) and nine BC-specific items (Breast Cancer Specific, BCS). The subscales comprise physical, social and family, emotional, and functional wellbeing dimensions as well as a subscale to specifically address BC-related psychological and physical concerns. A 5-point Likert-type scale was used, and

respondents were required to assess how true each statement had been for them over the past week on a scale from 0 to 4. All 36 items were summed to obtain a total quality of life score (ranging from 0 to 144), and scores for each subscale were obtained. A higher score indicates a better quality of life. Quality of life was the primary outcome of the study, as it encompasses physical, psychological, social and functional aspects of the participants, and has been widely used in EW interventions among BC patients [25–27]. The validity of the FACT-B in BC patients has been reported to be 92.5% [25] and 92% [27].

Physical health-related outcomes Physical health-related outcomes were assessed using the Symptoms Assessment Inventory for Breast Cancer Patients Receiving Chemotherapy (SAI-B) [31]. The 26-item symptom assessment inventory was invented as a brief measure to assess the impact and severity of symptoms among BC patients who are receiving adjuvant chemotherapy. Each symptom is rated on a scale from 0 to 4 to indicate the severity and presence of symptoms, with 4 indicating “very serious” and 0 indicating “not present.” Patients were asked to indicate the worst instance of each symptom during the last cycle of chemotherapy. Finally, an overall symptom distress score was determined (ranging from 0 to 104). The SAI-B has been shown to have acceptable validity and reliability in Chinese BC patients. The scale content validity index was 0.977, the Cronbach’s α was 0.818, and the test-retest reliability was 0.745 [31].

Psychological wellbeing Psychological wellbeing was investigated by using the Hospital Anxiety and Depression Scale (HADS) [32], which has been widely used to assess the mental health of BC patients in EW interventions [15, 33]. The HADS consists of 14 items that can assess the severity of both anxiety and depression symptoms. Respondents are asked to indicate the extent to which they felt each particular feeling (e.g., nervous, scared) during the previous month on a scale from 0 to 3.

A brief general information questionnaire was used before randomization to assess age, educational level, occupation, marital status, faith, types of medical expense payment, economic burden, and some potentially relevant medical variables such as cancer stage, treatment approach, types of chemotherapy, number of completed chemotherapy cycles, number of planned chemotherapy cycles, time since diagnosis, and time since chemotherapy.

Ethical considerations

The trial was approved by the involved hospitals, including the Medical Ethics Committee of Nanfang Hospital (reference number: NFEC-2018-049), The Affiliated Hospital of Guangdong Medical University (reference number: PJ2018-

029), The Cancer Center of Guangzhou Medical University (reference number: 2018-003), The First Affiliated Hospital of Shantou University Medical College (reference number: 2018-039), and Shenzhen People’s Hospital (reference number: 2018-029). Written informed consent was obtained from each participant prior to the study. Participants were informed that they were free to withdraw from the research at any time without any prejudice. Patients’ names were substituted with a sequential number. The writing contents and other data of participants were kept confidential according to the Data Protection Act 1998 (DPA) [34], and during the writing intervention process, an experienced psychologist counselor could be consulted upon request from the BC patients. The study was carried out in accordance with the Declaration of Helsinki [35].

Validity and reliability

The trial was designed and reported based on the CONSORT 2010 Statement [36]. The registered protocol was strictly followed during the process. The research assistant who analyzed the data was blinded to group allocation. Due to the nature of the EW intervention, the BC patients and the trained research assistants in each setting who were responsible for enrolling participants were not blinded to group allocation. However, to reduce the risk of “patient-reported outcomes,” which might result in performance bias [37], the hypothesis of this research was masked, and participants were informed that the research purpose was to “explore in-depth how women adjust BC” and that they would be randomized to one of two groups that need to write about their experience with BC. Therefore, the writing assignments of other participants were not revealed. Moreover, to minimize performance bias, research assistants were also not aware of the study hypothesis [37].

Statistical analysis

The SPSS 20.0 software (IBM, USA) was used for statistical analysis. All data were tested for normality and homogeneity of variances. If no more than 50% of the data for a subscale were missing, the missing data were substituted by the means of the remaining completed items of the subscale for each respondent [38]. Otherwise, the total score was not calculated. The data of continuous variables are presented as the mean and standard deviation, and the categorical variables are presented as a frequency. If the distribution of data was skewed, the median (interquartile range) was used to report variables [39]. An independent samples *t* test was used to examine differences in continuous variables between the two groups. The chi-square test was used to compare proportions between the two groups [40]. Furthermore, the rank sum test was used to test between-group differences for ordinal data [41].

In addition to the main effects analysis, changes in quality of life, negative somatic symptoms, and psychological wellbeing over the four time periods (baseline, and 1, 3, and 6 months after intervention) between the two groups were analyzed using a linear mixed model with the SPSS MIXED procedure. The models included an AR (1): heterogeneous covariance structure and a random intercept. All *p* values were two-sided, and a significant difference was indicated when the *p* value was less than .05.

Results

Participant characteristics

The trial commenced in July 2018 and ended in March 2019, with recruitment ending in August 2018. In all, 112 BC patients undergoing chemotherapy were randomly assigned to the EW group or the prolonged

EW group ($n = 56$ per group). For the EW group, three patients were lost to follow-up at 1, 3, and 6 months, separately, and one patient withdrew due to discontinued chemotherapy. For the prolonged EW group, two patients were lost to follow-up at 3 and 6 months. All randomized participants were included in the data analysis. Therefore, the final sample included in the data analysis consisted of 56 patients in the prolonged EW group and 56 patients in the EW group (Fig. 1). No participants sought counseling or psychotherapy during the writing intervention process.

The demographic and pathological characteristics of patients in the two groups are provided in Table 1. The results showed that there were no significant differences between the two groups on all main characteristics (all $p > .05$). The mean age of the BC patients was 41.73 (7.63) years in the EW group and 44.95 (9.77) years in the prolonged EW group ($p = .16$). Most of the BC patients reported heavy or medium economic burdens due to the disease (96.4% vs 85.7%; EW vs

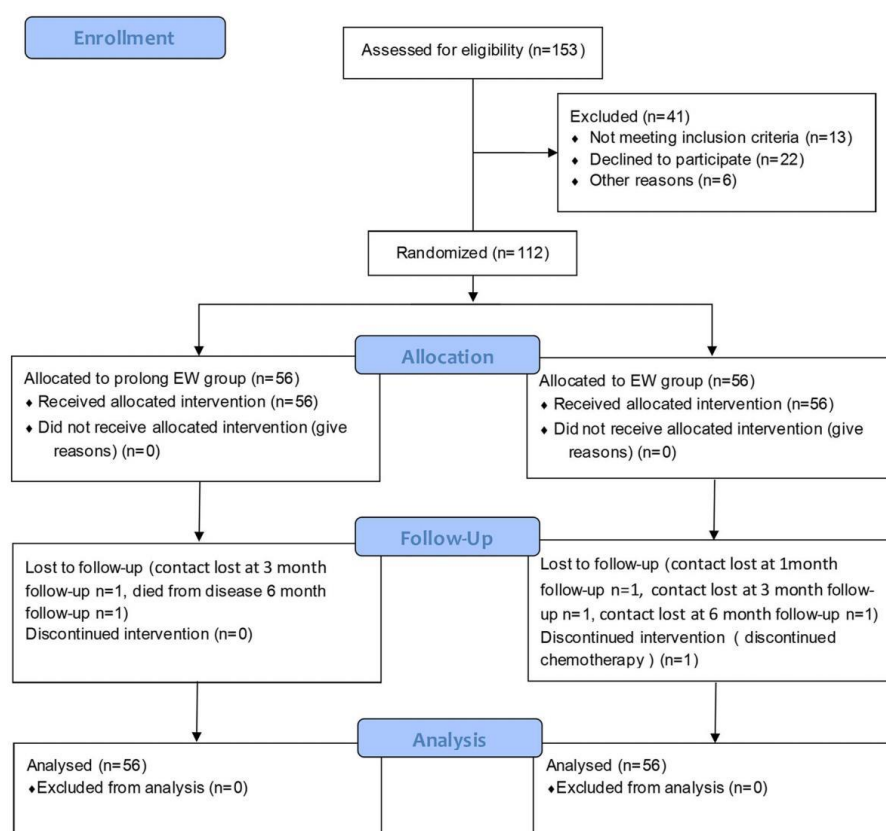


Fig. 1 The final sample included in the data analysis

Table 1 Demographic and pathological characteristics of patients between the two groups at baseline

Characteristic	Prolonged EW group (n = 56)				EW group (n = 56)				χ^2/t	p
	No.	%	Mean	SD	No.	%	Mean	SD		
Age (years)			44.95	9.77			41.73	7.63	1.40	.16 [†]
Educational level										
Primary school or below	8	14.3			12	21.4			1.41	.16 [#]
Junior high school	18	32.1			23	41.1				
High school	22	39.3			13	23.2				
University or above	8	14.3			8	14.3				
Occupation										
In-service	25	44.6			27	48.2			.55	.93 [*]
Retired	9	16.1			7	12.5				
Unemployed	18	32.2			17	30.4				
Farming	4	7.1			5	8.9				
Marital status										
Married	53	94.6			55	98.2			3.58	.24 [*]
Single	3	5.4			1	1.8				
Divorced	0	0			0	0				
Widowed	0	0			0	0				
Faith										
No	44	78.6			47	83.9			1.39	.58 [*]
Buddhism	11	19.6			7	12.5				
Christian	0	0			0	0				
Other	1	1.8			2	3.6				
Types of medical expense payment										
Free medical treatment	2	3.6			3	5.4			1.75	.75 [*]
Medical insurance	50	89.3			48	85.7				
Self-pay	3	5.4			5	8.9				
Other	1	1.7			0	0				
Economic burden										
Heavy	27	48.2			27	48.2			.56	.57 [#]
Medium	21	37.5			27	48.2				
Low	8	14.3			2	3.6				
Cancer stage										
I	12	21.4			8	14.3			.53	.60 [#]
II	29	51.8			33	58.9				
III	13	23.2			13	23.2				
IV	2	3.6			2	3.6				
Treatment approach										
Breast-conserving surgery	9	16.1			16	28.6			3.48	.34 [*]
Modified radical mastectomy	37	66.1			31	55.3				
Total mastectomy	7	12.5			8	14.3				
No surgery	3	5.3			1	1.8				
Types of chemotherapy										
Anthracycline-based	30	53.6			36	64.3			1.32	.54 [*]
Paclitaxel-based	12	21.4			11	19.6				
Other	14	25.0			9	16.1				
Number of completed chemotherapy cycles			3.21	2.20			2.93	1.91	.74	.46 [†]
Number of planned chemotherapy cycles			7.41	1.93			7.14	1.90	.74	.46 [†]
Time since diagnosis (days)			88.57	102.79			81.18	87.93	.41	.37 [†]
Time since chemotherapy (days)			51.59	50.60			57.79	90.93	.45	.73 [†]

*Chi-square test

†Independent samples *t* test

#Rank sum test

prolonged EW group, respectively; $p = .57$). Furthermore, the cancer stage ($p = .60$), treatment approach ($p = .34$), types of chemotherapy ($p = .54$), number of completed chemotherapy cycles ($p = .46$), time since diagnosis ($p = .37$), and time since chemotherapy ($p = .73$) were also similar between the two groups.

Effects of the intervention

Table 2 shows the results of the linear mixed effects model. There were no significant differences in the FACT-B scores, SAI-B scores, and HADS scores at each time point between the EW group and the prolonged EW group (all $p > .05$). The

Table 2 Group means and fixed effects omnibus tests from the linear mixed effects model

Measure	Time	Group means mean (SD)		Type III tests of fixed effects <i>F</i> (<i>df</i>)		
		Prolonged EW	EW	Group	Time	Group × time
FACT-B	Baseline	93.40 (23.53)	86.29 (19.77)	2.46 (1, 118.75)	40.64 (3, 254.39)*	1.63 (3, 254.39)
	1st month	87.36 (22.65)	81.85 (19.36)			
	3rd month	91.40 (21.47)	87.45 (16.52)			
	6th month	75.17 (8.94)	75.71 (11.85)			
SAI-B	Baseline	25.05 (14.18)	27.99 (12.95)	.07 (1, 110.43)	1.67 (3, 145.52)	.99 (3, 145.52)
	1st month	27.86 (11.88)	27.41 (11.13)			
	3rd month	24.49 (13.63)	25.72 (12.50)			
	6th month	26.33 (15.33)	24.75 (15.14)			
HADS	Baseline	20.77 (3.16)	20.75 (3.45)	.31 (1107.60)	.63 (3, 134.22)	.16 (3, 134.22)
	1st month	20.75 (3.13)	20.63 (3.02)			
	3rd month	21.07 (2.87)	20.57 (4.26)			
	6th month	21.31 (2.69)	21.08 (3.20)			

FACT-B, Functional Assessment of Cancer Therapy-Breast Cancer Version; SAI-B, Symptoms Assessment Inventory for Breast Cancer Patients Receiving Chemotherapy; HADS, The Hospital Anxiety and Depression Scale; Prolonged EW, prolonged expressive writing; EW, expressive writing

* $p < .001$

quality of life (FACT-B scores) of BC patients significantly decreased in both groups over time (86.29 (19.77) to 75.71 (11.85) vs 93.40 (23.53) to 75.17 (8.94); EW vs prolonged EW group, respectively; $F = 40.64$, $p < .001$). Figures 2, 3, and 4 display the trends of the FACT-B scores, SAI-B scores, and HADS scores, respectively, for each group over time.

Discussion

The current study explores the effects of a 3-fold “dosage” of EW intervention (12 sessions) and compares the effects of the classical dose (4 sessions). Our hypothesis that increasing the dosage could improve the efficacy of EW interventions in BC

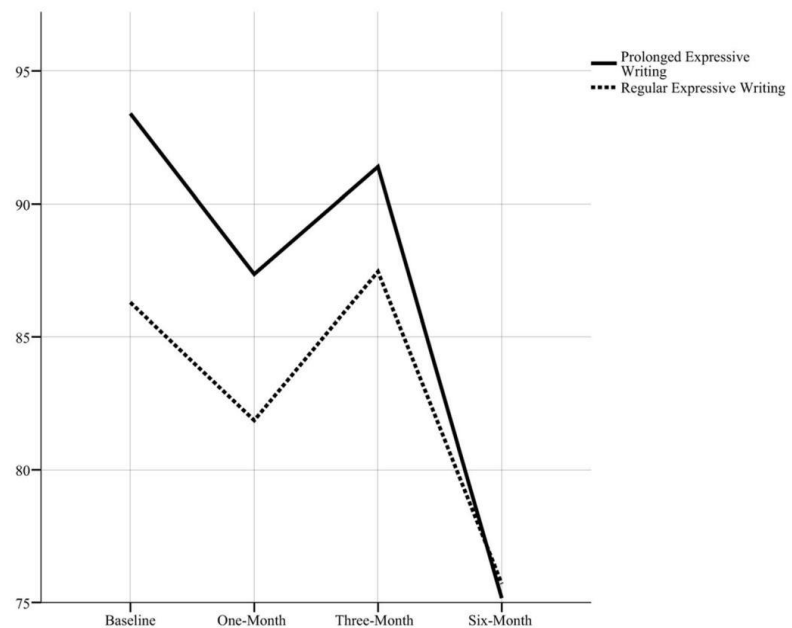
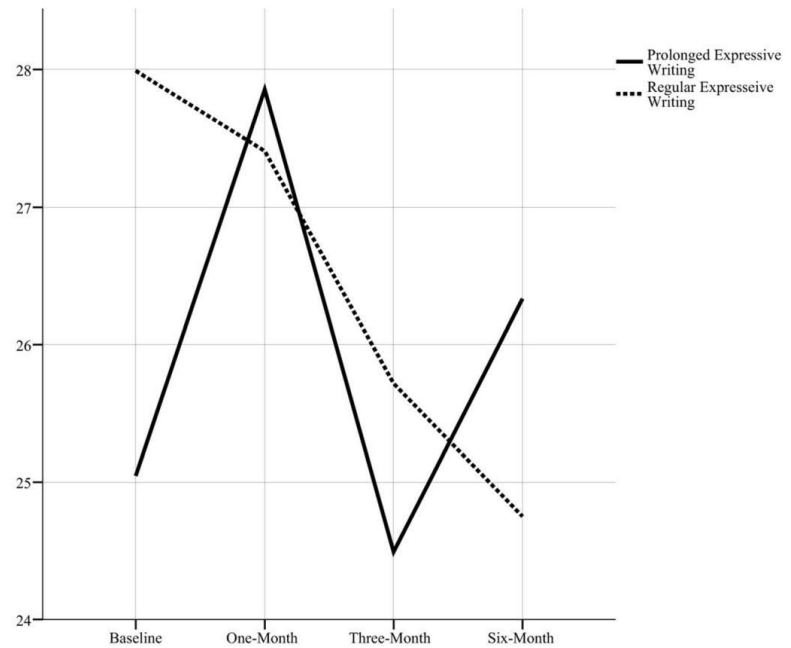
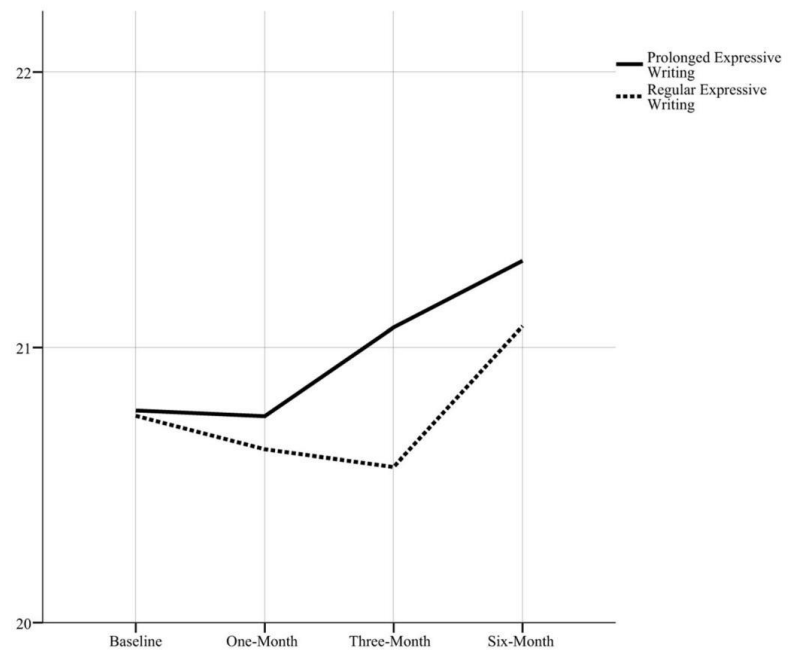
Fig. 2 The trends of the FACT-B scores

Fig. 3 The trends of the SAI-B scores**Fig. 4** The trends of the HADS scores

patients undergoing chemotherapy was not confirmed. The results showed that the FACT-B scores, SAI-B scores, and HADS scores were not different between the two groups at any time point after the intervention. The study provides further evidence regarding how the dosage might moderate the effects of EW interventions among BC patients undergoing chemotherapy.

In this study, we also found that the quality of life of BC patients undergoing chemotherapy in both groups worsened over time and was lower than that in prior studies on BC survivors [16, 25–27]. This is mainly because adjuvant chemotherapy has been proven to be related to increased physical and mental health problems in BC patients, and these problems do not significantly decrease over time [2, 5, 6]. Thus, BC patients often experience severe somatic symptoms and a decreased quality of life while undergoing chemotherapy [4, 24]. On average, BC patients in the current study in the two groups still had four remaining chemotherapy cycles upon beginning the intervention. Furthermore, the significantly decreased quality of life in both groups might indicate that the EW intervention is not beneficial to the wellbeing of BC patients, which is in accordance with the null findings from prior meta-analyses [18, 19, 21, 22]. If there is no effect of the EW intervention on BC patients over time, there is no effect to moderate.

The hypothesis of this research—that the efficacy of EW is associated with the dosage—is based on a prior research by Smyth [42], who conducted a meta-analysis and examined three different “doses” of EW. The meta-analysis found that the number of EW sessions (ranging from 1 to 5) and the length of each EW session (from 15 to 30 min) were unrelated to the efficacy of EW. The time period of writing (from 1 to 28 days) was a potential moderator: EW sessions spaced out over longer periods of time showed greater effects on some health outcomes. Furthermore, Frattaroli [20], Sloan and Marx [43], and Craft Davis [25] also suggested that the spacing and the number of EW writing sessions may moderate the effects of EW interventions and should be examined in-depth by researchers. However, the current study found a null main effect, which suggests that increasing the dosage does not appear to improve the efficacy of EW in BC patients undergoing chemotherapy. We found that the studies included in the meta-analysis by Smyth [42] were all focused on healthy participants rather cancer patients. Our results suggest that increasing the dosage of EW failed to show any main effects among BC patients undergoing chemotherapy.

The limitations of the present study warrant mention. First, the physical and psychological health outcome measures relied on self-report, which could introduce some bias [44]. Second, although the sample of 56 BC patients in each group is larger than the sample sizes in previous EW intervention studies reporting main effects [15, 25, 26, 33, 45–47], the present study may have been underpowered to detect main effects. However, the reporting and interpretation of effect

sizes in each group would have been helpful for explaining the results of our study. Furthermore, the generalizability of the findings to men and BC patients of different ethnicities needs further investigation. In addition, BC patients and the research assistants in the study were not totally blinded due to the nature of the EW intervention; each participant and researcher had to know the writing tasks and methods, which could introduce some risks of performance bias. Finally, given that the purpose of the current study is to try to understand how the dosage of the EW intervention might be a moderator in BC patients, there was no inactive control group in this study. The absence of an inactive control condition limits conclusions in the study.

Despite the limitations, the research has several strengths. First, this is a multicenter randomized controlled trial including five large tertiary hospitals from four different cities in China, thus reducing the influence of hospital site. Second, to maintain compliance with this intervention and the 6-month follow-ups, we engaged with and trained all the head nurses from the Breast Surgery Departments of the five tertiary hospitals. The five head nurses helped research assistants communicate with participants and contact them through WeChat during the follow-up time to maintain compliance with the research. In addition, to our knowledge, this is the first RCT focused on exploring the moderating effects of writing dosage on EW interventions in cancer patients. The research improved our understanding of what factors moderate the efficacy of EW in patients with cancer. Although Lu and Dong [17] conducted EW-related research among BC patients undergoing chemotherapy in China, their research focused on exploring the effects of three different writing conditions.

Based on the findings of the present study, the prolonged EW intervention showed no beneficial effects over the original EW intervention on health outcomes in BC patients undergoing chemotherapy. However, the findings of the study could be a relevant addition to the existing EW intervention research, showing that increasing the dosage does not appear to improve the efficacy of EW interventions in BC patients and survivors. Additional research is warranted to determine whether individual differences, the ability to express emotion, avoidance, and other possible moderators are associated with the efficacy of EW interventions among BC patients undergoing chemotherapy.

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Data availability The corresponding author has full control of all primary data. Primary data are available on request.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Informed consent statement The trial was approved by the involved hospitals, including the Medical Ethics Committee of Nanfang Hospital (reference number: NFEC-2018-049), The Affiliated Hospital of Guangdong Medical University (reference number: PJ2018-029), The Cancer Center of Guangzhou Medical University (reference number: 2018-003), The First Affiliated Hospital of Shantou University Medical College (reference number: 2018-039), and Shenzhen People's Hospital (reference number: 2018-029). Written informed consent was obtained from each participant prior to the study.

Code availability Not applicable.

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Original Article

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Can emotional expressivity and writing content predict beneficial effects of expressive writing among breast cancer patients receiving chemotherapy? A secondary analysis of randomized controlled trial data from China

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Abstract

Background. To explore whether emotional expressivity and the patterns of language use could predict benefits from expressive writing (EW) of breast cancer (BC) patients in a culture that strongly discourages emotional disclosure.

Methods. Data were obtained from a recent trial in which we compared the health outcomes between a prolonged EW group (12 sessions) and a standard EW group (four sessions) ($n = 56$ per group) of BC patients receiving chemotherapy. The Chinese texts were tokenized using the THU Lexical Analyser for Chinese. Then, LIWC2015 was used to quantify positive and negative affect word use.

Results. Our first hypothesis that BC patients with higher levels of emotional expressivity tended to use higher levels of positive and negative affect words in texts was not supported ($r = 0.067$, $p = 0.549$ and $r = 0.065$, $p = 0.559$, respectively). The level of emotional expressivity has a significant effect on the quality of life (QOL), and those who used more positive or fewer negative affective words in texts had a better QOL (all $p < 0.05$). However, no significant difference was identified in physical and psychological well-being (all $p > 0.05$). Furthermore, the patterns of affective word use during EW did not mediate the effects of emotional expressivity on health outcomes (all $p > 0.05$).

Conclusions. Our findings suggest that the level of emotional expressivity and the pattern of affective word use could be factors that may moderate the effects of EW on QOL, which may help clinicians identify the individuals most likely to benefit from such writing exercises in China.

Introduction

Breast cancer (BC) is the most common cancer in women worldwide, and approximately 12% of women will be diagnosed with the disease over their lifetime (Bray et al., 2018; Waks & Winer, 2019). Despite improvements in treatment and supportive care, psychological problems and somatic symptoms are still commonly reported by BC patients, particularly those who receive chemotherapy (Chu et al., 2021; Godinho-Mota et al., 2021). Furthermore, increased side effects of adjuvant chemotherapy have been proven to be related to psychological distress and emotional suppression in BC patients, and these problems do not significantly decrease over time (Alquraan et al., 2020; Brown et al., 2021).

Emotional disclosure is a term used to describe the release of previously unshared or unexpressed feelings and thoughts, resulting in reduced psychological work of inhibition (McInerney et al., 2019; Pennebaker & Beall, 1986). Expressing emotions has been suggested as a psychological treatment, and numerous studies have shown that the process of disclosure is associated with improvements in physical and mental health (Bantum & Owen, 2009; McInerney et al., 2019).

Expressive writing (EW) is one of the first systematically evaluated kinds of emotional disclosure interventions. EW is a method developed by Pennebaker and Beall (1986) to facilitate disclosure through writing about one's traumatic feelings or stress-related upsetting feelings for four consecutive days, 20 min each day. Since the first EW study was published in 1986, numerous studies have emerged to explore the potential effectiveness of EW in various groups of people, such as cancer patients (Zachariae & O' Toole, 2015; Zhou, Wu, An, & Li, 2015),

Table 1. The effects of emotional expressivity and patterns of affective word use on health outcomes in EW interventions

				Estimate	S.E.	Z	p
FACT-B	ICEPT	<---	EES	0.553	0.282	1.966	0.049
	SLOPE	<---	EES	-0.056	0.046	-1.233	0.218
	ICEPT	<---	Positive emotion	3.050	1.283	2.378	0.017
	SLOPE	<---	Positive emotion	-0.398	0.207	-1.921	0.055
	ICEPT	<---	Negative emotion	-3.345	0.957	-3.495	<0.001
	SLOPE	<---	Negative emotion	0.439	0.157	2.801	0.005
HADS	ICEPT	<---	EES	0.047	0.034	1.392	0.164
	SLOPE	<---	EES	0.003	0.008	0.363	0.717
	ICEPT	<---	Positive emotion	-0.192	0.156	-1.236	0.217
	SLOPE	<---	Positive emotion	0.023	0.037	0.624	0.533
	ICEPT	<---	Negative emotion	-0.034	0.121	-0.277	0.782
	SLOPE	<---	Negative emotion	0.019	0.028	0.686	0.493
SAI-B	ICEPT	<---	EES	-0.098	0.145	-0.673	0.501
	SLOPE	<---	EES	-0.010	0.036	-0.265	0.791
	ICEPT	<---	Positive emotion	-0.982	0.660	-1.487	0.137
	SLOPE	<---	Positive emotion	0.106	0.165	0.644	0.519
	ICEPT	<---	Negative emotion	0.930	0.508	1.833	0.067
	SLOPE	<---	Negative emotion	-0.118	0.127	-0.925	0.355

FACT-B, Functional Assessment of Cancer Therapy-Breast Cancer Version; HADS, The Hospital Anxiety and Depression Scale; SAI-B, Symptoms Assessment Inventory for Breast Cancer Patients Receiving Chemotherapy; EES, Emotional Expressivity Scale.

Parkinson's disease (Corum, Cash, & Lageman, 2014), and students (Hijazi, Tavakoli, Slavin-Spenny, & Lumley, 2011).

Although writing treatment has generally been considered beneficial, the results from numerous meta-analyses have identified little effect on cancer patients (McInnerney *et al.*, 2019; Mogk, Otte, Reinhold-Hurley, & Kröner-Herwig, 2006; Zachariae & O' Toole, 2015). Given its cost-effectiveness, convenience and ease of implementation by nurses in the clinic, numerous studies have been conducted to test the factors that may moderate the effectiveness of EW interventions. For example, a recently published randomized controlled trial conducted by Wu *et al.* (2021) explored the effects of prolonged EW on health outcomes in BC patients receiving chemotherapy to help understand how the dosage of the writing intervention might moderate its effectiveness.

EW interventions produce a wealth of data on participants' feelings and thoughts that end up in the written texts. These linguistic data are particularly useful for exploring the mechanisms of the writing action and for improving EW methodologies. Previous studies on essays from EW have identified associations between the patterns of language use and health outcomes (Bantum & Owen, 2009; Pennebaker & Stone, 2003). For example, Niles, Byrne Haltom, Lieberman, Hur, and Stanton (2016) found that positive and negative emotional word use was correlated with physical and psychological symptoms. This is in accordance with the findings from Laccetti (2007) that positive emotional word use was positively correlated with emotional well-being in women with advanced BC. Furthermore, Pulverman, Lorenz, and Meston (2015) also identified that language changes in EW may predict mental health in women with a history of childhood sexual abuse.

However, relevant research is absent among Chinese BC patients, whose culture particularly discourages emotional disclosure (Louie,

Oh, & Lau, 2013; Ting & George, 2012). Given the different cultural beliefs about cancer and forms of emotional expression in Chinese BC patients, understanding the association between the patterns of affective word use and health outcomes within this population will help to identify medical and informational needs that clinicians can intervene in with future services. Previous studies with Chinese or Chinese immigrants have shown a number of specific cultural values associated with emotional expression (Chen & Zhou, 2019; Chen, Zhang, Chen, & Li, 2012; Luo, Tamis-LeMonda, & Song, 2013). For example, Lu, Man, You, and LeRoy (2015) identified positive associations between ambivalence over emotional expression and depressive symptoms in Chinese BC survivors. Asian individuals benefited more from EW than Caucasians (Lu & Stanton, 2010). Furthermore, Chen and Zhou (2019) found that cultural values were uniquely associated with emotional expressivity in Chinese American immigrant parents.

Based on these findings of the relationship between the patterns of affective word use and health outcomes, one might infer that any barriers to emotional disclosure could inhibit cognitive processing of traumatic events and thereby would influence individuals to express their emotions and feelings about traumatic events. Previous studies have identified the relationship between external constraints (e.g. social constraints) and the level of expressing one's emotions in relation to traumatic events (Martin *et al.*, 2020). According to this view, one could expect internal constraints to have similar consequences as external constraints. Someone may not be naturally inclined to express their emotions through writing or talking with others. Therefore, it is also essential to identify stable individual differences in the tendency to express feelings and emotions that could influence the effects of writing interventions.

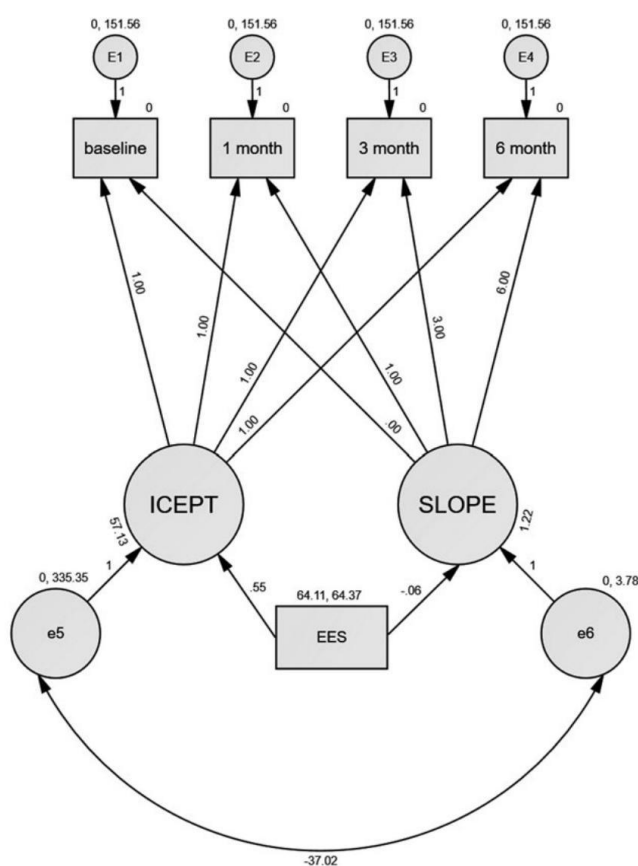


Fig. 1. LGCM for EES and FACT-B.

To address this idea, the main objective of the current study was to explore whether emotional expressivity and the patterns of language use could predict benefits from EW interventions in Chinese BC patients, whose culture strongly discourages emotional disclosure. Emotional expressivity has been defined as the extent to which a person outwardly displays emotions regardless of valence or channel (Kring, Smith, & Neale, 1994). People with lower levels of emotional expressivity are associated with depression, social anhedonia and other psychological impairments (Leung, Couture, Blanchard, Lin, & Llerena, 2010; Sloan, Strauss, & Wisner, 2001). Conversely, higher levels of emotional expressivity have been linked to greater pleasure from social interactions (Kring et al., 1994). The importance of individual differences in emotional expressivity in psychology and clinical practice and its possible role in physical and psychological health have long been recognized (Jacobson, Hill, Pettit, & Miranda, 2015).

Based on the literature reviewed above, the present study tested the following four hypotheses among Chinese BC patients receiving chemotherapy: (1) BC patients with higher levels of emotional expressivity tended to report higher levels of positive or negative affect words in texts; (2) those who have higher levels of emotional expressivity would demonstrate greater improvements in health outcomes after the EW intervention compared to those

who tend to be less emotionally expressive; (3) those who used more positive or less negative affect words in texts would demonstrate greater improvements in health outcomes after the EW intervention; (4) the patterns of affective word use would mediate emotional expressivity in exerting an impact on health outcomes after EW interventions.

Methods

Design

This study was a secondary analysis, using data collected initially from a multicentre randomized controlled trial (Wu et al., 2021), in which we examined the effects of a prolonged EW intervention (12 sessions) on health outcomes in BC patients receiving chemotherapy and comparing the effects to that of a classical EW intervention (four sessions). Using a descriptive, correlational design, the emotional expressivity of patients and the patterns of affective word use in EW texts were analysed in the present study to explore whether emotional expressivity and the patterns of language use could predict the benefits of EW. This study was registered in the Chinese Clinical Trial Register (ChiCTR) (registration number: ChiCTR1800016278, at <http://www.chictr.org.cn/>).

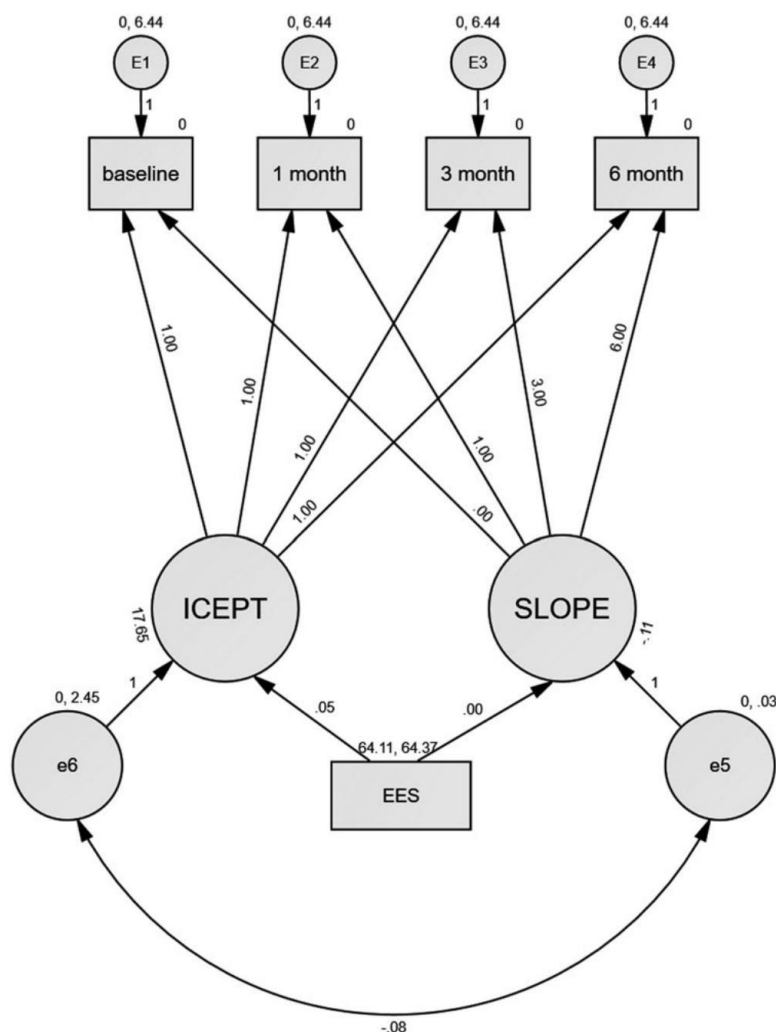


Fig. 2. LGCM for EES and HADS.

Participants

BC patients receiving chemotherapy were randomly recruited from five tertiary hospitals in Guangdong Province in China. Eligibility criteria were: (1) BC patients diagnosed by pathology; (2) patients undergoing chemotherapy with chemotherapy cycles continuing for more than 1 month; (3) patients who were able to write Chinese and physically able to write by hand for more than 20 min at a time; (4) patients with Chinese fluency and a primary education and above; (5) female patients with an age older than 18 years; (6) patients who were expected to survive for more than 6 months; and (7) patients who provided signed informed consent.

A total of 112 participants were randomly assigned to the prolonged EW group or the EW group ($n = 56$ per group). The

sample size was calculated based on the Functional Assessment of Cancer Therapy-Breast Cancer Version (FACT-B), which is the primary outcome of the randomized trial. Power analysis revealed that 56 participants per group would yield 80% power to test the hypothesis with an estimated effect size of $d = 0.58$ derived from previous studies (Craft, Davis, & Paulson, 2013; Stanton, 2002) and considering an expected dropout rate of 20%. For the current study, two participants in the prolonged EW group were excluded from analysis, including one participant lost to follow-up at 3 months and one participant who died from disease at the 6-month follow-up. Four participants in the EW group were excluded from the analysis: three participants were lost to follow-up at 1, 3 and 6 months, and one discontinued chemotherapy. Thus, 54 BC patients in the prolonged EW group and 52 in

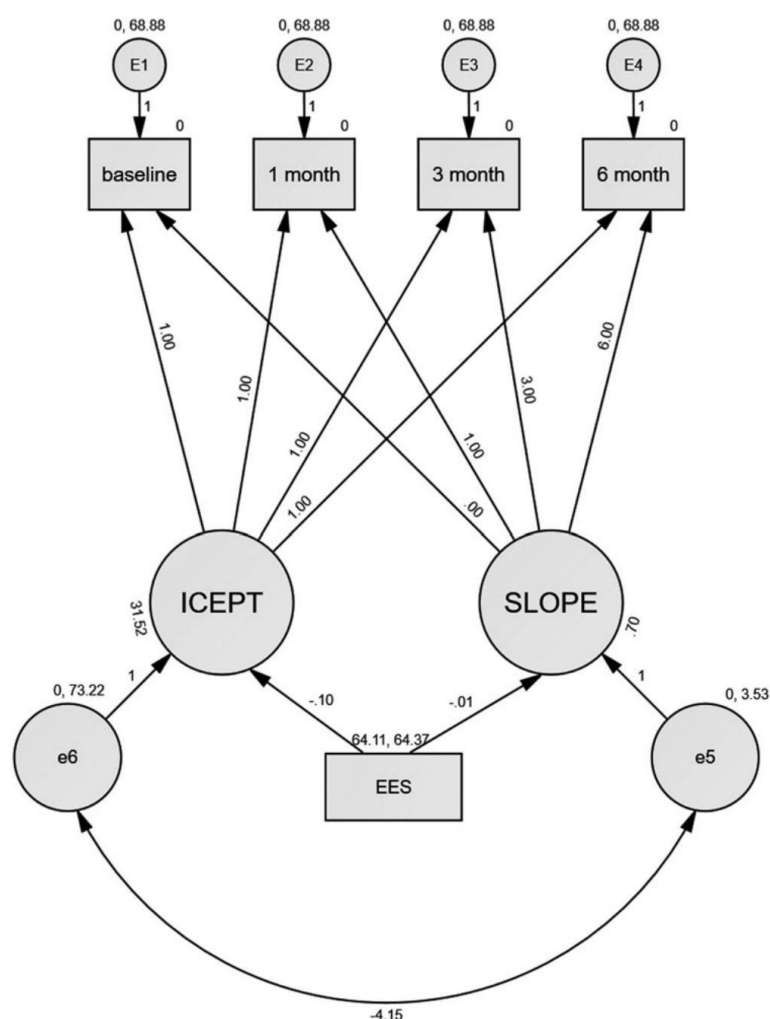


Fig. 3. LGCM for EES and SAI-B.

the EW group in the primary study finished the writing intervention and the planned 6-month health outcome assessment.

The participants were an average of 43.07 years old (*S.D.* = 9.14, range = 26–69). A total of 95.2% were married, 51.8% were being treated as inpatients, 89.2% had medical insurance. For the cancer stage: 18.1% were at stage I, 51.8% were at stage II, 27.7% were at stage III and 2.4% were at stage IV. The average number of completed chemotherapy cycles was 3.17 (*S.D.* = 2.09, range = 1–10) [for a diagram of the participant flow through the research, see Wu et al. (2021)].

Instruments

Emotional expressivity

The emotional expressivity of the BC patients was assessed using the Chinese version of the Emotional Expressivity Scale (EES),

which is a 17-item self-report instrument (Chan et al., 2010). It was designed to test the extent to which people outwardly display their emotions (Kring et al., 1994). A six-point Likert-type scale (6 = always true and 1 = never true) was used to indicate the extent to which each item applies to each participant. A higher score indicates that a participant is more likely to display their emotions to others. The Cronbach's α of EES was 0.91, and the test-retest reliability was 0.90.

Quality of life

The participant's quality of life (QOL) was investigated by using the FACT-B (Brady et al., 1997). The 36-item self-report instrument was invented to assess the multidimensional health-related QOL of patients with various stages of BC. Each item is rated on a scale from 0 to 4 to indicate how accurately each statement

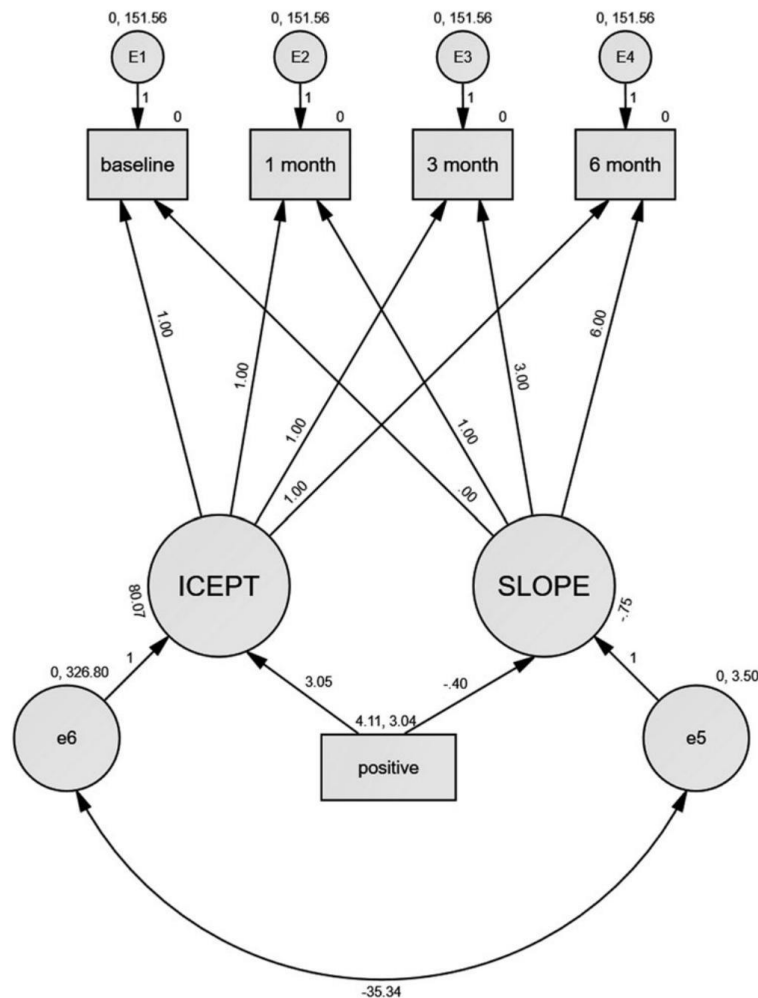


Fig. 4. LGCM for positive emotion and FACT-B.

represents the BC patients' personal condition over the past week. The total QOL score of the FACT-B ranged from 0 to 144. Higher scores on the scale indicate higher QOL. The FACT-B has been widely used in EW interventions among BC patients (Craft et al., 2013; Gellaitry, Peters, Bloomfield, & Horne, 2010). The validity of the scale in BC patients was reported to be 92% (Stanton, 2002) and 92.5% (Craft et al., 2013).

Physical health-related outcomes

Physical health-related outcomes were assessed using the 26-item Symptoms Assessment Inventory for Breast Cancer Patients Receiving Chemotherapy (SAI-B) (WEN Cuiju et al., 2012). The SAI-B was invented to assess the severity and impact of symptoms among BC patients who are receiving chemotherapy. A five-point Likert-type scale was used, and BC patients were

required to indicate the worst instance of each symptom during the last cycle of adjuvant chemotherapy (0 = 'not present' to 4 = 'very serious'). The Cronbach's α of the SAI-B in Chinese BC patients has been reported to be 0.818, the content validity index was 0.977 and the test-retest reliability was 0.745 (WEN Cuiju et al., 2012).

Psychological well-being

Psychological well-being was assessed using the Hospital Anxiety and Depression Scale (HADS), which is a 14-item self-report instrument (Zigmond & Snaith, 1983). The HADS was invented as a brief instrument to assess the severity of both depression and anxiety symptoms. Respondents are required to indicate the extent to which they felt each particular feeling (e.g. scared, sadness) over the past month on a scale from 0 to 3. The HADS has

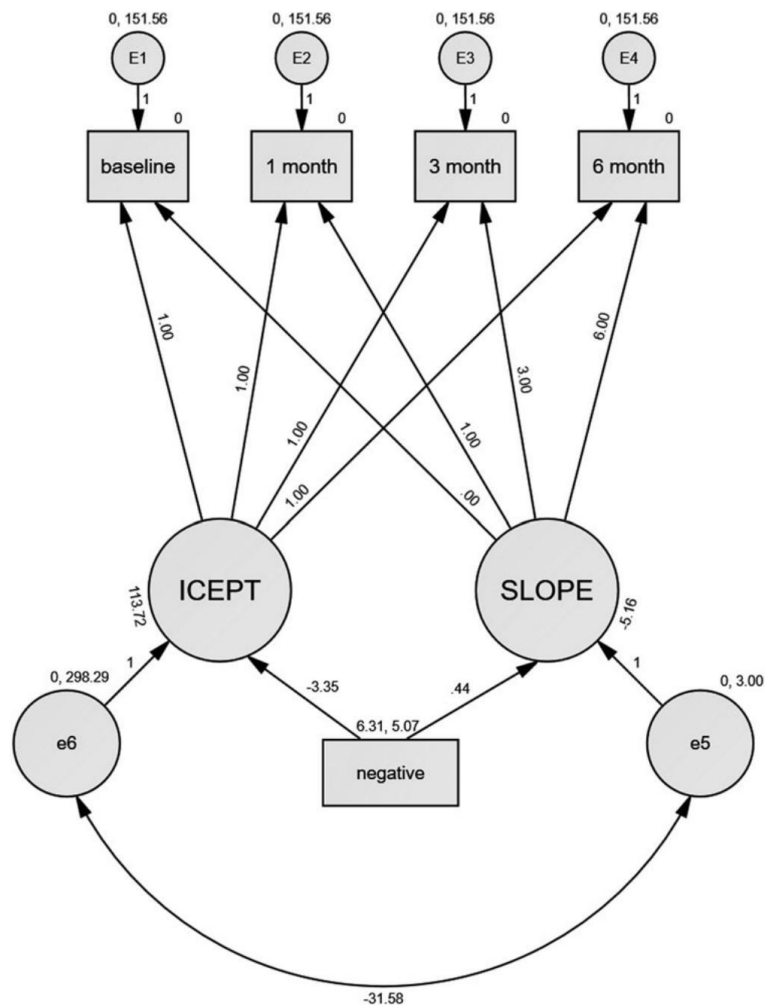


Fig. 5. LGCM for negative emotion and FACT-B.

been widely used to assess the psychological health of BC patients in EW (Mosher et al., 2012; Park & Yi, 2012).

A brief general information questionnaire was used before randomization in the primary study to assess occupation, educational level, age, marital status, types of medical expense payment and some potentially relevant medical variables, such as treatment approach, cancer stage and number of completed chemotherapy cycles. The FACT-B, SAI-B and HADS were used at baseline and 1, 3 and 6 months after the final writing session, and the EES was used at baseline to investigate the emotional expressivity of the BC patients.

Procedures

Potential participants were identified by a trained research assistant at each study site. The research was described to the

participants using a standardized script. At the time of enrolment, written informed consent was obtained, and randomization was conducted.

Participants in the EW group were required to write for at least 20 min a day for four consecutive days (four sessions) based on Pennebaker's prompt (Pennebaker & Beall, 1986). The prolonged EW group used a modified prompt: write for at least 20 min three times a week over a 4-week period (12 sessions); participants can choose whether to write on consecutive days or not. Participants in each group were all required to write about their traumatic feelings or stress-related upsetting feelings about BC based on the standard instructions from Pennebaker and Beall (1986). The writing instructions for each session were the same, and participants could choose to write about different topics or the same topic each time. An experienced psychology counsellor could be

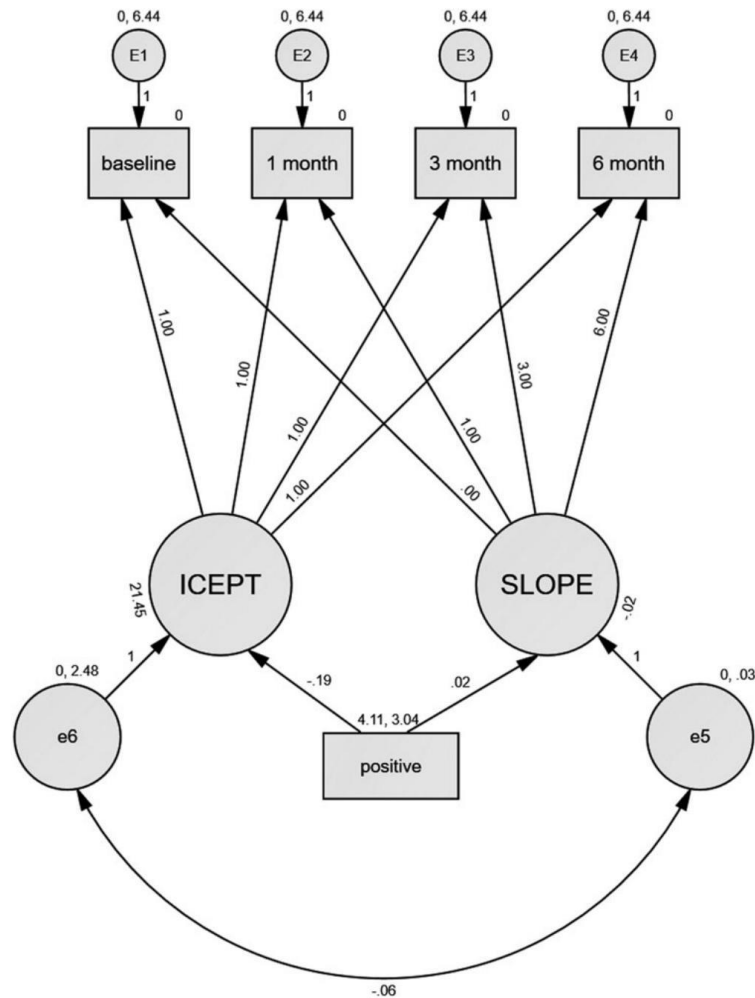


Fig. 6. LGCM for positive emotion and HADS.

consulted upon request by the BC patients during the writing intervention process. The questionnaires were collected by a trained research assistant through an online survey platform (www.wjx.cn). After the final writing session, the participants were required to hand in their writing texts. For additional details of the research procedures, see Wu *et al.* (2021).

Data analysis

The following steps were conducted to analyse Chinese words that resulted from writing texts. First, the texts were tokenized using the THU Lexical Analyser for Chinese (Natural Language Processing and Computational Social Science Laboratory of Tsinghua University, 2017). THULAC was developed by the

Natural Language Processing and Computational Social Science Laboratory of Tsinghua University and has been widely used as a Chinese tokenizer.

Second, LIWC2015 software was used to calculate the percentages of positive affect words (e.g. happy, love) or negative affect words (e.g. sad, hurt) among the total words in each writing text (Pennebaker, Both, & Boyd, 2015). LIWC (Linguistic Inquiry and Word Count) has been widely used for psychological text analysis to explore different types of word samples in English or other languages (Agosti & Rellini, 2007; Francis & Pennebaker, 1993; Piolat, Booth, Chung, Davids, & Pennebaker, 2011). In our study, the Simplified Chinese version of the LIWC2015 Dictionary (SCLIWIC) was used, which is a translation of the LIWC English dictionary and has been adapted according to

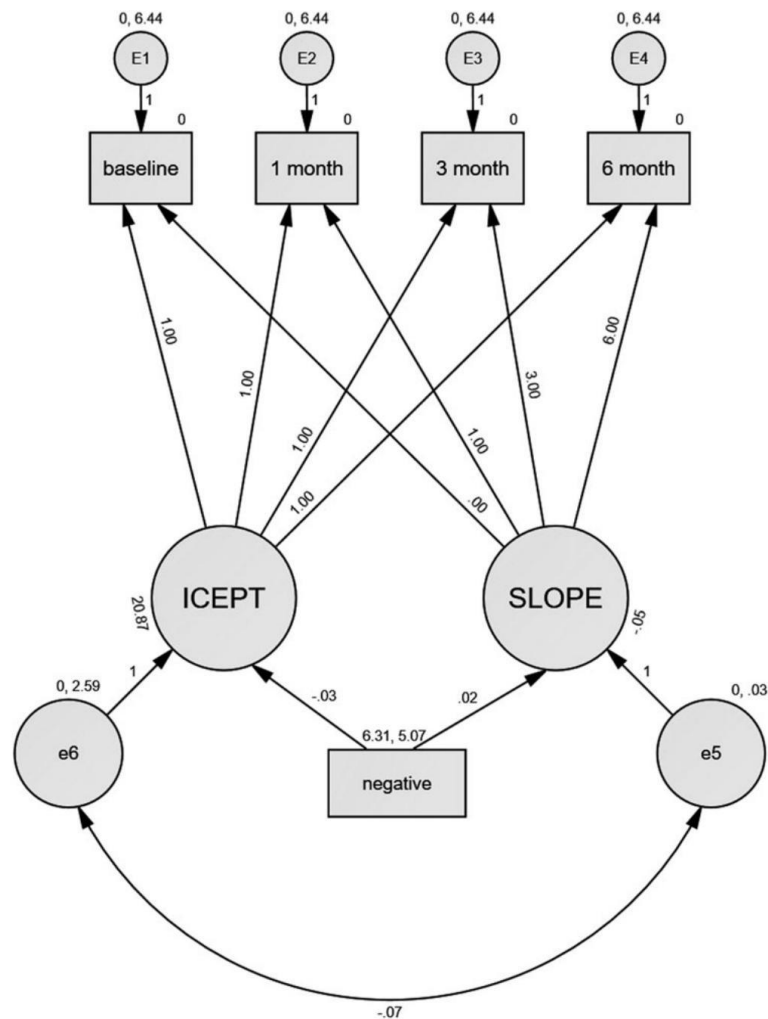


Fig. 7. LGCM for negative emotion and HADS.

culturally relevant Chinese forms of emotional expression by researchers from the Chinese Academy of Sciences (Gao, Hao, Li, Gao, & Zhu, 2013). SCLIWIC has been identified to have good reliability and validity to capture culturally relevant emotional expressions and has been widely used for Chinese text analysis (Gao et al., 2013; Su et al., 2020).

In addition, although LIWC has been widely used for text analysis, it cannot capture all of the nuances of writing texts. For example, LIWC cannot discriminate between the use of 'happy' and 'not happy'. Both sentences received the same positive emotionality score. To address these important nuances, two postgraduate research assistants independently reviewed each text manually to effectively identify negative and positive modifiers (i.e. *not* happy). During the process, first, the 'negate' category in LIWC

software was used to identify negations in each text. Then, two research assistants independently reviewed each identified negation manually to judge whether the meaning of the calculated emotional words needed to be changed. A standard form was used to record the modification in each text. Disagreements were resolved by consensus or a third person. Finally, a total of 471 positive or negative emotion words calculated by LIWC software were modified due to negations and idiomatic language in China.

All data were tested for homogeneity and normality of variances. To test the relationship between EES and affective word use (hypothesis 1), the data were analysed using Pearson correlation analysis in SPSS 20.0 (IBM, USA). To test whether EES and the patterns of affective word use predicted health outcomes (hypotheses 2 and 3), the data were analysed using the latent variable

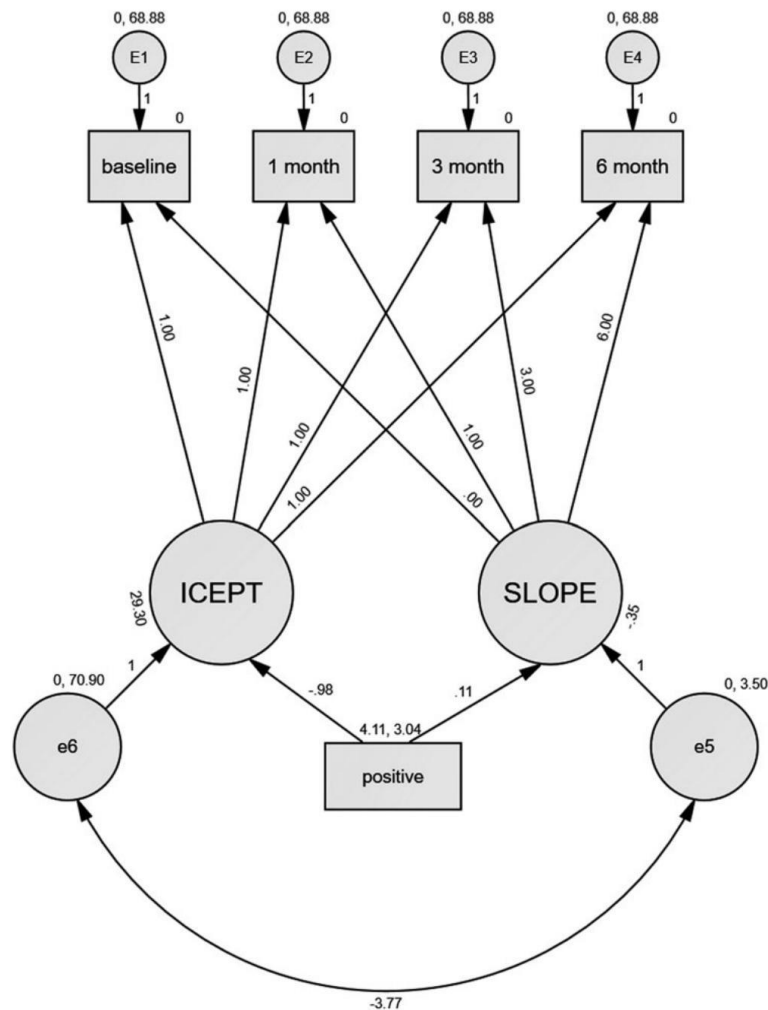


Fig. 8. LGCM for positive emotion and SAI-B.

growth curve model (LGCM) in AMOS 23.0 (IBM, USA). In addition, according to the findings of our previous analysis based on the data of this randomized controlled trial, there was no significant difference in the FACT-B, SAI-B and HADS scores between the prolonged EW group (12 sessions) and the standard EW group (four sessions) at any time point (Wu et al., 2021). It was shown that the writing dosage does not moderate the effects of EW. Therefore, subjects in the two groups were not analysed separately in the current study. Furthermore, to test the direct and/or indirect effects of the patterns of affective word use mediating EES for exerting an impact on health outcomes in EW, the data were analysed using a structural equation model in Mplus version 7.4 (hypothesis 4). In the analysis, the 6-month postintervention FACT-B, SAI-B and HADS scores for each participant were used. A two-sided $p < 0.05$ was considered statistically significant.

Results

A total of 158 227 Chinese words that resulted from the EW intervention were analysed. No participants sought psychotherapy or counselling during the writing intervention process. The first hypothesis of our study that BC patients with higher levels of emotional expressivity tended to report higher levels of positive or negative affect words in texts was not supported ($r = 0.067$, 0.065 , $p = 0.549$, 0.559 , respectively).

For the second hypothesis that those who have a higher level of emotional expressivity would demonstrate greater improvements in health outcomes after the EW intervention, the latent variable growth curve model showed that the level of emotional expressivity has a significant effect on FACT-B scores ($p = 0.049$) but did not have a significant slope ($p = 0.218$) (Table 1 and Fig. 1). The

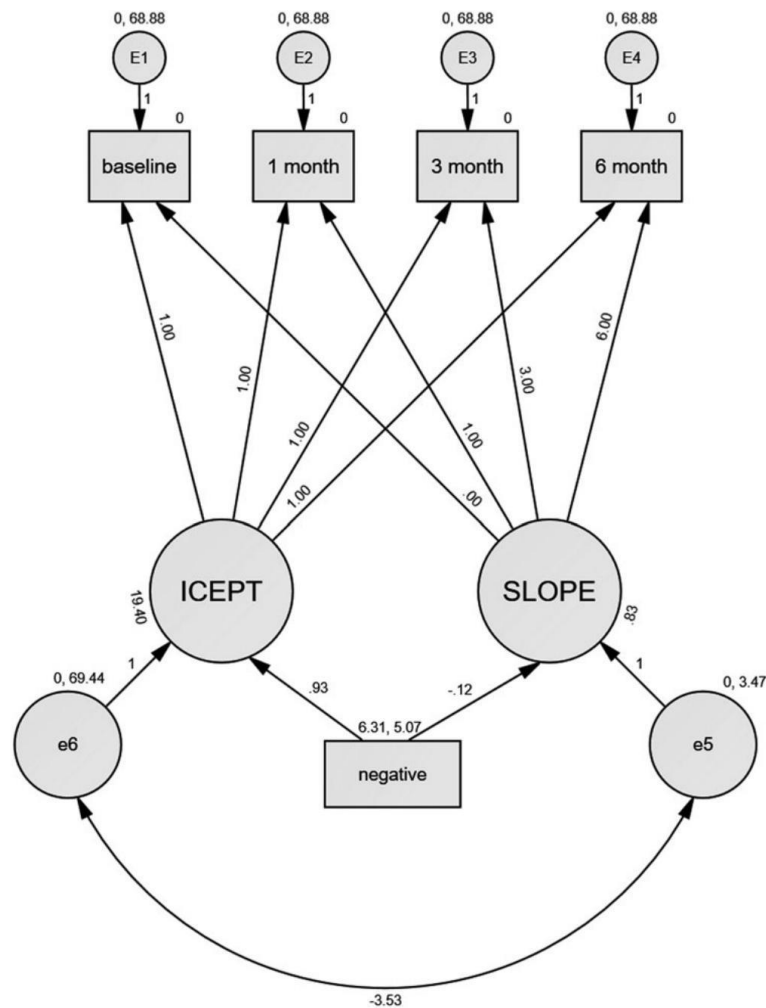


Fig. 9. LGCM for negative emotion and SAI-B.

results indicating that the higher level of emotional expressivity, the higher FACT-B scores identified, but the influence of emotional expressivity in the change in FACT-B scores was not statistically significant over time. In addition, no significant difference was identified in HADS and SAI-B (all $p > 0.05$) (Table 1, Figs 2 and 3).

Then, the third hypothesis of our study that BC patients who used more positive or less negative affect words in texts would demonstrate greater improvements in health outcomes after EW was demonstrated on one of the measured variables and there were no significant differences on two other measures. The data were analysed by the latent variable growth curve model, and the results showed that the level of positive emotion has a significant effect on FACT-B scores ($p = 0.017$) but did not have a significant slope ($p = 0.055$) (Table 1 and Fig. 4). In addition,

Table 1 and Fig. 5 also showed that the level of negative emotion has a significant effect on FACT-B scores ($p < 0.001$) and a statistically significant slope was identified ($p = 0.005$), indicating that the higher level of negative emotion, the faster the FACT-B scores declined over time. However, no significant difference was identified in HADS and SAI-B (all $p > 0.05$) (Table 1, Figs 6–9).

Furthermore, as shown in Tables 2–4, the patterns of affective word use did not mediate the effects of emotional expressivity on health outcomes after the EW intervention in BC patients receiving chemotherapy (all $p > 0.05$).

Discussion

In contrast to prior studies on linguistic analysis following EW that primarily focused on Caucasian populations, our study

Table 2. The direct and/or indirect effects of patterns of affective word use mediating EES in exerting an impact on FACT-B in EW interventions at 6-months follow-up (bootstrap = 1000)

	Point estimate	Product of coefficients		Bootstrap			
				Percentile 95% CI		BC 95% CI	
		S.E.	Z	Lower	Upper	Lower	Upper
Indirect effects							
Positive emotion	0.003	0.021	0.156	−0.023	0.067	−0.021	0.070
Negative emotion	−0.009	0.023	−0.401	−0.067	0.032	−0.102	0.017

EES, Emotional Expressivity Scale; FACT-B, Functional Assessment of Cancer Therapy-Breast Cancer Version; EW, expressive writing.
 * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

Table 3. The direct and/or indirect effects of patterns of affective word use mediating EES in exerting an impact on HADS in EW intervention at 6-months follow-up (bootstrap = 1000)

	Point estimate	Product of coefficients		Bootstrap			
				Percentile 95% CI		BC 95% CI	
		S.E.	Z	Lower	Upper	Lower	Upper
Indirect effects							
Positive emotion	−0.002	0.007	−0.210	−0.022	0.008	−0.024	0.006
Negative emotion	0.001	0.005	0.151	−0.011	0.010	−0.004	0.020

EES, Emotional Expressivity Scale; HADS, The Hospital Anxiety and Depression Scale; EW, expressive writing.
 * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

Table 4. The direct and/or indirect effects of patterns of affective word use mediating EES in exerting an impact on SAI-B in EW intervention at 6-months follow-up (bootstrap = 1 000)

	Point estimate	Product of coefficients		Bootstrap			
				Percentile 95% CI		BC 95% CI	
		S.E.	Z	Lower	Upper	Lower	Upper
Indirect effects							
Positive emotion	−0.002	0.029	−0.058	−0.087	0.030	−0.076	0.038
Negative emotion	0.006	0.030	0.192	−0.068	0.068	−0.025	0.128

EES, Emotional Expressivity Scale; SAI-B, Symptoms Assessment Inventory for Breast Cancer Patients Receiving Chemotherapy; EW, expressive writing.
 * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

focused on a Chinese BC survivor population whose culture particularly discourages emotional disclosure. The present study adds to the existing literature by exploring whether emotional expressivity and the patterns of language use could predict benefits from EW interventions and the possible interaction between the two variables. Our hypothesis that BC patients with higher levels of emotional expressivity tended to report higher levels of positive or negative affect words in texts was not supported. Consistent with our hypotheses, this study found that emotional expressivity and the patterns of affective word use were related to QOL but there were no significant differences on two other measures. In addition, our findings suggest that the patterns of affective word use did not mediate the effects of emotional expressivity on health outcomes in EW interventions in Chinese BC patients.

Consistent with previous data on Caucasian populations, our study also identified correlations between the patterns of affective word use and health outcomes in Chinese BC patients. The present study showed that BC patients who used more negative emotional words reported lower levels of QOL over time, which is supported by Niles *et al.* (2016), who identified that negative emotional word use was significantly positively correlated with increased depression. Sullivan, Leifker, and Marshall (2018) found that men's posttraumatic stress disorder symptom severity was associated with the expressivity of negative emotions. Our findings are also in accordance with the results by Pennebaker and Chung (2007), who reported that very high negative word use was associated with less benefit from EW. A possible explanation for this is that perhaps participants who overuse negative

emotion words are generally higher in negative affect and use the EW intervention as a ruminative process that could inhibit the achievement of closure through the writing intervention (Niles et al., 2016; Pennebaker & Chung, 2007).

To test the hypothesis that EW might be contraindicated for Chinese BC patients who do not typically express emotions, the possible role of emotional expressivity was analysed in the present study. Consistent with our hypothesis, BC patients with higher levels of emotional expressivity demonstrated higher FACT-B scores than those who tended to be less emotionally expressive. This is in accordance with previous findings that women with high emotional expressivity experienced relatively low levels of distress (Zakowski, Valdimarsdottir, & Bovbjerg, 2001). Niles, Haltom, Mulvenna, Lieberman, and Stanton (2014) also found that young adult participants high in emotional expressivity experienced a significant reduction in anxiety after EW.

However, other studies have identified different patterns of results as in our study. Namely, that writing interventions are more effective for those who are reluctant or unable to express emotions. Lu and Stanton (2010) investigated the moderating effects of ambivalence over emotional expression on EW in 130 undergraduates. The EW intervention showed greater reductions in negative affect for highly ambivalent undergraduates than for less ambivalent undergraduates. Solano, Donati, Pecci, Persichetti, and Colaci (2003) examined the effects of EW on 40 patients after bladder papilloma resection and found that compared to those low in alexithymia, writing intervention significantly reduced psychological and physical symptoms for those high in alexithymia.

In addition, the hypothesis that BC patients with higher levels of emotional expressivity tended to report higher levels of positive or negative affect words in texts was not demonstrated in our study. Previous studies have identified a link between emotional expressivity and psychological and physical symptoms in writing interventions (Niles et al., 2014; Zakowski et al., 2001). Our research and previous evidence also showed that the patterns of language use in texts could predict the intervention effects of EW (Niles et al., 2016; Sullivan et al., 2018). However, the failed demonstrated hypothesis from our study suggests that BC patients with high levels of emotional expressivity do not mean that they will express more emotions through writing compared to those with low levels of emotional expressivity. This was also supported by the results from our study that the patterns of affective word use did not mediate the effects of emotional expressivity on health outcomes in EW interventions. This is perhaps because people differ individually in the extent to which they express their emotions (Trierweiler, Eid, & Lischetzke, 2002). Emotions could be expressed in various ways, such as body cues, facial cues, verbal or EW. Perhaps not all expressive people like to express their feelings in writing. Therefore, it is suggested that matching a person's naturally selected disclosure approach with an assigned intervention is beneficial.

The study has some limitations. First, although LIWC2015 calculated the percentages of positive or negative affect words among the total words in each writing text, the information from the prolonged EW group was much richer and possibly more nuanced than that from the standard EW group, which may have produced some biases in the study. In addition, because this study investigated writing interventions and emotional expression in Chinese BC patients, it is unclear how these findings would generalize to Caucasian or other cultures. However, BC patients in our study were recruited from five large tertiary hospitals from four different cities in China, which could demonstrate the generalization of the findings in Chinese BC patients.

In conclusion, the current study is the first to test the relationship between emotional expressivity and health outcomes in EW in Chinese BC patients and its role in influencing the patterns of affective word use in writing texts. The findings of the present study support the hypothesis that the level of emotional expressivity and the pattern of affective word use could be factors that moderate the effects of EW on QOL of BC patients, which may help clinicians identify the individuals most likely to benefit from writing exercises in China. However, a relationship between emotional expressivity and linguistic changes in EW was not demonstrated and additional research is necessary to identify possible factors that may moderate the patterns of affective word use in EW that could be used to enhance the positive effects of writing interventions.

Data

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

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Author contributions. YW and CZ were responsible for the design of the research. YW, DY, BJ, LL, CL, WL and XL collected and analysed the data. YW wrote the manuscript. All authors read and approved the final manuscript.

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Conflict of interest. None.

Ethical standards. The study was approved by the involved hospitals including the Medical Ethics Committee of Nanfang Hospital (reference number: NFEC-2018-049), Cancer Center of Guangzhou Medical University (reference number: 2018-003), Shenzhen People's Hospital (reference number: 2018-029), Affiliated Hospital of Guangdong Medical University (reference number: PJ2018-029) and The First Affiliated Hospital of Shantou University Medical College (reference number: 2018-039). Written informed consent was obtained from each participant prior to the study.

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Appendix 2: Statement of candidate's independent work and individual contribution

Funded studies, especially systematic reviews and multi-center trials, are typically team endeavours. Collaborating with team members is often a necessary way to reduce bias in a systematic review. However, the candidate has made a unique contribution in each of the papers within the portfolio. Following is a statement outlining the extent to which the works are based on the candidate's own independent work; an indication as to the extent that the work was produced jointly and the clear quantitative and/or qualitative apportioning of the extent of the sharing of the work; and statements by those with whom work was shared agreeing that apportioning (Appendix 3).

No	Paper	Independent/Unique Contribution	Joint Contribution	Impact Factor/Number of Citations
1	Liping Liu, Yanni Wu, et al. 2021	Advise and lead on study design, supervise the review process	Evidence searches and data extraction, critical appraisal, wrote and revised the paper. Co-authored of paper	IF: 4.147 Citations-18#
2	Huihui Zhao, Xiaojin Li, Chunlan Zhou, Yanni Wu, et al. 2022	Advise on study design	Revised the paper. Co-authored of paper	IF: 3.187 Citations-8#
3	Liping Liu, Yikai Xu, Yanni Wu, et al. 2021	Performed the analyses and revised the manuscript	Translate and culturally adapt the scale. Co-authored of paper	IF: 2.067 Citation-1#
4	Chunlan Zhou, Yanni Wu, et al. 2015	Overall project management, lead on study design, defined the inclusion and exclusion criteria, wrote and revised the paper	Data analysis, Designed the search strategy and performed and updated the search, screened the reference files and extracted the data. Co-first and co-corresponding author of paper	IF: 3.240 Citations-50#
5	Yanni Wu et al. 2021	Secured funding ^① , overall project management, study design, data analysis, generate random serial number, sample calculation, trial registration, ethical approval, wrote and	Collect data, recruit patients (a multi-center trial). Principal author on paper	IF: 3.603 Citation-3#

		revised the paper		
6	Yanni Wu et al. 2021	Secured funding②, overall project management, study design, trial registration, ethical approval, wrote and revised the paper	Collect and analysis the data, recruit patients (a multi-center trial). Principal author on paper	IF: 10.592 Citation-1#

IF=Impact Factor (only supplied if available for journal); #=number of citations according to Google Scholar; ①= Yanni Wu (100%). Funded by the Health Commission of Guangdong Province (grant no.A2018090); ②= Yanni Wu (100%). (2020-2023). Funded by the Natural Science Foundation of Guangdong Province (grant no.2020A1515110894) (15,390 USD).

Appendix 3: Letters from collaborating authors confirming contribution



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2nd September 2022

This letter is to confirm the contribution of Yanni Wu to the following paper:

Liu, L., Wu, Y., Cong, W., Hu, M., Li, X., & Zhou, C. (2021). Experience of women with breast cancer undergoing chemotherapy: a systematic review of qualitative research. *Quality of life research: an international journal of quality of life aspects of treatment, care and rehabilitation*, 30(5), 1249–1265.

<https://doi.org/10.1007/s11136-020-02754-5>

This paper synthesized existing findings to better understand the experience of women with breast cancer undergoing chemotherapy. Yanni Wu advised and guided the study design, and supervised the review process. In addition, Yanni Wu was involved in evidence searches and data extraction, critical appraisal, wrote and revised the paper.

Yours sincerely

A handwritten signature in black ink that reads 'Liping Liu'.

First author of the paper:

Liping Liu

RN of Nanfang Hospital, Southern Medical University



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2nd September 2022

This letter is to confirm the contribution of Yanni Wu to the following paper:

Zhao, H., Li, X., Zhou, C., Wu, Y., Li, W., & Chen, L. (2022). Psychological distress among Chinese patients with breast cancer undergoing chemotherapy: Concordance between patient and family caregiver reports. *Journal of advanced nursing*, 78(3), 750–764.

<https://doi.org/10.1111/jan.15004>

This paper examined patient-caregiver concordances about psychological distress among Chinese patients with breast cancer undergoing chemotherapy and identified factors related to concordance among patients and family caregivers. Yanni Wu advised on the study design and was involved to write and revise the paper.

Yours sincerely

Chunlan Zhou

Corresponding author of the paper:

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30th August 2022

Dear Sir/Madam,

I am writing this letter to confirm the contribution of Yanni Wu to the following paper:

Liu, L., Xu, Y., Wu, Y., Li, X., & Zhou, C. (2021). Cross-Cultural Adaptation and Validation of the Emotional Inhibition Scale in a Chinese Cancer Sample. *Frontiers in psychology*, 12, 654777.

<https://doi.org/10.3389/fpsyg.2021.654777>

This cross-sectional study was used to adapt the Emotional Inhibition Scale (EIS) to Chinese conditions and examine the psychometric characteristics of the scale in patients with cancer. Yanni Wu performed the analyses and revised the manuscript. In addition, Yanni Wu was involved in translate and culturally adapt the scale.

Yours sincerely

First author of the paper:

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2nd September 2022

This letter is to confirm the contribution of Yanni Wu to the following paper:

Zhou, C., Wu, Y., An, S., & Li, X. (2015). Effect of Expressive Writing Intervention on Health Outcomes in Breast Cancer Patients: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *PloS one*, 10(7), e0131802.
<https://doi.org/10.1371/journal.pone.0131802>

This meta-analysis evaluated the effects of expressive writing, which is a brief emotional expression intervention, on physical and psychological health outcomes in breast cancer patients. Yanni Wu managed the overall project, guided study design, defined the inclusion and exclusion criteria, and wrote and revised the paper. In addition, Yanni Wu guided the data analysis, designed the search strategy, and worked with others to perform and update the search, screen the reference files, and extract the data. Yanni Wu is the co-first and co-corresponding author of paper.

Yours sincerely

Co-first author of the paper:

Chunlan Zhou

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2nd September 2022

This letter is to confirm the contribution of Yanni Wu to the following paper:

Wu, Y., Liu, L., Zheng, W., Zheng, C., Xu, M., Chen, X., Li, W., Xie, L., Zhang, P., Zhu, X., Zhan, C., & Zhou, C. (2021). Effect of prolonged expressive writing on health outcomes in breast cancer patients receiving chemotherapy: a multicenter randomized controlled trial. *Supportive care in cancer: official journal of the Multinational Association of Supportive Care in Cancer*, 29(2), 1091–1101.

<https://doi.org/10.1007/s00520-020-05590-y>

This multicenter RCT tested the hypothesis that increasing the writing dosage could improve the efficacy of expressive writing intervention in breast cancer patients undergoing chemotherapy. Yanni Wu secured funding of the research and was in charge of the project. Yanni Wu managed the overall project, determined the study design and data analysis methods, generated random serial number, calculated the sample, registered the trial, conducted the ethical approval, and wrote and revised the paper. As a multi-centre trial, Yanni Wu was involved in collecting data and recruiting patients. Yanni Wu is a principal author of the paper.

Yours sincerely

Corresponding author of the paper:

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2nd September 2022

This letter is to confirm the contribution of Yanni Wu to the following paper:

Wu, Y., Yang, D., Jian, B., Li, C., Liu, L., Li, W., Li, X., & Zhou, C. (2021). Can emotional expressivity and writing content predict beneficial effects of expressive writing among breast cancer patients receiving chemotherapy? A secondary analysis of randomized controlled trial data from China. *Psychological medicine*, 1–15. Advance online publication.

<https://doi.org/10.1017/S0033291721003111>

This study was a secondary analysis, using data collected initially from a multicenter RCT. Yanni Wu secured funding of the research and was in charge of the project. Yanni Wu managed the overall project, determined the study design, registered the trial, conducted the ethical approval, and wrote and revised the paper. In addition, Yanni Wu was involved in collecting and analyzing the data, and recruiting patients. Yanni Wu is a principal author of the paper.

Yours sincerely

Chunlan Zhou

Corresponding author of the paper:

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Director of the PR China Nanfang Nursing Centre of Evidence-based Practice: A JBI Centre of Excellence

Appendix 4: Ethical approval letters

伦理审查批件 Approval Letter			
批件号 No.	NFEC-2018-049		
研究项目名称 Protocol Title	乳腺癌化疗患者长期书写表达干预有效性的随机、多中心临床研究 Effect of Prolonged Expressive Writing on Health Outcomes in Breast Cancer Patients Receiving Chemotherapy: A Multi-centre Randomized Controlled Trial		
申请者 Submitter	南方医科大学南方医院 Nanfang Hospital of Southern Medical University		
研究科室 Research department	护理部, 乳腺科 The Nursing Department, The Galactophore Department		
主要研究者 Principal Investigator	周春兰 Chunlan Zhou		
审查类别 Scope of review	初始审查 (科研项目)		
审查方式 Review mode	☒ 会议审查 Full board review ☐ 快速审查 Expedited review		
审查日期 Review Date	2018-4-19	审查地点 Review Place	伦理委员会会议室
审查委员 Review members	张训 (主任医师), 汤明芳 (女, 主任医师), 薛莲 (女, 助理研究员), 鲁鸿 (女, 副教授), 冯茹 (女, 主任医师), 吴志华 (处长), 刘浩 (副主任医师), 沈少林 (律师), 严金海 (非医药专业, 外单位)		
审查文件 Documents	1. 递交信 2. 初始审查申请 3. 主要研究者简历 4. 研究人员职责及签名表 5. 主要研究者责任声明 6. GCP 培训证书 7. 研究方案, V1.0, 2018-3-19 8. 知情同意书, V1.0, 2018-3-19 9. 资料收集表格 10. 经费证明 11. 风险预案		
审查意见 Comments	同意		
年度/定期跟踪审查频率 Annual Follow-Up Review Frequency	☐ 3 个月 3 Months ☐ 6 个月 6 Months ☒ 12 个月 12 Months		
批件有效期 Expiry of Approval Letter	三年		

主任委员或副主任委员签名:  张九一
Signature of the Chair or Vice-chair
南方医科大学南方医院医学伦理委员会 (盖章)
Medical Ethics Committee of Nanfang Hospital (Seal)
日期:
Date: 2018.5.2

注意事项:

1. 本批件可能在其他中心机构及其他伦理委员会备案。如果对方案在贵机构的可行性(包括研究者的资格与经验、设备与条件等)有不同意见,请及时与本伦理委员会联系。
2. 请遵循 CFDA/GCP,《药物临床试验伦理审查工作指导原则》和《赫尔辛基宣言》的原则、遵循伦理委员会批准的方案开展临床研究,保护受试者的健康与权利。
3. 研究过程中若变更主要研究者,对临床研究方案、知情同意书、招募材料等的任何修改,请申请人提交修正案审查申请。
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6. 研究纳入了不符合纳入标准或符合排除标准的受试者,符合中止试验规定而未让受试者退出研究,给予错误治疗或剂量,给予方案禁止的合并用药等没有遵从方案开展研究的情况;或可能对受试者的权益健康以及研究的科学性造成不良影响等违背GCP原则的情况,请申办者/监查员/研究者提交违背方案报告。
7. 申请人暂停或提前终止临床研究,请及时提交暂停/终止研究报告。
8. 完成临床研究,请申请人提交结题报告。

声明:本伦理委员会按照中国 GCP、ICH GCP 和有关法规组成和工作,其审查
和工作过程不受任何组织及个人的影响

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伦理审查批件

批件号	PJ2018-029	受理编号	2018-029-02
项目名称	乳腺癌化疗患者长期书写表达干预有效性的随机、多中心临床研究		
试验药品名称	NA	临床研究分期	临床科研
申办方	南方医科大学南方医院		
合同研究组织	NA		
研究单位	广东医科大学附属医院		
主要研究者	郑婉婷		
审查方式	☐ 会议审查 ☒ 简易审查		
审查类别	复审	会议审查日期	2018年06月25日
审查委员	初审会审：包仕廷，李媛媛 复审简审：李媛媛		
审查文件	1. 复审申请 2. 修正的知情同意书（划线版）（版本号：V1.1，版本日期：2018年06月21日） 3. 修正的知情同意书（版本号：V1.1，版本日期：2018年06月21日）		
批准文件	初审批准的文件： 1. 临床研究方案（版本号：V1.0，版本日期：2018年03月15日） 2. 知情同意书（版本号：V1.0，版本日期：2018年03月19日） 3. 乳腺癌患者生命质量测定量表 FACT-B 中文版（V4.0） 4. 医院焦虑抑郁量表 5. 一般资料调查表 复审批准的文件 1. 修正的知情同意书（版本号：V1.1，版本日期：2018年06月21日）		
审查意见	根据卫生部《涉及人的生物医学研究伦理审查办法》（2016）、CFDA《药物临床试验质量管理规范（2003）》、《药物临床试验伦理审查工作指导原则》（2010年）、《医疗器械临床试验质量管理规范（2016）》、《人类遗传资源管理暂行办法（1998）》、《人类遗传资源采集、收集、买卖、出口、出境审批行政许可事项服务指南（2015）》、WMA《赫尔辛基宣言》和 CIOMS《人体生物医学研究国际道德		

地址：广东省湛江市人民大道南 57 号广东医科大学附属医院电话：0759-2386971 Email: fyllwyh@126.com

指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本研究。

请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。

研究开始前，请申请人完成临床试验注册。符合《人类遗传资源管理暂行办法（1998）》适用范围的研究项目，需要取得遗传办批件，并提交本中心伦理委员会备案后方可启动项目。

研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。

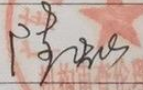
发生严重不良事件，请申请人在获知后 15 个工作日内提交严重不良事件报告，如发生死亡事件，应在获知后 7 个工作日内报告伦理委员会。

请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；申办者应当向组长单位伦理委员会提交各中心研究进展的汇总报告；当出现任何可能显著影响试验进行、或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。

研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益/健康以及研究的科学性造成不良影响等违背 GCP 原则的情况，请申办者/监察员/研究者提交违背方案报告。

申请人暂停或提前终止临床研究，请及时提交暂停/终止研究报告。

完成临床研究，请申请人提交研究完成报告。

年度/定期跟踪审查频率	12 个月
下次跟踪审查截止日期	2019 年 06 月 24 日
批件有效期	2018 年 06 月 25 日至 2018 年 06 月 01 日
伦理委员会 GCP 声明 我院伦理委员组成及操作方式严格遵循 GCP（包括 ICH-GCP）及相关法律、法规的规定，实施各项操作规程。	
主任委员签字	
伦理委员会	广东医科大学附属医院机构审查伦理委员会 (盖章)
日期	2018 年 06 月 25 日

广州医科大学附属肿瘤医院药物临床试验伦理委员会
临床项目研究审批件

(2018) 研伦审第 (3) 号

审查类别	初始审查
审查日期	2017 年 8 月 10 日
研究项目名称	乳腺癌化疗患者长期书写表达干预有效性的随机、多中心临床研究
审查文件	相关资料 (每单项必须填写, 提交资料标记为√, 未提交资料的标记为×, 如无版本标记为一) ☐ √ 研究方案, 版本号: 1.0 版本日期: 2018-03-15; ☐ √ 知情同意书, 版本号: 1.0, 版本日期: 2018 年 3 月 18 日; ☐ √ 其他 (请说明): 研究者手册, 病例报告表 无受试者招募广告声明 临床试验评估表
研究来源	研究者发起项目
研究发起人	周春兰 单位 南方医科大学南方医院
本中心项目负责人	徐敏
投票人数	函评人数 2 人, 投票人数 2 人。
审批意见	已严格按照 ICH-GCP 原则及中国相关的法规/指南, 详细审阅相关送审材料。我院伦理委员会经过对“乳腺癌化疗患者长期书写表达干预有效性的随机、多中心临床研究”项目审批, 同意并批准开展该研究。研究过程中请严格按照已通过审查的试验方案进行。 主任委员签字:   广州医科大学附属肿瘤医院 药物临床试验伦理委员会 2018 年 8 月 14 日
注意: (请仔细阅读) 1. 该研究进行过程中将接受伦理委员会的跟踪审查, 跟踪审查方式为: 快速审查, 持续审查频率为研究批准之日起: 一年, 下次跟踪审查报告递交日期为: 2019 年 8 月 14 日之前。(伦理委员会有权根据实际进展情况改变持续审查频率) 2. 暂停/提前终止临床研究, 请及时通知伦理委员会。 3. 发生严重不良事件及影响研究风险收益比的非预期事件, 须及时报告本伦理委员会。 4. 对已批准的临床研究方案、知情同意书等材料的任何修改及主要研究者更换等, 须及时通知本伦理委员会重新审查, 获得批准后执行。 5. 发现违反方案情况须及时报告伦理委员会。 6. 根据伦理委员会对持续审查频率的意见, 无论试验开始与否, 请在持续审查日期前 1 个月提出持续审查的申请。 7. 完成临床研究, 须提交结题报告供伦理委员会审查。	

汕头大学医学院第一附属医院伦理审查表

申请日期: 2018 年 05 月 15 日

研究科室: 甲状腺乳腺外科

项目名称: 乳腺癌化疗患者长期书写表达干预有效性的随机、多中心临床研究
项目负责人: 陈晓红 电话: 15817960292 邮箱: chenxiaohong1818@163.com
项目联系人: 陈晓红 电话: 15817960292 邮箱: chenxiaohong1818@163.com
合作研究单位: 南方医科大学南方医院 负责人: 周春兰 电话: 18818860076
研究者: 陈晓红
预期研究工作起止时间: 2018.06-2019.01
研究项目来源: 校、院级项目, 项目名称: 表达性书写在化疗期间乳腺癌患者中的应用-- 一项基于前期证据制作项目的临床应用
递交审查资料清单 (提交 1、4 项纸质版及 1-7 项资料电子版): 1、本伦理审查表 (签名并注明日期, 纸质版原件一份, 双面打印); 2、临床研究方案【注明版本号 (日期)】; 3、临床研究方案摘要; 4、研究者专业履历 (最新的, 签名并注明日期, 纸质版原件一份); 5、受试者须知和知情同意书【注明版本号 (日期)】; 6、医疗器械/药品产品安全资料 (注册产品标准或相应的国家、行业标准, 产品质量检测报告, 必要时提供医疗器械/药品动物实验报告); 7、其他相关资料。
涉及人的生物医学研究方案摘要: 为进一步探讨长期书写表达在乳腺癌化疗患者中应用的效果, 明确干预时间与疗效持续时间关系, 假设对于乳腺癌化疗患者, 延长书写表达干预时间能获得长期疗效。干预组依据 Pennebaker 常规书写表达指令进行干预, 要求干预对象将患病以来所担心的问题以及疾病对其工作或生活等造成的不良影响通过书写的方式表达出来, 连续书写 4 次 (4 天), 每次书写至少 20 分钟; 试验组将书写表达干预延长至 4 周, 每周干预 3 次, 总共 12 次。主要指标为乳腺癌患者生存质量, 次要指标为负性躯体症状、焦虑抑郁评分, 安全性指标为乳腺癌患者焦虑抑郁评分。随访 3 次, 时间点分别为 2 组干预后 1、3、6 个月。优效性验证: 试验组采用延长书写表达较干预组在乳腺癌患者生存质量改善上效果更持久。统计学方法 拟采用 SPSS 20.0 软件进行资料的统计分析, 计量资料采用均数±标准差 (±S) 表示, 计数资料采用频数、百分比 (%) 进行描述, 拟对资料进行正态性检验、方差齐性检验, 采用卡方检验 (Fisher's 精确概率法)、Mann-Whitney U 检验、t 检验比较两组患者各项观察指标的差异, 采用重复测量方差分析及 ITT 分析比较两组各观察指标的纵向变化趋势。检验水准 $\alpha=0.05$。预计 2018 年 6 月完成病例入组, 2019 年 1 月完成对 2 组病人的随访。
所在科室意见: 同意 学科主任/科室主任签字: 邱峰 2018 年 05 月 18 日

伦理委员会审查意见:

经审查,乳腺癌化疗患者长期书写表达干预有效性的随机、多中心临床研究项目,将采取研究对象乳腺癌化疗患者,采取延长书写表达将在征得受试者知情同意后,经伦理委员会审核,此项目符合卫生部《涉及人的生物医学研究伦理审查办法(试行)》及赫尔辛基宣言关于生物学人体试验的相关规定,同意开展研究。

主任委员签字:



伦理委员会章

2018 年 6 月 16 日

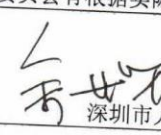


深圳市人民医院医学伦理委员会

审查批准函

声明：本伦理审查委员会遵从 ICH-GCP、中国 GCP 和有关法规组成和工作，其审查和工作过程不受伦理审查委员会以外任何组织及个人的影响。

批件号：深医科研伦审【2018】29 号

审查会议日期	NA					
审查会议地点	NA					
研究项目名称	乳腺癌化疗患者长期书写表达干预有效性的随机、多中心临床研究 Effect of Prolonged Expressive Writing on Health Outcomes in Breast Cancer Patients Receiving Chemotherapy: A Multi-centre Randomized Controlled Trial					
申办者	南方医科大学南方医院					
主要研究者	郑春晓	临床研究单位	深圳市人民医院甲乳外科			
伦理审查方式	☐ 会议审查 (Meeting Reviews) ☒ 书面审查 (Documented Review)					
审查文件清单	见附件 1	审查委员	陈怀生、李亚丽			
投票情况	同意	修改后同意	修改后复审	不同意	终止或暂停	弃权
	2 票	0 票	0 票	0 票	0 票	0 票
审查意见	1. 本伦理委员会对该研究项目的初始伦理审查决定如下 (请勾选 ☒) ☒ 同意 ☐ 修改后同意 ☐ 修改后复审 ☐ 不同意 ☐ 终止或暂停试验 2. 该研究进行过程中将接受伦理委员会的持续审查? ☒ 是 ☐ 否 3. 审查频度为研究批准之日起: ☐ 3 个月 ☐ 6 个月 ☒ 1 年 4. 伦理委员会有根据实际进展情况改变持续审查频率的权利。					
主任委员签名:	 深圳市人民医院医学伦理委员会 (盖章):		日期: 2018-6-27			
注意:	1. “同意”的研究应遵循已经伦理委员会批准的方案执行, 应符合中国 GCP、相关法规和《赫尔辛基宣言》的原则 2. “修改后同意”的研究方案在提交复审方案前, 应按评审意见进行逐条修改并在修改处做出标记或说明, 修改后的方案连同初审意见一并递交伦理委员会申请复审 3. “不同意”和“暂停或终止”的研究方案, 申办者和研究者可就伦理委员会的意见和建议中提及的问题做书面申诉, 并陈述理由。伦理委员会可就申诉作重新审查					

4. 研究过程中, 对研究方案和知情同意书等相关文件所作的任何修改, 均须得到伦理委员会审查同意后方可实施
5. 本中心发生的严重不良事件或意外不良事件需向伦理委员会作书面通报, 伦理委员会有权根据对其评估做出新的决定
6. 无论研究开始与否, 请在持续审查日到期前 1 个月提出再次审查的申请
7. 暂停或终止临床研究, 请及时通知伦理委员会。
8. 发生方案违背/违反情况须及时汇报。
9. 临床研究完成后, 须提交结题报告供伦理委员会审查。

地址: 深圳市罗湖区东门北路 1017 号深圳市人民医院 2-3 栋连廊 3 楼国家药物临床试验机构; 邮编: 518020; 电话: 0755-22942690

附件 1: 审查文件清单

项目名称: 乳腺癌化疗患者长期书写表达干预有效性的随机、多中心临床研究
Effect of Prolonged Expressive Writing on Health Outcomes in Breast Cancer Patients Receiving
Chemotherapy: A Multi-centre Randomized Controlled Trial

1. 研究人员履历表及项目组成员职责分工签名表
2. 临床研究方案 (版本号: V1.0, 版本日期: 2018 年 3 月 19 日)
3. 知情同意书 (干预性临床研究) (版本号: V1.0, 版本日期: 2018 年 3 月 19 日)
4. 资料收集表格 (版本号: V1.0, 版本日期: 2018 年 3 月 19 日)
5. 风险预案
6. 主要研究者简历及资格证书
7. 组长单位伦理批件
8. 参加临床研究各单位名称及联系方式



深圳市人民医院医学伦理委员会委员名单

序号	姓名	职位	性别	职称/行政职务	职业背景	工作单位
1	余小舫	主任委员	男	主任医师/副院长	外科医学	深圳市人民医院
2	王建红	副主任委员	女	正高/副院长	医院管理	深圳市人民医院
3	张伟	副主任委员	男	主任医师/副院长	外科医学	深圳市人民医院
4	陈怀生	委员	男	副主任医师	内科医学	深圳市人民医院
5	傅小宽	委员	男	主任医师/科副主任	外科医学	深圳市人民医院
6	胡芷洋	委员	女	副主任医师/科副主任	妇产科医学	深圳市人民医院
7	吴本清	委员	男	主任医师/副院长	新生儿科	深圳市光明集团医院
8	吴诗品	委员	男	主任医师/科主任	内科医学	深圳市人民医院
9	李亚丽	委员	女	主任医师	麻醉医学	深圳市人民医院
10	张万帆	委员	男	主任医师/科副主任	内科医学	深圳市人民医院
11	吴伟晴	委员	女	主任医师/科主任	儿科医学	深圳市人民医院
12	陈振德	委员	男	主任药师/科主任	药学	深圳市人民医院
13	罗慧	委员	女	主任医师/科副主任	影像医学	深圳市人民医院
14	龚文波	委员	男	主任技师/科副主任	医学检验学	深圳市人民医院
15	成志强	委员	男	主任医师/科主任	病理学	深圳市人民医院
16	刘新琼	委员	女	主任医师/科主任	妇产科医学	深圳市人民医院
17	孟庆宝	委员	男	主任技师/科主任	免疫学	深圳市人民医院
18	苏旺东	委员	男	律师/科长	法务	深圳市人民医院
19	李体远	委员	男	研究员/科长	生物化学	深圳市人民医院
20	张华翔	委员	男	副主任药师/科副主任	药理学	深圳市人民医院
21	张妍	委员	女	中级	新闻传播学	深圳报业集团深圳商报社
22	杨国安	委员	男	副主任技师/所长	文学	深圳市健康教育与促进中心
23	王齐明	委员	女	一线社工/国家二级心理咨询师/助理社工师	理学	深圳市龙岗区春暖社工服务中心

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