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Evaluating the Effectiveness of Nurse Led Psycho Social Intervention to Improve Mental Well-Being among Bereaved Families, Karachi, Pakistan: A Protocol of Quasi-Experimental Study

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Abstract

Background: One of the most traumatic experiences a person can have is losing a loved one, which may substantially affect their physical, socioeconomic, and emotional health.

Aim: To determine whether six weeks of positive psychology based psychosocial intervention, comprising, mindfulness, spirituality, physical activity, happiness, gratitude, and social support can assist in enhancing mental health.

Methods: A quasi-experimental study on the females of bereaved families living within premises of Karachi, (Sindh), Pakistan. The non-probability (consecutive sampling) will be used to select the study participants. The participants will be divided into two groups. Booklet of self-care strategies will be given to all participants in both groups but the intervention group will receive intervention in 6 sessions after the completion of the study. Data will be collected at pre intervention and then at the end of intervention (T2) 6 weeks and after 12th weeks (T3). The acceptability, and applicability of this intervention will also be assessed quantitatively *via* a questionnaire on a 1 to 4 Likert scale.

Discussion: The development of a positive psychology-based psychosocial intervention and testing its efficacy and feasibility to improve the mental well-being and life satisfaction of bereaved families. This study will considerably contribute to the global body of knowledge on the effectiveness of positive psychology based psychosocial interventions as a viable method for managing the psychological repercussions of sudden bereavement in low-resource settings.

Conclusion: Results will assist the work of researchers, clinicians, and policymakers to support the implementation of effective practices and improve the quality of services for bereaved families.

Keywords: Positive psychology intervention • Bereaved families • Mental wellbeing • Psychosocial intervention • Nurse led intervention

Introduction

The grieving that comes with the loss of a loved one, particularly a partner or spouse, is one of the most challenging life events a person can go through. The death of a loved one has a deep psychological impact which has a distinct grieving process than natural death. Sadri, Khanjani, Younesi, and Nabati Saravan described that losing a family member causes severe distress and endangers mental and physical health [1]. As a result, the loss of a relationship is a profoundly devastating and life-threatening catastrophe.

Bereavement may play a causative role in exceeding mortality by implying mental stress [2]. Bereavement is a traumatic life experience that can have long-term negative consequences for one's welfare and quality of life. Every type of bereavement presents substantial difficulties in adjusting to life without the deceased [3]. Some may face challenges in effectively coping with bereavement. It is critical to recognize that intense sadness can sometimes result in unresolved feelings that last for a long time. At least ten out of every hundred bereaved adults suffer from prolonged grief disorder [4]. Mental illnesses like anxiety, depression, and prolonged grieving are much more common in women who have lost their loved ones. More than half of the bereaved spouses experienced psychological isolation [5]. To preserve their mental health, it is essential to assess stress, anxiety, and depression so that, if necessary, prompt supportive measures can be followed. According to the World Health Organization, approximately 300 million people are suffering from mental health problems due to traumatic experiences and females are much more prone than males to experience mental illnesses [6,7].

Among international surveys, the most widely documented traumatic experience is the Unexpected Death (UD) of a loved one which may lead to serious mental disorders, a significant risk factor that raised public health concerns. Even though losing a loved one could be profoundly distressing, unexpected deaths tend to be extremely traumatic because there is less time to anticipate ahead and adjust. It raises the danger of mental illnesses and the likelihood of experiencing protracted grieving reactions.

Numerous studies have proved that positive psychological interventions have a role in promoting mental well-being outcomes, including life satisfaction, resilience, and optimism, and reducing negative effects, including depressive symptoms and pessimism [8-11]. These interventions, which have received considerable attention in recent years, are based on human strengths and positive adaptability measures and serve as buffers against psychological illnesses [8,12]. Additionally, the study of positive psychology based psychosocial intervention places a strong emphasis on satisfying personal relationships, admirable character

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traits, and virtues that enhance well-being and protect against mental illnesses [13]. Therefore, the current intervention program's objective was to improve the mental well-being of families in Pakistan by encouraging satisfaction with life, gratitude, and subjective happiness.

Kakoschke et al., proclaim that mindfulness is a type of psychological exercise that attempts to develop emotional and mental capability [14]. Likewise, Huberty et al., have highlighted that individuals who practice mindful breathing may be able to acquire qualities such as compassion, acceptance, and personal serenity [15]. Gratitude interventions have been shown to increase happiness and contentment; saying simply "thank you", providing little gifts of appreciation, or making gratitude visits are interactive ways to express gratitude. A cross-sectional analytical study on 197 participants (69.5% women), to examine the relationships between gratitude, well-being, spirituality, and meaningful work, depicted that gratitude was strongly associated with happiness, life satisfaction, flourishing, positive affect, spirituality, and meaningful work [16].

Supportive intervention and mental health services may be an effective alternate strategy to fill up these service gaps and offer the earliest possible intervention [12]. Social support has been shown to improve wellness after traumatic occurrences in general. These non-pharmacological interventions also proved to be useful as a first-line intervention technique to improve not only psychological well-being but also enhance physical, emotional, and spiritual well-being [17].

Nurse led Interventions based on positive psychology substantially improve psychological and subjective well-being, lessen depression symptoms, strengthen social resources, develop resilience, and get ready to resume normal life [18,19]. The purpose is to enhance bereaved families' well-being and capacities to perform activities of daily living efficiently. Moreover, opportunities to interact with people of the same background enable them to develop coping strategies to deal with the stresses and enhance their subjective well-being. Although mental diseases are relatively widespread, many rarely seek medical assistance for their mental health issues because many find it embarrassing and stigmatizing to do so. Due to their reluctance to seek help from the mental health department, they are prone to many illnesses.

The current study will provide insight into how to improve the social, emotional, and psychological well-being of bereaved Families, which will ultimately result in their mental well-being. The purpose of the current study is to determine whether six weeks of nurse led psycho social intervention, comprising, mindfulness, spirituality, physical activity, happiness, gratitude, and social support can assist in enhancing mental health. This study will help in undertaking the feasibility of a full-scale study. This will also give recommendations for setting up a psychosocial intervention, which will help in supporting the bereaved families during times of crisis.

Research aim

This quasi-experimental study will be conducted at the community center of Malir, Karachi, Pakistan. The study aims to: a) develop the contextual specific and culturally relevant psychosocial intervention module for improving the mental well-being of the martyrs' families; b) To assess the effectiveness of the psychosocial intervention in improving the mental well-being among bereaved families; c) To determine the feasibility and acceptability of psychosocial intervention module among Martyrs' Families.

Research questions

- What is the effect of the psycho-social intervention on mental well-being among Martyrs' Families?
- What is the feasibility and acceptability of the psychosocial intervention module among Martyrs' Families?

Hypothesis testing

- Null hypothesis: There is no difference in the mental well-being of Martyrs' families getting the psycho-social intervention as compared to the control group.
- Alternative hypothesis: There is a difference between the mental well-being of Martyr's families getting the psycho-social intervention as compared to the control group.

Conceptual model of the study

Martin Seligman introduced positive psychology in 1998. Positive Psychology Intervention (PPI) seeks to look at people's abilities and capacities as they seek a better life and happiness [20]. The five fundamental pillars of the PERMA Theory of Well-Being are; positive emotion (happiness), engagement (flow), relationships (interpersonal), meaning (purpose), and accomplishment (achievements) [21]. PERMA is negatively associated with depression and anxiety while positively associated with hope, positivity, and resiliency [22].

Since PPI prioritizes successes over failures, virtues over vices, and characteristics that lead to the thriving of a well-functioning and evolving community, the application of this model can provide bereaved families the opportunity to enjoy the basic pleasures of life while striving to be better versions of themselves every day [20].

Although many theories have been put forth regarding well-being, the Selgiman Model, which is based on flourishing to improve mental well-being, is practically the most applicable and has been used in many settings to improve the mental well-being of families. Given that, this Psychosocial intervention based, on the PERMA model focuses on cultivating positivity, hope, growth, and self-worth, developing problem-solving skills, and inspiring clients to pursue communal support for health-promoting strategies. Moreover, the model allows families to move towards a healthy state by boosting their positivity [23]. Hence, the PERMA model is very effective in adjusting and adapting positive coping strategies for families facing distress as shown in Figure 1.

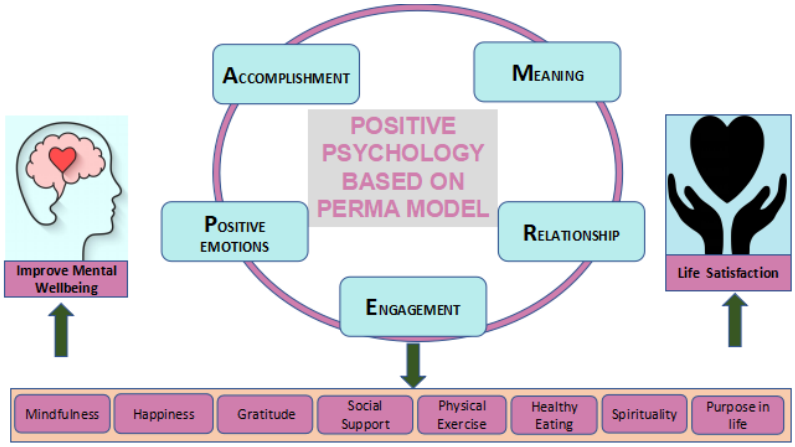

Figure 1. Theoretical framework of psychosocial interventions based on the PERMA Model.

In this study, the unexpected death of a family member was a stressor for the women. Positive Psychology based psychosocial interventions can be used as supplementary therapy by nurses to alleviate psychological distress and encourage positive thinking and behaviors. By focusing on an individual's strengths, these interventions can help occupy the mind with pleasant thoughts and feelings, promoting mind-body interactions. This positive coping can help families re-evaluate the situation, leading to increased compliance with coping strategies and improved patient satisfaction.

Materials and Methods

Study design

A quantitative research study, using a double-arm quasi-experimental, controlled, pretest-posttest designwill be used for comparing two groups (intervention group and wait-list control group) [18,19,24]. Randomization will be less feasible in the current study because this will be conducted in a singular setting within a narrow time frame. Rogers et al., claim that in a quasi-experimental study, the researcher evaluates the effect of the intervention and it allows comparison between two groups when blinding and randomization is not possible [25,26]. This study design will be deemed the best for examining the research question, which will be to evaluate the effectiveness of psychosocial interventions on mental health and well-being in families. The six-month study, which began in March, after getting ERC approval, and ended in August 2023, will be divided into three phases. Phase I involved developing the psycho-social intervention and testing its validity, while Phase II evaluated its effectiveness [27]. Phase III is to assess the feasibility and practicality of the psycho-social interventions.

Phase I: Module development

This phase comprised the procedure of module development including, objectives, lesson plan, content, activities, and time allocated to each session. The primary investigator developed a 9-hour module per session (6 sessions) based on a literature review of published articles and the input of experts [27].

Phase II: Intervention and evaluation phase

The participants will be divided into two groups.

Wait-list control group: The women who fulfilled the eligibility criteria will be recruited in the control arm after obtaining their consent. They will be assessed for demographics, given a pre-intervention questionnaire at 0 weeks (T1), and will be provided with a booklet on self-care strategies, data will be allocated at 0 weeks, post-intervention I at 6th week (T2), and Post-intervention II at 12th weeks (T3). They will be given the same treatment after the completion of the study. This strategy will be adopted because it is commonly anticipated that intervention would benefit all parties and would overcome the ethical dilemma of the untreated control group. Ramaswamy et al., (employed a similar strategy to promote cervical health literacy among jailed women in a quasi-experimental study done in Kansas City, United States [28].

Intervention group: The women who met the eligibility criteria will be recruited in the intervention arm. They will be assessed for demographics and given the pre-intervention questionnaire by the primary investigator at T1. The psychosocial intervention will be provided face to face to each woman in a group of four for about 6 weeks (90 min each) and then post-intervention data I (T2), and post-intervention data II, at the 12th week (T3) will be collected accordingly. The timing of the intervention delivery will be contingent upon the availability of the participants as shown in Table 1. Furthermore, participants in the experimental group received the same booklet as those in the control group.

Table 1. Study plan of intervention and control phases at Malir venue, comparing pre-and post-intervention assessments at different time points (T1, T2, T3).

Pre-intervention data T1 (0 weeks) Venue: Waiting room Malir	Intervention Weeks Venue: Counselling room Malir						Post-intervention Phase T2 and T3 Venue: Waiting room Malir
Assessed at the beginning of the first intervention using the mental well-being and subjective well-being and life satisfaction questionnaire.	The face-to-face intervention is followed by a Telephone reminder before the beginning of the session and responding to their concerns/Queries if any.						Reassessed at the end of intervention using the Mental well-being subjective well-being and life satisfaction Questionnaire after 6 weeks (T2) and 8 weeks (T3)
	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	
	Six aspects of intervention						
	• Mindfulness						
	• Gratitude						
	• Happiness and healthy eating						
	• Self-care (Physical exercise)						
	• Spirituality and purpose in life						
	• Social support						
	Need-based telephonic support						
	Provision of a booklet of self-care strategies						
Wait-list control group assessed at the beginning of the first intervention using the mental wellbeing and subjective well-being and life satisfaction questionnaire	No intervention (A booklet of self-care strategies will be given to all participants)						Reassessed at the end of intervention mental well-being and subjective well-being and life satisfaction questionnaire after 6 weeks (t2) and 8 weeks (t3)

Study population and study setting

Study population: The females of bereaved' families (18 years and above, wife, mother, daughters, and sisters) living within the premises of Malir, Karachi (Sindh), Pakistan.

Study setting: For data collection, the tertiary hospital in the metropolitan city of Pakistan, Karachi, boasts a substantial capacity of 750 beds. This choice will be made because a considerable number of women visit the hospital daily for routine check-ups. The study will be conducted in the counseling center, in Malir, Karachi. The settings will be selected based on safety concerns and the convenience of participants, as directed by the General Headquarters, Pakistan. For intervention sessions, a calm room, (noise-free) with limited interruption, will be selected.

Participant eligibility criteria

The study comprised only women who met the eligibility standards.

Inclusion criteria: All families (only females) living in Karachi, Pakistan, who satisfied the following criteria will be enrolled in the study.

- Adult women, 18 years and above, because the official age of puberty in Pakistan is 18 years, this age requirement will be established as the foundation.
- Experienced the loss of cherished family members within the past 1 to 5 years
- Females, including a mother, sister, wife, and daughter are mostly highly dependent. Likewise, the literature revealed that women mostly perceived the loss of a loved one as “extremely unnatural" and this will be linked to significant distress [29].
- Living within the premises of Malir, Karachi, Pakistan.

Exclusion criteria: The following will not included in the study

- The women with a self-reported history of any mental illness or any chronic illness diagnosed during the last 6 months will not include because treatment of these disorders could have impacted the results.
- Pregnant women
- Participants who scored for depression>6, anxiety>5, and stress>9 on the screening tool (DASS-21) will be referred to a psychiatrist in the mental health department, Malir, and will be not included in the study.

Study duration

The study will be conducted from March 21, 2023, to August 21, 2023, after reviewing consent from designated study sites and the Aga Khan University (AKU) Ethical Review Committee (ERC).

Sample size determination

The sample size was determined by estimating Power (80%), level of significance alpha (5%), and effect size (0.59) based on a previous study, anticipating a 20% attrition rate using Open-epi Software and using the Taro Yamane formula, n=N/ (1+Ne2) [30,31]. The calculated sample size will be 390. In this study, considering the attrition rate of 10% (40), 430 women will be included, with 215 in the intervention group and 215 in the control group [32]. Moreover, a pilot study will be conducted on 10% (40) of the participants, before the full-scale study [33]. The research will be completed in two phases over six months (March to August).

Sampling

The non-probability consecutive sampling will be used to choose the study participants, based on the researcher's convenience [34]. A consecutive sampling methodology is a non-probability sampling method that entails recruiting participants who meet the eligibility criteria from a readily accessible population, over a specified period or for a specific sample size, hence this will be considered the best option. To avoid contamination, the first three months will be allotted to the control group, while the next two months will be allotted to the intervention group. To control the confounders, this sampling method will be adopted [35].

Recruitment of the participants

The recruitment of the participants will be carried out in steps,

Step 1: Following permission from the Malir Hospital, the researcher held a meeting with the administration of Malir for the availability of a counseling room for activity sessions with the martyrs’ families,

Step 2: A participant flyer will be used as a recruitment strategy. At the time of registration for their appointment, interested women will be asked to go to the counselling room adjacent to the registration room.

Step 3: The researcher met them face-to-face in the waiting room and explained the study's procedure and goals and gave them a chance to ask questions and have time to think about participating. Women's informed consent including permission to conduct eligibility screening, contact details, access to medical records, participate in the intervention or control group, and carry out the intervention in a group of 4 will be obtained. Furthermore, women will be asked whether to take the information sheet and consent form to their home.

Step 4: Those potential participants who agreed will be requested to give written informed consent. The women will be then assessed for meeting the eligibility criteria and screened through the DASS-21 questionnaire.

Step 5: Those meeting the full eligibility criteria will be finally included in the study. The participant will be added to a WhatsApp group of bereaved families as depicted in Figure 2.

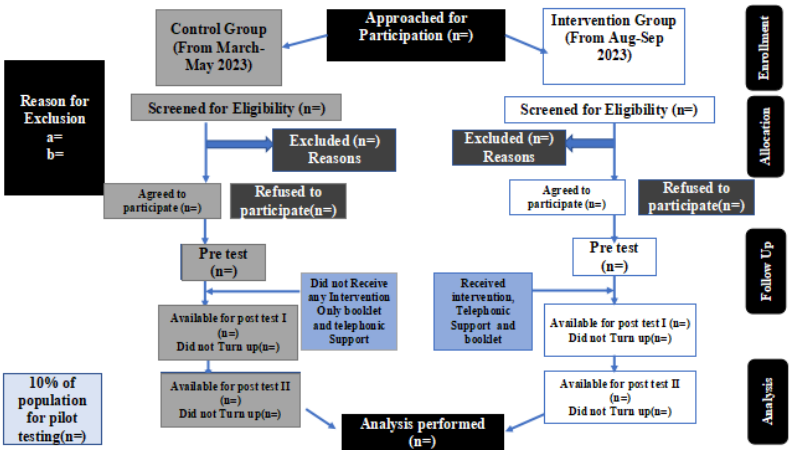

Figure 2. Consort diagram of the participant.

Referral: Due to the possibility that the bereaved families might experience emotional trauma as a result of flashbacks, in cases where individuals with any substantial reaction are found they will be referred to psychologists in the Mental health department of Malir for counselling, and, to the psychiatrist for further appropriate management and the cost will be bear by the primary investigator and they will be excluded from the study.

Results

Study intervention

The study psychosocial intervention based on positive psychology intervention focusing on gratitude, mindfulness, physical exercise, happiness, spirituality, and social support [30,36-39]. The participants received six intervention sessions once a week, in a group of 4 women, since group-based interventions promoted social inclusion and engagement [17]. The purpose of this intervention is to create a place for participants to express their emotions and discuss ways to improve their mental health. The technique incorporates supportive counseling and facilitative strategies, as well as compassionate and non-judgmental listening to the women's difficulties. Offering practical support is akin to providing psychological first aid, and participants are urged to maintain ongoing contact with the study staff, empowering them to seek help when needed. Women's emotional health is regarded to benefit most from consistent assistance. The intervention will be administered by the primary investigator with motivational skills, including techniques such as clarifying, paraphrasing, and reflecting will be employed to ensure a clear understanding of the modules. The emphasis will be on building a strong rapport with the participants, and they will be actively encouraged to express their concerns and problems.

A guide will be developed to provide instructions on how to conduct the intervention. However, it's important to note that this guide will not be rigidly prescriptive; instead, it will serve as a flexible reference. The aim is to maintain a natural conversational style during the sessions, incorporating examples that are culturally relevant to the women involved. While all topics will be covered with the same level of attention, the PI will prioritize ensuring that the key points outlined in the intervention delivery guide are effectively addressed.

The intervention involves the following components:

Engaging educational sessions: Individuals can participate in specifically designed module-based activities while also receiving important education *via* examples and reflections through this session.

Information brochure: An instructive brochure, delivered in basic Urdu and accompanied by relevant images, on self-care strategies. It also provides contact information for local emergency and help services.

Facilitative strategies: Women will be provided the researcher's contact information in the expectation that they may seek support and guidance in dealing with daily stressors or family issues as needed. Empathetic listening and need-based counseling will be provided in a non-judgmental manner.

Intervention program

The program's main elements will be organized around positive psychology, and the social support framework [30,40-42]. Based on the recommendation of a study on bereaved wives by Cozza et al., the intervention will be planned face-to-face, along with telephonic support [29]. The intervention mainly included exercises, brief videos, group discussions, and group activities. The group sessions lasted approximately 90 minutes, in two stages. Stage 1 comprised of lectures (15 min), group discussion (20 min), videos (5min) in Urdu, and (20 min) of group interaction activity in phase 1, followed by (10 min) refreshments, and will hold a designated place in the counselling room. In stage 2, initially, members interacted for about 10 minutes, to encourage them to share their thoughts and feelings, with one another, followed by 10 min follow-up session to address questions and talk about difficulties. Then the group members will be encouraged to give an example relevant to the strategies they had used previously. In the end, home activities will be assigned in each session, which will be assessed at the start of the next session including daily and weekly home practices, for six weeks. The participants also will access the WhatsApp group during the intervention period, which will be utilized to give reminders before the session and to increase retention rates.

Phase IA: Development of the Psycho-social Intervention Module. The module will be developed by an interdisciplinary team, a group that includes mental health nurses, nurse educators, and a team from the Brain and Mind Institute, Aga Khan University, Karachi, Pakistan. The objectives, content, timing, and activities for each module will be developed. The summary of the module's sessions is depicted in Table 2. The module will be reviewed by experts in the mental health department for clarity and appropriateness. The researcher led the intervention with assistance from a volunteer assistant facilitator.

Phase IB: Pilot testing of the module. After the module is created, it will be tested for clarity, appropriateness, validity, and language. The pilot test subjects were four participants who provided verbal informed consent but were not a part of the study.

Table 2. Overview of psychosocial intervention module (Be Happy) module.

Session/week	("Be Happy") Module Theme	Objective
Week 1=session 1 (S1)	Be mindful	• Learn about mindfulness. • Develop skills to practice mindfulness breathing exercises. • Discuss the relationship between mindfulness and mental well-being.
Week 2=session 2 (S2)	Eat healthy and stay happy	• Discuss the importance of eating healthy for mental well-being. • Determine the impact of happiness on the body, mind, relationship, and health. • Explore happiness and its benefits in daily life.
Week 3=session 3 (S3)	Have social connections	• Discuss social support and identify its significance in terms of mental health. • Describe ways to develop the skill of engagement with others. • Describe the benefits of having a strong social network.

Week 4=session 4 (S4)	Admire your strengths	• Relate the importance of spirituality in strengthening one's purpose in life. • Prioritize one's strengths over one's weaknesses.
Week 5=session 5 (S5)	Pay gratitude	• Learn about gratitude and its importance. • Develop ways of expressing gratitude. • Practice gratitude journaling.
Week 6=session 6 (S6)	· Perform physical activity · Your life's purpose	• Learn about the benefits of physical exercise. • Relate how physical exercise can improve mental well-being • Identify the purpose and meaning of life.

Data collection tool

Phase A: For the development of the module, experts will be asked about the topics that should be a part of this psychosocial intervention module, as per their proficiency in the content part, as well as the context.

Phase B: Initially, a semi-structured questionnaire will be used to collect demographic information. Multiple scales will be studied during this research study but the Depression, Anxiety, and Stress Scale (DASS-21) for screening while the Warwick Edinburg Mental Wellbeing Scale (WEMWBS), and Satisfaction With Life scale (SWLS) for determining the effect of the psychosocial intervention were found to be more relevant. The authors provided permission to use the tools.

DASS_21: The DASS-21 had already been converted into Urdu, the national language of Pakistan, to judge the perceived stress level and psychological well-being of the Pakistani population in Islamabad, by Bukhari, in 2022 and its internal consistency had been determined (Cronbach's alpha=0.94). The DASS-21 (Depression, Anxiety, and Stress Scale) will be used as a screening tool. The 21 items of DASS assessed the three variables, i.e., stress, depression, and anxiety, over the preceding week with a set of seven questions. Each question on DASS-21 was scored on a Likert scale, with never=0, sometimes=1, frequently=2, and always=3. A score of 0 indicated that the participant believed the question "did not relate to them," and a score of 3 meant that they felt the question "applied very much, or most of the time [43]." Women's depression, anxiety, and stress levels will be evaluated using pre-defined cut-off values such as depression<6, anxiety<5, and stress<9 based on the DASS-21 guide [44].

Warwick Edinburg mental wellbeing scale: Those participants who will be recruited will assessed through the Warwick Edinburg Mental Wellbeing Scale (WEMWBS) before and after the study. The tool had been tested in the Pakistani population using its Urdu version. It had 14 components that will be rated on a Likert scale from 1 to 5. The Warwick Edinburg Mental Wellbeing Scale (WEMWBS) appeared to be suitable for use in the Pakistani population in its Urdu version, and the findings confirmed its internal reliability for this population sample. Test-retest reliability was found to be 0.93, with a 95% confidence interval of 0.87-0.96, indicating a very high level of reliability.Hence, it proved to be appropriate for use in the Pakistani context and its internal consistency was satisfactory (Cronbach's alpha=0.87).

Subjective wellbeing and life satisfaction scale: The life satisfaction questionnaire had already been validated by Barki et al., in Lahore, Pakistan (Cronbach's alpha=0.90) [45]. This scale had good psychometric qualities, such as internal consistency=0.82 [46]. It had five components that measured subjective well-being, and it is a part of the trait well-being inventory. Each item will be measured on a 7-point Likert scale ranging from strongly agree to strongly disagree. The permission of the copyright holder had already been taken. The test-retest reliability and construct validity of the tool will be assessed. The reliability statistics reveal a Cronbach's Alpha of 0.907 for a 5-item scale, demonstrating a significant degree of internal consistency among the items and implying they assess the same concept effectively.

Self-structured sociodemographic tool: The sociodemographic tool was divided into three subcategories: Sociodemographic variables, family-associated variables, and academic variables. The demographics and socioeconomic portion of the questionnaire was developed with the consensus of the research team.

Sociodemographic variables: These included gender, age, marital status, mother language, history of mental illness, sleeping hours per day, and family history.

Family-associated variables: This included family history, earning members, financial support system in the family, and recreational activities

Academic variables: These included academic qualifications:

Co-variates: Another variable that can influence the outcome is covariates. Age (18-30 years, 31-40 years, 41-50 years, 51-60 years, >60 years), relationship with the martyred member (mother, wife, sister, daughter), religion (Muslim, Hindu, Christian, others), years passed since martyred (1-2,3-5,6-8,9-10 years), and the number of children/family members (not any, 1, 2-3, 4-5, >5) will all considered in this study. This unbalanced distribution of variables across both arms, at the time of analysis, is the limitation of a quasi-experimental study.

Data collection

Phase A: Experts (Mental health nurses, Psychologists) will be approached, based on their knowledge of both the context and the content, and will be asked for their opinions on the proposed module material.

Phase B: Data will be collected from March to August 2023, a month, after getting approval from ERC. After meeting the inclusion criteria, the written consent will be signed through a formal consent form in the initial session of the questionnaire. The consent form included information about the study, its objective, and the voluntary nature of participation. The potential participants will be directed to the survey questionnaire once they agree to provide consent which was in an easily understandable Urdu language. In case participants have any questions, the researcher's phone number and email address will be provided.

Pre-intervention data (T1) will be collected by the researcher from both groups, after the enrollment of participants in the first session. Demographic variables such as age, economic status, housing style, number of children and relationship with the bereaved, time passed since the bereaved, education, current employment status, and placement will be collected *via* a self-structured sociodemographic questionnaire. The time required to fill out the questionnaire will be 20-30 minutes. Post-intervention data (T2) will be collected from the Intervention group, after 6 sessions by using the same questionnaire while the 2-week Post-intervention data (T3) will be collected, after 2 weeks of sessions by using the same questionnaire as depicted in Table 3. The duration of the data collection process will be between 6 months, after receiving ethical approval from the ERC, Aga Khan University, Pakistan. The data obtained will be kept in a locked cupboard and a password-protected file on a laptop, and a password-protected backup copy will be saved on Google Drive.

Table 3. The phases, timing of interventions, and tools used to measure the module's effectiveness for bereaved families.

Phase I	Phase II			
Module development	**Testing the effectiveness of module**			
Development of modules testing of modules by psychologists validation through content validity index	Pre-test baseline data: T1 Demographic DASS-21 WEMWBS SWLS	Intervention to bereaved Families	Post-intervention I: T2 (At 6th week) WEMWBS SWLS	Post- Intervention II: T3 (At 12th week) WEMWBS, SWLS Feedback Performa

Phase III: Feasibility of the study

The module's acceptability, applicability, and practicality will also be assessed. Furthermore following the completion of the sessions, the participants will asked to fill in the following questions on four Scale Likert Scale

- How did you find the information?
- Was the terminology used in the modules comprehensible?
- Were the strategies effective?
- How much time did you spend on the positive strategies each week?
- Was the session enjoyable?
- Were the activities easy to follow?

Study rigor

Module: The module will be developed based on existing literature searches and professional judgments. Six Experts (three psychologists and three experts in the Mental Health Stream) evaluated the module's language and content for validity, and 10% of the participants took part in a pilot test. They provided feedback, which will be also taken into consideration.

Tool validity and reliability: The tool used for evaluating whether the intervention will be trustworthy and effective has been employed in Pakistan. Furthermore, the Content Validity Index (CVI) will be developed by six mental health nursing professionals, psychologists, and mental health specialists, who reviewed the instrument. CVI will be completed in two stages. In the first step, professionals assessed the questionnaire (tool) for relevancy and clarity with a four-point Likert scale. Expert evaluations will be used to calculate the CVI. According to Yusoff, the researcher should have concrete evaluation evidence of the tool [47]. The rubric also included a Likert scale for relevancy (1 not relevant, 2=somewhat relevant, 3=pretty relevant, 4=very relevant) and clarity (1=not clear, 2=somewhat clear, 3=quite clear, 4=very clear). While scores one and two will be taken into consideration for adjustments, the evaluators' three and four will be judged as acceptable. Pilot testing will be conducted on 10% of the sample size, or 4 participants, to ensure reliability; thus, CVI and Cronbach alpha coefficient values statistically ensured the study questionnaire's reliability, validity, and clarity.

Quality check and data entry

The primary researcher vigilantly managed the data organization. Soon after the data collection process, the researcher will ensure the consistency and completeness of the data on the questionnaire through a quality check. To facilitate data management, serial numbers will be assigned to each participant's data file. Each participant's pre-intervention (T1), post-intervention (T2), and 2-week post-intervention (T3) data will be labelled separately in each file for identification. Data editing will be done in two stages: field editing and office editing. During field editing, after completion, the questionnaire will be checked by the primary researcher for any missing information. Office editing of the data entry will be done by assigning a serial number to each file in the SPSS. The data record will be compared, and shortcomings will be made by consulting the relevant questionnaire. A secured backup file will be made for data storage in a password-protected file.

Statistical analysis

Data will be analyzed by using IBM SPSS version 24. Data will be entered and it will be double-checked. During the analysis, the focus will be on assessing the effectiveness of the psychosocial support intervention in improving psychological well-being. Percentages, frequencies, and Chi-Square test were calculated for demographic variables (gender, age, years passed since soldier martyred, qualification). Mean, standard deviation, and variance will be calculated for quantitative variables. The independent sample t-test will be applied to measure the difference in the mean values of two independent groups, after assessing the data for normality check, otherwise, a non-parametric test will be used to measure the difference [48]. Analysis of Covariance will be utilized to analyze the influence of intervention on primary outcome with covariate adjustment, baseline measurement, and group allocation.

Pre-testing: Pilot testing: Pre-testing of the study tool (Urdu and English questionnaire) will be carried out on 10% of the total sample size, on 4 women. These women will not include in the final study. The pre-testing aimed to check the correctness (content, language, strategies, and activities) of the filing of the study questionnaire and the appropriateness and feasibility of the psycho-social intervention module for the understanding of the women [27]. Furthermore, the goal will also be to predict how long it would take participants to complete the questionnaire and rule out any discrepancies in the tools and modules used to assess the data-gathering methods. All the required amendments were added to the tool based on the responses and suggestions and the tool will finalized after the thesis committee members' review. During the pilot testing, one participant contacted the researchers and asked them to clarify questions about terminology. The terms in the questionnaire were changed by inserting synonyms in brackets.

Ethical consideration

All the interventions strictly adhered to the principles and procedures specified in the Helsinki Declaration. Furthermore, all experimental protocols were thoroughly reviewed and approved by the Aga Khan University Ethical Review Committee. Informed consent will be obtained from all study participants, ensuring that ethical standards are followed throughout the research process.

The Hospital's Ethical Review Committee will contacted for ethical approval. Ethical and safety guidelines recommended by the WHO will be strictly followed [49]. The researcher emphasized to the participants that involvement will be optional and that their confidentiality, objectivity, secrecy, protection, and security will be guaranteed throughout the entire study, before getting their informed consent. The participants will be introduced to the areas of the research, its benefits, and its risks, in the native language through a phone call and will be asked to participate. Those willing to participate will be requested to come to a nearby tertiary care hospital and get assessed as per the eligibility criteria. Before the data collection process, the informed consent form will be given to the study participants in Urdu or English, as per their preference. Written informed consent will be obtained from those meeting the inclusion

criteria. The participants will have the option to leave the study whenever they choose to do so. Moreover, ethical approval from the specified community department will be obtained. The study is committed to strict adherence to its established protocol, and any deviations from this protocol will be promptly reported to the ethics committee for transparency and accountability. While the likelihood is low, there is a potential risk of women experiencing distress during the study, which may manifest as behaviors like becoming quiet, crying, expressing anger, or appearing distracted. To mitigate this risk, the study will employ trained researchers who can provide appropriate support and assistance to the participants as needed. Moreover, should any participant require or prefer additional support, they will have the opportunity to seek assistance from a qualified psychosocial counselor. Both intervention groups will receive a concise one-page information booklet as part of the study.Additionally, the research outcomes will be submitted for publication in peer-reviewed journals to contribute to the broader scientific knowledge base to preserve information confidentiality, codes will be used for each participant. Moreover, data access will be limited to the primary researcher and the Thesis Committee members. However, for monitoring or audit purposes, an ethics committee or any regulatory body can access the data. Following data collection, the forms will be kept under lock and key, and the data entered on computers will be secured in password-protected folders. The original forms will only be accessible to the researcher and the thesis committee.

The study's findings will be disseminated through various channels. They will be presented at the hospital in Pakistan where the research is conducted, as well as at national and international conferences.

Mitigating risk during the study

The study will be carried out by protocol, and any deviations will be formally and immediately reported to the principal investigator and the ethics committee for further action. Conducting a study on sensitive families may cause the researcher psychological strain, which will be mitigated by regular monthly meetings with the research team.

Discussion

In this study, a well-structured trial that compares 6 face-to-face intervention sessions with an instructional booklet to a control group using quantitative research methodologies. The major goal of this study is to observe if there are statistically significant differences in mean mental well-being and life satisfaction levels between women in the intervention group and those in the control group.

This research provides a vital basis for future scholars to critically review and improve the conception and implementation of comparable programs by examining the effectiveness, feasibility and applicability of the intervention. This study will considerably contribute to the global body of knowledge on the effectiveness of psychosocial interventions as a viable method for managing the psychological repercussions of sudden bereavement in low-resource settings.

The trial has several major strengths. To begin with, it is the first study of its sort in Pakistan, demonstrating its pioneering nature. The intervention itself has been painstakingly designed, drawing on an extensive literature review to provide a detailed brochure and intervention manual. This document meticulously details the precise protocol for carrying out the intervention, ensuring consistency and the possibility of replication in future research attempts. The measures used to assess therapy effectiveness are strong and dependable. Furthermore, the study sample will be drawn from a tertiary hospital, which attracts a large and broad range of people from various social and cultural backgrounds.

It is critical to recognize the study's limitations. For example, study participants will be recruited in a specific area, which may limit the sample's representativeness when extending findings to bereaved families in a broader context. Furthermore, the relatively short duration of the follow-up period may have underestimated the long-term effects of the intervention. Unfortunately, due to time and financial constraints, extending the follow-up period is not an option. Nonetheless, multiple promising research has shown that the average follow-up duration is six weeks. In terms of ethics, it is vital to note that women in the control group will receive a basic information packet and contact information for support, even though their level of intervention will be lower [50].

Conclusion

The results of this quasi-experimental study will provide valuable insights into the effectiveness of a nurse-led, positive psychology-based psychosocial intervention aimed at improving the mental well-being of bereaved families in Karachi, Pakistan. By evaluating the impact of components such as mindfulness, spirituality, physical activity, happiness, gratitude, and social support over a six-week intervention period, the study seeks to offer evidence on how these strategies can positively influence mental health and life satisfaction. Additionally, assessing the acceptability and applicability of this intervention in a low-resource setting will offer practical insights into its feasibility for broader implementation.

Ultimately, the findings are expected to contribute to the body of knowledge on bereavement care, guiding researchers, clinicians, and policymakers in designing effective, culturally appropriate interventions for bereaved families. This study will not only inform the development of future psychosocial interventions but also support the integration of evidence-based mental health support into community and healthcare services, improving the overall quality of care for bereaved individuals in low-resource settings.

Declaration

Ethics approval and consent to participate

All the interventions strictly adhered to the principles and procedures specified in the Helsinki Declaration. Furthermore, all experimental protocols were thoroughly reviewed and approved by the Aga Khan University Ethical Review Committee (Attachment file 1). Informed consent will be obtained from all study participants, ensuring that ethical standards are followed throughout the research process.

Consent for publication

Participants will be asked for their consent during the data collection process, understanding that the collected data may be utilized for the dissemination of scientific knowledge. However, no personal names or specific identifying information will be revealed in the published material to ensure confidentiality and privacy. Moreover, Participants will also be requested permission to publish any relevant data or materials without disclosing their identity.

Author's contributions

The Primary Author Mehreen Aslam helped to conceptualize the study. Ambreen Tharani was in charge of developing the study's intervention and modules. Yasmin Parpio was instrumental in establishing the technique. Rafat Jan made significant contributions to the study's completion by offering critical reviews and suggestions.

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