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Received: 31 October 2025

Accepted: 3 February 2026

Published online: 10 February 2026

Cite this article as: Sun J., Xue J. & Li X. Empowering community volunteers improves the well-being of family caregivers of musculoskeletal disorder patients: a randomized controlled trial. *BMC Nurs* (2026). <https://doi.org/10.1186/s12912-026-04410-8>

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## Empowering Community Volunteers Improves the Well-being of Family Caregivers of Musculoskeletal Disorder Patients: A Randomized Controlled Trial

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### Abstract

**Background** Musculoskeletal (MSK) disorders cause major global disability and strain caregivers' mental health. In China, aging and limited rehabilitation amplify this burden. Empowering community volunteers through structured training may provide emotional and practical support to family caregivers, yet its effectiveness for MSK caregiving remains insufficiently studied.

**Methods** A randomized controlled trial was conducted in a coal-mining community. Eighty-eight family caregivers were randomly assigned to an intervention group, which received regular home visits from trained community volunteers, or a control group receiving routine community services. Volunteers completed a standardized four-week training program covering caregiving, communication, risk management, and resource navigation. Primary outcomes—caregiver burden (Zarit Burden Interview), depressive symptoms (Self-Rating Depression Scale), and care-related quality of life (CarerQoL-7D)—were assessed at baseline and six months. Data were analyzed using paired t-tests and Generalized Estimating Equation (GEE) models to evaluate intervention effects.

**Results** Compared with the control group, the intervention group showed significant improvements across all measured outcomes over the 6-month period, including reduced caregiver burden ( $p < 0.001$ ), decreased depressive symptoms ( $p = 0.010$ ), and enhanced care-related quality of life ( $p = 0.001$ ). Effect sizes ranged from 0.50 to 0.68, reflecting moderate practical significance. GEE analyses further confirmed significant group-by-time interaction effects, demonstrating greater positive changes in the intervention group over time.

**Conclusions** The findings suggest that structured volunteer support may help reduce caregiver burden and depressive symptoms while improving care-related quality of life among family caregivers of musculoskeletal (MSK) patients. The results indicate the potential feasibility of integrating trained community volunteers into caregiving systems. This low-cost, scalable approach may offer a practical way to enhance community-based care and psychosocial support in resource-limited settings.

**Keywords** Musculoskeletal disorders; Family caregivers; Community volunteers; Empowerment; Caregiver burden; Care-related quality of life; Depression; Randomized controlled trial; China

## Background

Musculoskeletal (MSK) disorders, affecting around 1.71 billion people globally, are among the leading causes of disability and impose substantial health and economic burdens<sup>[1]</sup>. In China, older adults and industrial workers are disproportionately affected as rapid population aging, sedentary lifestyles, and repetitive manual labor converge to heighten risk<sup>[2][3][4][5]</sup>. With these structural drivers intensifying, the prevalence of MSK-related disability continues to grow, placing increasing strain on families, communities, and health systems.

Beyond physical limitations, MSK disorders substantially affect psychological well-being and quality of life, often leading to long-term dependence on family caregivers<sup>[6][7]</sup>. Caregivers frequently experience stress, fatigue, and depressive symptoms, which may disrupt care continuity and worsen patient outcomes<sup>[8][9]</sup>. Despite their pivotal role, caregivers remain an overlooked group in community-based interventions. Previous research has shown that caregivers require emotional relief, respite care, and opportunities for social interaction to manage caregiving stress effectively<sup>[10][11]</sup>. In response to these needs, the intervention in this study aims to provide structured emotional and practical support, offering respite services and enhancing social engagement, thereby alleviating caregiver burden and improving well-being.

Volunteering—defined as the unpaid provision of time to benefit others<sup>[12][13]</sup>—has been widely utilized in chronic disease, dementia, and cancer care. Evidence indicates that trained volunteers can alleviate caregiver burden and enhance well-being by providing emotional, practical, and informational support<sup>[14][15][16]</sup>. In palliative care settings, for example, volunteers often deliver respite and companionship, helping family caregivers sustain long-term care<sup>[17]</sup>.

Nevertheless, the benefits of volunteer involvement are not universal. Evidence from hospital and dementia care suggests that outcomes depend on volunteer selection, continuity, and—critically—role preparation<sup>[18]</sup>. Needs-tailored training that aligns with caregivers' priorities, communication challenges, and referral pathways can enhance volunteers' adaptability and impact<sup>[19][20]</sup>. Empowerment-oriented interventions that combine information, skill-building, and supportive relationships have demonstrated positive outcomes in chronic disease management<sup>[21]</sup>. However, within the MSK field, such structured empowerment approaches remain scarce. Building on emerging feasibility work (e.g., JOINT SUPPORT<sup>[22]</sup>), this study develops a community-based empowerment program that standardizes volunteer preparation and supervision while addressing caregivers' practical and emotional needs.

China provides a unique context for implementing community-embedded approaches. Deep-rooted traditions of neighborhood reciprocity and collective responsibility, formalized through neighborhood committees and volunteer organizations, offer an existing infrastructure for standardized training, supervision, and referral<sup>[23][24]</sup>. In these close-knit environments, neighbor-volunteers can be readily recruited and deliver culturally attuned support<sup>[25]</sup>. Strong social capital further buffers caregiver stress and enhances resilience<sup>[26]</sup>. Integration with primary and community health services provides vertical linkages for escalation and follow-up, ensuring sustainability. However, empirical evidence on whether such structured empowerment truly benefits caregivers of MSK patients remains limited.

To address this gap, we designed and tested a community-embedded volunteer empowerment program that delivers standardized preparation—including caregiving knowledge, communication skills, risk recognition, and referral pathways—along with continuous supervision for volunteers paired with family caregivers of MSK patients. Using a randomized controlled design, we assessed short-term effects over six months on three outcomes: caregiver burden (Zarit Burden Interview, ZBI), depressive symptoms (Self-Rating Depression Scale, SDS), and care-related quality of life (CarerQoL-7D). We hypothesized that, compared with usual community services, the program would significantly reduce caregiver burden and depressive symptoms while improving care-related quality of life. Unlike previous studies that have explored empowerment-based volunteer approaches mainly in hospital or institutional settings such as dementia and palliative care, this study extends the model to musculoskeletal caregiving within a resource-constrained community context, leveraging community volunteers as an accessible and sustainable support mechanism.

### **Theoretical Framework**

This study is guided by three interrelated theoretical perspectives—Empowerment Theory, Social Support Theory, and the Stress–Coping Model—which together offer a plausible, testable account of how empowering community volunteers can improve the well-being of family caregivers of patients with musculoskeletal disorders (MSK). These theories jointly inform the design, implementation, and expected psychological mechanisms of the community volunteer–assisted intervention, shaping how volunteer training, supportive communication, and resource linkage ultimately translate into changes in caregiver burden, depressive symptoms, and care-related quality of life.

### **Empowerment Theory**

Empowerment Theory posits that access to resources and participatory roles cultivates perceived competence, control, and agency at psychological, organizational, and community levels<sup>[27]</sup>. In the present study, volunteers are empowered through structured preparation, including caregiving knowledge, communication and motivational skills, risk recognition, and referral pathways, combined with ongoing supervision. Such preparation is expected to strengthen volunteers' role clarity, competence, and self-efficacy<sup>[28]</sup>.

In the context of caregiving support, empowered volunteers serve as knowledgeable and confident helpers who can transfer empowerment to caregivers by offering guidance, encouragement, and resource navigation. This process may enhance caregivers' mastery, sense of control, and ability to handle daily care challenges. Prior research in community and nursing settings similarly suggests that empowerment-based volunteer training improves volunteers' effectiveness, strengthens supportive behaviors, and contributes to positive caregiver outcomes<sup>[14][15]</sup>. Thus, Empowerment Theory provides a capability-building rationale for why structured volunteer training is expected to influence caregiver well-being.

### **Social Support Theory**

Social Support Theory explains how emotional, informational, and instrumental support buffer the psychological effects of stress<sup>[29]</sup>. Family caregivers of MSK patients frequently experience social isolation, emotional exhaustion, and limited access to professional support, making them highly vulnerable to stress. By establishing a structured network of trained volunteers, the intervention ensures that caregivers receive consistent emotional, informational, and practical support.

Volunteers' companionship, empathy, and guidance foster a sense of belonging and reassurance, reducing uncertainty and distress. Informational and instrumental support—such as clarification of caregiving tasks, practical tips, and linkage to community resources—further reinforces caregivers' confidence and problem-solving capacity<sup>[30]</sup>. Evidence from community health and caregiver-support research similarly indicates that volunteer-based social support enhances caregivers' resilience and reduces emotional burden<sup>[15][17]</sup>. Thus, Social Support Theory provides a connection-building mechanism explaining how sustained volunteer engagement can mitigate caregiver stress.

### **Stress-Coping Model**

The Stress-Coping Model proposed by Lazarus and Folkman conceptualizes caregiving as an ongoing stressor that challenges emotional and physical resources<sup>[31]</sup>. In this framework, individuals' well-being is shaped by their appraisal of stressors and their ability to employ adaptive coping strategies. Volunteer interactions can serve as both a coping resource and a coping facilitator, helping caregivers reappraise stressful situations and adopt adaptive problem-focused coping (e.g., improving caregiving skills, seeking help) and emotion-focused coping (e.g., emotional expression, acceptance, relaxation)<sup>[32]</sup>. Through regular, empathic contact, volunteers create opportunities for emotional ventilation, guided reflection, and stress management. These coping-enhancing interactions are expected to reduce psychological distress and strengthen caregivers' capacity to sustain caregiving responsibilities over time.

Taken together, the three theories represent complementary pathways through which the intervention is expected to exert its effects. Empowerment Theory highlights capability building (volunteer competence→caregiver self-efficacy), Social Support Theory emphasizes

connection building (enhanced support→reduced stress), and the Stress-Coping Model explains psychological adaptation (improved coping→reduced burden and depressive symptoms). By simultaneously strengthening caregivers' access to emotional, informational, and practical resources and enhancing their coping capacity, the intervention is hypothesized to reduce caregiver burden (ZBI) and depressive symptoms (SDS), and to improve care-related quality of life (CarerQoL-7D). These mechanisms provide a coherent and theoretically grounded foundation for understanding how community-based volunteer empowerment can strengthen informal caregiving systems, particularly in resource-constrained settings.

## **Method**

### **Study Design**

Participant recruitment for this study commenced on February 1, 2023, and the trial was retrospectively registered with the Chinese Clinical Trial Registry (ChiCTR2500105602) on July 7, 2025, following the completion of data collection and follow-up. Caregiver burden, assessed via the Zarit Burden Interview (ZBI), was pre-specified as the primary outcome in the study protocol. Psychological distress (SDS) and care-related quality of life (CarerQoL-7D) were pre-specified as the key secondary outcomes. No additional exploratory outcomes were added after the trial initiation. Nevertheless, the absence of prospective trial registration limits transparency regarding the original analysis plan and introduces an inherent risk of selective reporting.

### **Setting and Participants**

This study was conducted in a coal-mining community in central Shandong Province, China. The community is composed primarily of miners and their families and represents a typical working-class population situated at the urban–rural interface. Due to long-term engagement in physically demanding labor and limited access to healthcare resources, middle-aged and older residents exhibit a high prevalence of musculoskeletal (MSK) disorders. This context provides a representative setting for examining the caregiving challenges associated with MSK conditions.

The community also functions as a close-knit “acquaintance society”, characterized by strong social ties and a well-organized volunteer network. Community volunteers commonly participate in health promotion and peer-support activities. Leveraging this social structure, the present intervention was designed to empower community volunteers and strengthen informal support networks to alleviate caregiver burden and enhance caregivers' psychological well-being and quality of life.

### **Participant Identification and Recruitment**

Participants were identified and recruited through a structured, community-based process coordinated with the neighborhood committee and the community health service center.

Licensed general practitioners first reviewed community health records and chronic disease registries to identify residents with physician-confirmed musculoskeletal (MSK) disorders based on ICD-10 diagnostic criteria.

Community physicians and social workers then conducted household visits and telephone screenings to verify symptom persistence, functional limitations, and caregiving needs. When clinical documentation was insufficient, caregiver reports were used as supplementary verification.

For each eligible patient, the primary family caregiver was approached by trained research staff, informed about the study, and invited to participate. Consecutive recruitment continued until the target sample size was reached. Recruitment posters and community announcements were also used to support outreach efforts.

### **Inclusion and exclusion criteria**

Participants were required to have a confirmed diagnosis of musculoskeletal (MSK) disorders, encompassing but not limited to conditions such as osteoarthritis, chronic low back pain, neck or shoulder strain, limb-related MSK disorders, and rheumatic diseases, as diagnosed by licensed physicians according to International Classification of Diseases, 10th Revision (ICD-10) criteria. To ensure that the enrolled patients indeed required ongoing caregiving support, eligible individuals were also required to present with typical MSK-related symptoms—such as moderate to severe pain, joint stiffness, reduced mobility, limitations in range of motion, or difficulties performing daily activities (e.g., walking, transferring, bathing, dressing, or household tasks).

Symptoms must have persisted for at least three months, indicating a chronic and stable condition. In addition, patients were required to demonstrate at least one functional impairment affecting activities of daily living (ADL) or instrumental activities of daily living (IADL), thereby necessitating routine assistance from a family caregiver. Eligible patients had to demonstrate clinical stability without recent exacerbations, acute flare-ups, or marked fluctuations in their condition.

Individuals with severe psychiatric illnesses or cognitive dysfunctions were excluded. Severe psychiatric illnesses were defined as conditions such as schizophrenia, schizoaffective disorder, bipolar disorder with recent episodes, major depressive disorder with severe functional impairment, or any psychiatric condition requiring hospitalization within the past six months. Cognitive dysfunctions were defined as diagnosed dementia, mild cognitive impairment with documented deficits affecting daily functioning, or any cognitive condition that limits the ability to provide informed consent or reliably participate in study procedures.

These conditions were assessed based on physician diagnosis, medical records, or caregiver reports. Patients receiving palliative care, pregnant women, and those entirely unable to perform essential daily living activities independently were also excluded.

Inclusion criteria for family caregivers:

1. The participant must be the primary person responsible for providing daily care to a family member diagnosed with an MSK condition.
2. The caregiver must share a close familial relationship with the patient (e.g., spouse, child, daughter-in-law, son-in-law, grandchild, or other immediate relatives).
3. Eligible caregivers were required to have no serious mental or cognitive disorders and be capable of completing study-related procedures and providing informed consent.
4. Those allocated to the intervention group were expected to actively participate in activities organized by the research team, including engagement in supportive and behavioral programs. Caregivers in the control group received only routine community-based services without additional intervention.

Additionally, caregivers were excluded if they declined participation, withdrew communication during the study, or if the care recipient died or was re-hospitalized due to disease relapse during the study period.

### **Sample Size Estimation**

An a priori power analysis was conducted using G\*Power 3.1<sup>[33]</sup> to determine the required sample size. Based on a previously observed effect size (Cohen's  $d \approx -0.658$ <sup>[34]</sup>), it was estimated that a minimum of 38 participants per group (total  $N = 76$ ) would be needed to detect statistically significant differences between groups with 80% power at a two-tailed alpha level of 0.05. Accounting for an anticipated attrition rate of 15%, the final recruitment target was set at 88 participants, with 44 allocated to each group.

### **Randomization and Allocation**

Prior to the commencement of the study, all eligible family caregivers were stratified by gender, age, and the severity of the patient's condition. Within each stratum, participants were randomly assigned (1:1) to either the intervention or control group using a computer-generated random number sequence prepared by an independent statistician. Block randomization (block size = 4) was applied to maintain balanced group sizes. The allocation sequence was concealed using sequentially numbered, opaque, sealed envelopes, which were opened by the research coordinator only after participant enrollment to ensure allocation concealment. Because of the nature of the behavioral intervention, caregivers and intervention implementers could not be blinded to group allocation. However, outcome assessors were blinded to participants' group assignments and were not involved in either randomization or intervention delivery. To preserve blinding, participants were instructed not to reveal their allocation status during assessments, and no unblinding occurred during the study.

### **Ethical Considerations**

This study was approved by the Ethics Committee of the School of Social Development, Langfang Normal University prior to the commencement of the intervention (Approval Number: 20220001). All methods were performed in accordance with the Declaration of Helsinki. Informed consent was obtained from all participants.

### **Intervention Program Development**

The intervention program was developed using a structured, evidence-informed process to ensure that its content aligned with the needs of MSK caregivers and the capacities of community volunteers. First, a focused literature review was conducted on volunteer-assisted caregiver programs, empowerment-based interventions, and community health volunteer models in chronic disease and aging care. This review highlighted key components associated with effective caregiver support, including structured training, clear role definition, communication skills, and referral pathways.

Second, needs assessment interviews were conducted with community physicians, social workers, and ten family caregivers to identify the most common caregiving challenges in the local setting. Key issues included physical strain, emotional distress, insufficient disease-related knowledge, and limited awareness of community resources. These findings helped determine the core priorities for volunteer training.

Third, an expert panel consisting of a general practitioner, a rehabilitation specialist, a psychologist, and two community social workers reviewed and refined the program content. Through iterative discussion, the panel finalized a five-module curriculum covering MSK knowledge, home-visit safety, communication and active listening, stress recognition and psychological first aid, and community resource navigation. All training materials were adapted to the local context to ensure feasibility, cultural relevance, and ease of implementation.

This systematic development process ensured that the intervention was theoretically grounded, evidence-based, and responsive to the practical needs of both volunteers and family caregivers.

### **Intervention**

The intervention was designed to empower community volunteers to provide structured, safe, and sustainable support for family caregivers of patients with MSK disorders. The design was informed by Empowerment Theory, Social Support Theory, and the Stress–Coping Model, which emphasize that enhancing social support and caregiver capacity can effectively reduce burden and improve well-being. The intervention consisted of five interrelated components: recruitment and training, caregiver–volunteer matching, intervention delivery, supervision and quality assurance, and safety and ethical safeguards.

#### **1. Volunteer Recruitment and Training**

Volunteers were recruited from the community-based volunteer registry, long-term residents, and newly enrolled members recommended by neighborhood committees. Eligibility criteria included: age 18–70 years, residence in or near the community, availability to provide at least one visit per week for six months, good physical and mental health, effective communication skills, and willingness to sign confidentiality and safety agreements. Exclusion criteria comprised unstable psychiatric illness, unresolved conflicts of interest with participating families, or inability to complete training. A withdrawal mechanism was also in place to ensure that volunteers unable to continue participation were replaced promptly.

All eligible volunteers underwent a standardized four-week training program (approximately 20 hours of face-to-face training), delivered by general practitioners, rehabilitation specialists, psychologists, and social workers. The curriculum consisted of five core modules—details of which are presented in Table 1: (1) musculoskeletal (MSK) diseases and caregiving basics; (2) home-visit protocols and safety standards; (3) communication and active listening skills; (4) recognition of caregiver stress and psychological first aid; and (5) navigation of community health, rehabilitation, and social welfare resources. Each training module was aligned with the theoretical framework: empowerment (Modules 1–3), social support (Modules 3–5), and coping enhancement (Modules 4–5), ensuring consistency between theory and practice. Ethical principles, confidentiality, and role boundaries were emphasized as cross-cutting themes and integrated throughout all training sessions. Training was conducted through lectures, role-play, simulations, group discussions, and case-based exercises. Competence was assessed by short written tests, practical simulations, and structured evaluations of home-visit scenarios. Only volunteers who successfully passed the assessments were certified to participate in the intervention. Of 45 trainees, 38 (84%) successfully completed certification.

## 2. Volunteer–Caregiver Matching

Volunteers were matched with caregivers based on geographic proximity (e.g., same building or neighborhood block), pre-existing social connections or endorsements from community leaders, and stability (fixed pairing for six months). Each volunteer was assigned to support one or two families, ensuring manageable caseloads and continuity of care. Matching aimed to foster trust and reduce attrition. In cases of volunteer dropout, new matches were established within two weeks to maintain intervention continuity.

## 3. Intervention Delivery

The intervention lasted for six months. Each volunteer conducted at least one scheduled home visit per week, with flexibility to provide additional contacts when necessary. Remote interactions via telephone or WeChat were used only as supplementary methods in cases of illness, emergencies, or temporary unavailability, but the standard mode of delivery was face-to-face visits. Each session lasted approximately 45–60 minutes. Core responsibilities included:

Educational support: providing information on common MSK, functional limitations, and practical caregiving strategies;

Emotional support: offering active listening, encouragement, and basic stress management techniques;

Resource navigation: linking caregivers to available community health, rehabilitation, and welfare resources;

Referral mechanism: identifying caregivers with severe stress, depression, or unmet health needs and promptly referring them to professional services.

In addition, digital communication tools such as WeChat were used to coordinate visit schedules, send reminders, share educational materials, and maintain contact between volunteers, caregivers, and the study team. Although not a formal data collection platform, these tools facilitated timely communication and enhanced continuity of support throughout the intervention period.

Adherence was defined as completing at least eighteen of the twenty-four scheduled home visits ( $\geq 75\%$  of contacts), with each family receiving a minimum of 800 minutes of intervention exposure. Volunteers documented activities and caregiver feedback after each visit using simplified digital forms (e.g., WeChat-based checklists), which were reviewed weekly by the study team.

#### 4. Supervision and Quality Assurance

Monthly supervision meetings were held, facilitated by a multidisciplinary team of general practitioners, psychologists, and social workers. These sessions provided volunteers with guidance, peer support, and opportunities for case discussion. Quality assurance measures included: (1) use of a standardized intervention manual to ensure intervention fidelity; (2) review of digital reports for completeness and accuracy; (3) random spot-check calls to caregivers by the study team; and (4) structured feedback to volunteers. These procedures ensured consistency across volunteers and timely resolution of challenges.

#### 5. Safety and Ethical Safeguards

The study protocol was reviewed and approved by the Ethics Committee of Langfang Normal University. All participants provided written informed consent prior to enrollment, and confidentiality was strictly maintained throughout the study. Safety and ethical considerations were embedded in all phases of the intervention. Adverse events, including emotional distress or any incidents occurring during home visits, were continuously monitored. A designated medical team was responsible for the immediate evaluation and management of any reported incidents. No serious adverse events occurred during the trial.

Table 1 Training Modules and Competency Framework for Community Volunteers

Module	Key Content	Trainers	Methods	Evaluation	Competency
1. MSK Diseases & Caregiving Basics	Common MSK disorders, functional limitations, caregiving tips; safe body mechanics and transfer techniques; pain self-assessment tools (VAS/NRS); basic assistive device guidance	General Practitioner, Rehabilitation Specialist	Lecture, Case Analysis	Short Test + Skill Check	Master basic knowledge, provide daily care support, perform safe transfers, guide basic pain management
2. Home-visit & Safety	Home-visit etiquette; risk identification (fall hazards, fire/electrical risks, cluttered environments); safety standards; volunteer self-protection; emergency protocols (e.g., sudden illness, violence, fire)	Nurse, Social Worker	Role-play, Simulation	Practical Exercise	Ensure safety during home visits, identify risks systematically, respond to emergencies, protect personal safety
3. Communication & Active Listening	Listening skills, emotional recognition, conflict resolution; motivational interviewing techniques; de-escalation strategies; culturally sensitive communication	Psychologist, Social Worker	Role-play, Simulation	Simulation	Build trust and provide emotional support, motivate caregivers to adopt healthy practices, handle conflicts constructively
4. Caregiver Stress & Psychological First Aid	Identifying stress sources; basic psychological first aid; use of brief screening tools such as the Patient Health Questionnaire-2 (PHQ-2); referral criteria and pathways; and stress management and self-care strategies (e.g., mindfulness, relaxation).	Psychologist	Case Discussion + Simulation	Simulation Assessment	Effectively respond to caregiver stress, recognize mental health red flags, initiate referrals, promote caregiver and self well-being
5. Community Resources & Referral	Health, rehabilitation, social welfare resources; referral process and documentation; use of standardized referral	Social Worker	Information Brief + Handbook	Task Test + Case Exercise	Link caregivers to appropriate community resources, complete referral documentation, coordinate

forms; community resource mapping; case discussions of referral decision-making

follow-up, navigate multi-sectoral support

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## Data Collection

Data were collected at two time points: baseline (T0) and post-intervention (T1). At T0, participants provided demographic information and completed assessments for caregiving burden (ZBI), depressive symptoms (SDS), and caregiving-related quality of life (CarerQoL-7D). The same assessments were repeated at T1, following the completion of the 6-month intervention, to evaluate outcome changes. All data were double-entered and cross-verified by independent data clerks. Regular audits were conducted to minimize entry errors and ensure data integrity.

## Measurement

### Zarit Burden Interview (ZBI)

The Zarit Burden Interview (ZBI), originally developed by Zarit et al. in 1980<sup>[35]</sup>, comprises 22 items that assess caregivers' perceived burden across individual, social, emotional, and financial dimensions<sup>[36]</sup>. Each item is rated on a five-point Likert scale (0 = never to 4 = always), yielding a total score of 0–88, with higher scores indicating greater caregiver burden. The Chinese version of the ZBI has demonstrated high internal consistency (Cronbach's  $\alpha = 0.875$ ) and good construct validity (RMSEA = 0.077; CFI = 0.841; NFI = 0.802; GFI = 0.886)<sup>[37]</sup>.

### Care-related Quality of Life Instrument (CarerQoL-7D)

Care-related quality of life was measured using the CarerQoL-7D, developed in the Netherlands to capture both positive and negative aspects of informal caregiving<sup>[38]</sup>. The instrument comprises seven domains: fulfillment, physical and mental health, financial strain, relationship issues, limitations in daily activities, and perceived social support. Responses are rated on three levels and summarized using an internationally validated utility-weighted additive scoring system (ranging from 0 to 100), with higher scores indicating better care-related quality of life. The Chinese version has shown good reliability and construct validity<sup>[39]</sup>.

In this study, a weighted additive model was applied to calculate the composite score, with each domain multiplied by its respective utility weight derived from the Dutch valuation system<sup>[34]</sup>. Higher scores indicate better care-related quality of life, reflecting more caregiving fulfillment and fewer caregiving-related difficulties.

### Self-Rating Depression Scale (SDS)

Depressive symptoms were assessed using the Self-Rating Depression Scale (SDS) developed by Zung in 1965<sup>[40]</sup>. The scale consists of 20 items covering affective, cognitive, and somatic symptoms of depression. Each item is rated on a four-point Likert scale (1 = a little of the time to 4 = most of the time), with higher scores indicating greater severity of depressive symptoms. The Chinese version has demonstrated high internal consistency (Cronbach's  $\alpha = 0.91$ ) and satisfactory construct validity<sup>[41]</sup>. Its simplicity and self-administration format make

it suitable for large-scale epidemiological studies and clinical screening of depressive symptoms.

### **Data Analysis**

The primary analysis followed a modified intention-to-treat (mITT) approach, defined as all randomized participants who completed at least one post-baseline outcome assessment. Of the 96 randomized caregivers, 88 provided evaluable data and were included in the mITT set. Eight participants who withdrew before contributing any post-baseline data were excluded. We acknowledge that this mITT approach represents a deviation from the strict intention-to-treat (ITT) principle, which requires the inclusion of all randomized participants regardless of follow-up. Regarding missing data, although all 88 participants in the mITT set had complete outcome assessments, we recognize that the eight excluded participants represent missingness at the randomized level (8.3% of the total 96 randomized). Following CONSORT guidelines, these exclusions were treated as missing data. Given the relatively small number of dropouts and their balanced distribution between groups, no formal statistical imputation procedures were applied, and the analysis was conducted using the observed data from the mITT population. However, we acknowledge that excluding participants without post-baseline data introduces a potential risk of attrition bias. While baseline characteristics did not meaningfully differ between participants included in and excluded from the mITT population, this does not fully eliminate the possibility of bias, and the potential influence of this missingness on the study's inferences is addressed in the Limitations section.

Baseline characteristics were summarized using descriptive statistics (means  $\pm$  SD or frequencies) and evaluated using independent-samples t-tests and chi-square tests. Within-group changes from pre-intervention (T0) to post-intervention (T1) were assessed using paired-samples t-tests. To evaluate longitudinal intervention effects and account for the correlation between repeated measures, a Generalized Estimating Equation (GEE) model with an autoregressive [AR(1)] working correlation structure was applied. The model included group, time, and the group  $\times$  time interaction as the primary treatment effect. GEE results were consistent with the conclusions derived from the prespecified paired-samples t-test analyses. Furthermore, the intervention design involved assigning caregivers to specific volunteers, creating a nested data structure. While the GEE framework was used to account for the correlation of repeated measures within individuals, observations were treated as independent at the volunteer-cluster level. We acknowledge that this approach does not explicitly model volunteer-level clustering. The implications of this structural feature for variance estimation and statistical inference are addressed in the Limitations section. Effect sizes were quantified using Cohen's d. All analyses were conducted using IBM SPSS Statistics version 29, with statistical significance set at  $p < 0.05$ .

### **Results**

A total of 103 caregivers were screened for eligibility; 3 did not meet the inclusion criteria, and 4 declined participation. Consequently, 96 caregivers were enrolled and randomized. During the study, 8 participants (8.3%, 8/96) were lost to follow-up (4 in the intervention group and 4 in the control group), and their data were treated as missing at the randomized level. These 88 participants who provided post-baseline assessments constituted the modified intention-to-treat (mITT) population used for the primary analyses. Continuous communication and structured follow-up strategies were employed to support participant retention. Given that the analyzed mITT population had complete follow-up assessments and the attrition rate was relatively low and balanced, the primary analyses were conducted using the observed data. The study's participant flow and data structure provided a consistent basis for subsequent analyses (see Fig. 1).

### Descriptive statistics and baseline comparisons

The caregivers' mean age was  $43.6 \pm 9.2$  years, with a nearly even gender distribution (52.3% female, 47.7% male). Most were married (79.5%) and had at least secondary education (70.5%). In terms of economic status, 61.4% reported adequate or very adequate financial resources. Regarding caregiver-care recipient relationships, 62.5% were spouses and 37.5% were children. The majority (60.2%) provided less than six hours of care per day.

At baseline, there were no significant differences between the intervention ( $n = 44$ ) and control ( $n = 44$ ) groups in sociodemographic characteristics, including age ( $p = 0.207$ ), sex ( $p = 0.522$ ), marital status ( $p = 0.429$ ), education ( $p = 0.816$ ), economic status ( $p = 0.827$ ), caregiver-care recipient relationship ( $p = 1.000$ ), and average daily caregiving hours ( $p = 0.663$ ) (Table 2). Similarly, baseline clinical outcomes did not differ significantly between groups for ZBI ( $p = 0.795$ ), SDS ( $p = 0.392$ ), or CarerQoL-7D ( $p = 0.893$ ).

**Table 2** Comparison of Sociodemographic Characteristics Between Intervention and Control Groups at Baseline

Characteristic	Intervention Group (n=44)	Control Group (n=44)	p-value
Age (years)	$42.3 \pm 9.1$	$44.8 \pm 9.1$	0.207
Sex			0.522
Female	25(54.3%)	21(45.7%)	
Male	19(45.7%)	23(54.3%)	
Marital status			0.429
Other marital status	11(23.9%)	7(15.2%)	
Married	33(76.1%)	37(84.8%)	
Education			0.816

Primary school or lower	12(26.1%)	14(32.6%)	
Secondary school or higher	32(73.9%)	30(67.4%)	
Economic Status			0.827
Very inadequate/ inadequate / fair	18(41.3%)	16(34.8%)	
Adequate/very adequate	26(58.7%)	28(65.2%)	
Caregiver-care recipient relationship			1.000
Spouse	27(60.9%)	28(65.2%)	
Child	17(39.1%)	16(34.8%)	
Average Daily Caregiving Hours			0.663
<6 hours	25(58.7%)	28(63.0%)	
≥6 hours	19(41.3%)	16(37.0%)	
ZBI	52.477±8.692	52.001±8.504	0.795
SDS	62.546±13.574	60.045±13.682	0.392
CarerQoL-7D	61.009±17.615	61.527±18.375	0.893

### Intervention Effects

Table 3 summarizes the effects of the community volunteer-led intervention on study outcomes. The intervention group demonstrated statistically significant improvements in all outcome measures, including reduced caregiver burden (ZBI;  $p < 0.001$ ), decreased depressive symptoms (SDS;  $p = 0.010$ ), and enhanced care-related quality of life (CarerQoL-7D;  $p = 0.001$ ). In contrast, no significant within-group changes were observed in the control group. Between-group comparisons at post-intervention (T1) indicated significantly greater improvements in the intervention group across all outcomes ( $p$  values ranging from 0.002 for CarerQoL-7D to 0.022 for ZBI). Effect sizes for intervention effects ranged from 0.50 (ZBI) to 0.68 (CarerQoL-7D), indicating moderately sized improvements across all primary outcomes.

**Table 3** Effects of the Community Volunteer-led Intervention on Study Outcomes in Intervention and Control Groups (T0 vs T1)

Outcome variables	Intervention group(T1)	P-value (Within)	Control group (T1)	P-value (Within)	Group Difference (T1)	P-value (Between-group)	Effect Size (Cohen's d)
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		n- group)	n- group)				
ZBI	45.43(8.88)	< 0.001	50.11(9.95 )	0.342	-4.68	0.022	0.50
SDS	54.93(13.6 5)	0.010	62.11(11.7 8)	0.449	-7.18	0.009	0.56
CarerQoL- 7D	74.68(18.1 1)	0.001	62.21(18.7 6)	0.863	12.47	0.002	0.68

T1 = Post-intervention. P-values indicate statistical significance for within-group comparisons (T0 vs T1) and between-group comparisons (Intervention vs Control) at T1.

### Longitudinal Effects: Generalized Estimating Equation (GEE) Analysis

The Generalized Estimating Equation (GEE) analysis revealed significant group-by-time interaction effects across all outcome variables (Table 4), indicating a differential change over time between the intervention and control groups. Specifically, participants in the intervention group exhibited significant reductions in caregiver burden ( $b = -5.159$ ,  $p < 0.001$ ) and depressive symptoms ( $b = -9.682$ ,  $p = 0.015$ ), along with significant improvements in care-related quality of life ( $b = 12.984$ ,  $p < 0.001$ ) throughout the study period. Overall, these findings suggest that the community volunteer-led intervention produced sustained and positive longitudinal effects on caregivers' mental health and quality of life.

**Table 4** Generalized Estimating Equation (GEE) models for the comparison of caregiver burden, depressive symptoms, and quality of life across the study period for intervention and control groups.

Outcome variables	Group - difference		Time1 - difference		Group*Time1 - difference	
	b (95%CI)	p	b (95%CI)	p	b (95%CI)	p
ZBI	4.682 (0.785,8.578)	0.01 9	7.045 (5.421, 8.670)	<0.00 1	-5.159 (-7.517, - 2.801)	<0.00 1
SDS	7.182 (1.916, 12.448)	0.00 8	7.614 (2.524, 12.703)	0.003	-9.682 (-17.467, - 1.897)	0.015
CarerQoL- 7D	-12.466	0.00 1	-13.670	<0.00 1	12.984	<0.00 1

(-20.082, -  
4.850)

(-16.373, -  
10.968)

(9.972,  
15.996)

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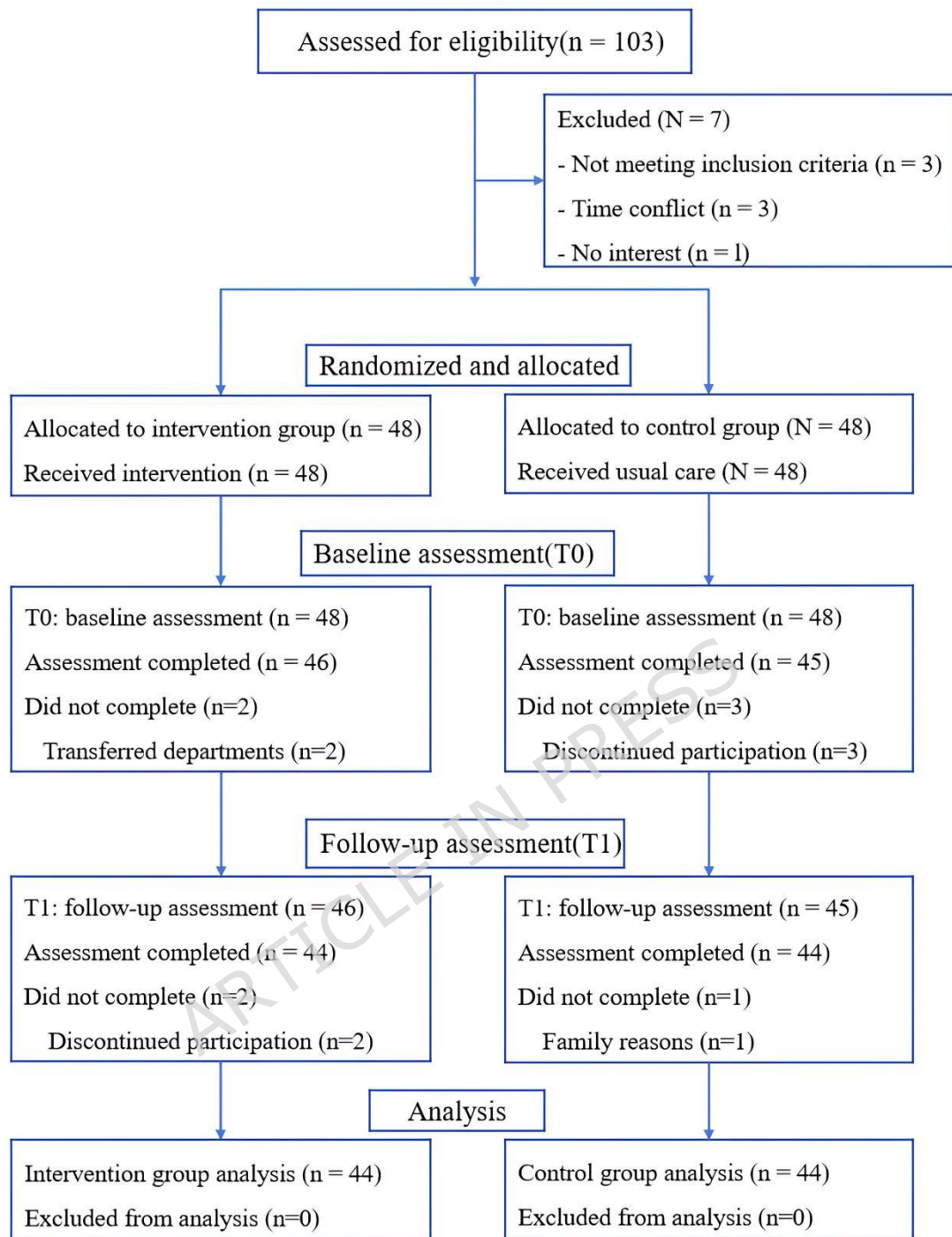
a. b-values represent the difference in outcome variables between the intervention and control groups, with p-values indicating statistical significance for the group-by-time interaction effect.

b. ZBI: Caregiver Burden; SDS: Self-Rating Depression Scale; CarerQoL-7D: Caregiver Quality of Life.

c. *GroupTime1* interaction effects indicate the differential impact of the intervention over time between the intervention and control groups, representing the primary treatment effect in this study.

d. Group was coded as 0 = control, 1 = intervention; Time as 0 = baseline (T0), 1 = post-intervention (T1). Negative  $\text{Group} \times \text{Time}$  coefficients for ZBI and SDS and positive coefficients for CarerQoL-7D indicate greater improvement in the intervention group relative to the control group.

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**Fig. 1** CONSORT-Flow diagram of the study

## Discussion

This study evaluated the effectiveness of a community-volunteer intervention for family caregivers of musculoskeletal (MSK) patients. The intervention significantly reduced caregiver burden and depressive symptoms and improved care-related quality of life, indicating that structured volunteer engagement can meaningfully alleviate caregivers' emotional and physical strain. These findings align with prior evidence showing that multicomponent interventions—integrating emotional, informational, and practical support—yield small-to-moderate improvements in caregiver burden and psychological well-being across chronic illness, dementia, and palliative care contexts<sup>[42][43][44]</sup>. Meta-analytic reviews similarly report enhanced emotional well-being and quality of life when interventions address both practical demands and psychosocial needs<sup>[45][46]</sup>. The magnitude of improvement observed here closely reflects these findings, suggesting broad applicability of structured support models beyond traditionally studied populations.

Despite this consistency, evidence from volunteer-based psychosocial programs has been mixed. A randomized trial by Charlesworth and colleagues reported no overall benefit of befriending for dementia caregivers, which was largely attributed to limited engagement and insufficient contact frequency. Notably, caregivers who received consistent visits demonstrated near-significant reductions in depressive symptoms, suggesting a possible dose–response relationship<sup>[47]</sup>. The present study advances this literature by employing an empowerment-oriented and supervised volunteer model. By strengthening volunteers' competence, confidence, and role clarity, the program addressed key limitations of earlier befriending interventions and demonstrated clear improvements in caregivers' psychological outcomes.

Compared with fields such as palliative care, oncology, and dementia—where volunteer interventions are well established<sup>[48][49][50]</sup>—MSK caregiving remains understudied<sup>[51]</sup>. This gap is particularly consequential in resource-constrained settings, where high physical demands and limited healthcare access intensify caregiver burden. Our findings contribute novel evidence that volunteer-supported programs can effectively meet the needs of MSK caregivers, offering emotional support, practical assistance, and resource navigation. Although promising, these results derive from a single-site trial with short-term follow-up. Larger multisite evaluations are needed to assess generalizability, sustainability, and cost-effectiveness.

The intervention's effectiveness can be understood through the study's theoretical framework: Empowerment Theory, Social Support Theory, and the Stress–Coping Model. By enhancing volunteers' self-efficacy, skills, and role clarity, the training program fostered volunteers' confidence and preparedness, which in turn empowered caregivers through role modeling, reassurance, and knowledge transfer. This aligns with evidence showing that empowerment-based interventions reduce caregiver burden and distress by strengthening perceived control and caregiving competence<sup>[52][53][54]</sup>.

Reductions in caregiver burden likely reflect increases in instrumental and informational support, which reduced uncertainty and task overload—key determinants of perceived burden in the Stress–Coping Model. Regular, empathic contact through scheduled volunteer visits also provided emotional reassurance, buffering the chronic stress associated with MSK caregiving. These mechanisms are consistent with systematic reviews showing that well-trained volunteers reduce caregiver stress and improve coping confidence through structured, ongoing support<sup>[55][56][57][17][14]</sup>.

The improvement in depressive symptoms further highlights the value of volunteer engagement. By providing emotional validation, companionship, and opportunities for meaningful interaction, volunteers helped caregivers reinterpret stressors and adopt more adaptive coping strategies. This process aligns with Social Support Theory, which posits that emotional and informational exchanges mitigate stress and promote resilience. Prior studies similarly indicate that enhanced social support mediates the relationship between caregiving stress and depression, suggesting that volunteer engagement may disrupt this pathway by increasing caregivers' emotional security and perceived support<sup>[58][59][60]</sup>.

Quality-of-life improvements observed in the intervention group reinforce these mechanisms. Volunteer engagement offered caregivers opportunities for respite (rest and self-care), and social connection—factors closely linked to improved well-being<sup>[61]</sup>. Evidence from rural and resource-limited settings in China likewise demonstrates that social support enhances caregiver quality of life by reducing burden and loneliness<sup>[62][63]</sup>. The present trial adds experimental support to this largely observational literature, highlighting the potential of community volunteer programs to strengthen caregiver well-being.

Beyond statistical significance, the magnitude of improvement observed in the intervention group demonstrates meaningful clinical relevance. Caregiver burden (ZBI) decreased by approximately 7 points, a change that meets or exceeds the minimal clinically important difference (MCID) of 5–7 points reported in previous studies<sup>[64][65]</sup>. Depressive symptoms (SDS) improved by approximately 7–8 points; based on established SDS severity cut-offs<sup>[66][67]</sup>—with scores of 60–69 indicating moderate depression and 50–59 indicating mild depression—this reduction reflects a shift from the moderate to the mild range and is generally regarded as clinically meaningful, indicating a substantial improvement in emotional well-being. Care-related quality of life (CarerQoL-7D) increased by approximately 13–14 points, exceeding thresholds in prior caregiver research that signal meaningful gains in daily functioning and overall quality of life<sup>[68][69]</sup>. Together, these changes show that the intervention produced not only statistically significant but also clinically meaningful improvements in caregivers' well-being.

Integrating these findings, the intervention appears effective because it simultaneously targeted capability (empowerment), connection (social support), and coping (stress management). Empowered volunteers served as both change agents and social mediators, bridging informal and formal care systems to ensure sustained psychological and practical

support for caregivers. This multicomponent design is consistent with contemporary caregiver-support models and reinforces the potential scalability of volunteer-assisted interventions in resource-constrained communities.

### **Practice Implications**

This study provides actionable insights for integrating volunteer empowerment programs into community-based care systems. The findings show that providing structured training, supervision, and clear role boundaries can substantially enhance the support available to family caregivers of musculoskeletal (MSK) patients.

From a practice perspective, primary health and community organizations should consider developing standardized volunteer training curricula that focus on three key areas: (1) caregiving knowledge and safety; (2) emotional communication and stress management; and (3) linkage to community health and welfare resources.

Integrating trained volunteers into existing community service networks can expand human resource capacity without increasing costs, while enhancing caregivers' psychological well-being and quality of life. Health administrators and policymakers can leverage these volunteer programs as cost-effective, scalable models to complement professional services—especially in resource-constrained or rural areas where access to formal rehabilitation and psychosocial care is limited. These programs can expand service capacity without additional financial burdens.

Furthermore, the empowerment framework used in this study provides a replicable blueprint for other chronic disease contexts, offering a sustainable approach to caregiver support in community-based care systems. Implementing ongoing supervision, feedback mechanisms, and competency assessments will be crucial to maintaining program quality and ensuring ethical and safe delivery of support. Integrating volunteer-based caregiver interventions into national community health strategies could ultimately strengthen informal care systems, reduce caregiver burnout, and promote sustainable, community-driven models of long-term care.

### **Limitations**

This study has several limitations. First and most significantly, the trial was registered retrospectively, and the primary analysis followed a modified intention-to-treat (mITT) approach that excluded eight randomized participants who provided no post-baseline data. We acknowledge that in the context of an RCT, post-randomization attrition and exclusions constitute a missing data problem at the randomized level (8.3%). Even though the number of excluded participants was small and their baseline characteristics were comparable to those retained, the lack of prospective registration and the omission of these individuals from the analysis may affect the perceived internal validity, compromise the integrity of the randomized groups, and introduce an inherent risk of selective reporting or attrition bias.

Consequently, the statistical inferences and the magnitude of the intervention effects should be interpreted with caution.

Second, the study's generalizability is limited by its conduct in a single community with a relatively small sample size and a six-month follow-up period, which may not capture the long-term sustainability of the intervention. Data collection relied on self-reported questionnaires (ZBI, SDS, CarerQoL-7D), which are susceptible to recall or social desirability bias. Furthermore, while MSK diagnoses were physician-confirmed, the partial reliance on caregiver reports for symptom severity when clinical records were incomplete may introduce measurement variability.

Third, the study focused exclusively on caregiver-level outcomes and did not incorporate patient-level data (e.g., pain severity) or volunteer-level metrics (e.g., satisfaction). As these factors could significantly influence the intervention's impact, their omission limits our understanding of the broader effects of the program. Finally, a structural limitation of this study is that volunteer-level clustering was not incorporated into the statistical analysis. Although the trial used individual-level randomization, the nesting of caregivers within volunteers represents a structural feature that should ideally be accounted for. Not modeling this dependency may result in underestimated standard errors and could affect the precision of our variance estimation and subsequent inferences. While the highly uneven cluster sizes posed practical constraints for hierarchical modeling, the intervention effects should be interpreted with this statistical dependency in mind.

Future multicenter studies should employ prospective registration, larger samples with longer follow-up periods, and include objective or observer-rated measures to validate and extend these findings.

## **Conclusion**

This randomized controlled trial demonstrates that empowering community volunteers through structured training and supervision effectively reduces caregiver burden, alleviates depressive symptoms, and enhances care-related quality of life among family caregivers of musculoskeletal (MSK) patients. Grounded in Empowerment Theory, Social Support Theory, and the Stress–Coping Model, the intervention enhanced caregivers' competence, social connectedness, and coping capacity. These findings demonstrate that volunteer-empowerment models are not only feasible but also scalable and cost-effective, offering a valuable complement to formal healthcare services, especially in resource-limited settings where they can significantly enhance psychosocial support and community resilience.

## **Abbreviations**

ZBI – Zarit Burden Interview

SDS – Self-Rating Depression Scale

CarerQoL-7D – Caregiver Quality of Life - 7 Dimensions

GEE – Generalized Estimating Equation

MSK – Musculoskeletal

RCT – Randomized Controlled Trial

T0 – Baseline (Pre-intervention)

T1 – Post-intervention (6-month follow-up)

### **Acknowledgements**

Not Applicable.

### **Authors' contributions**

Jinming Sun conceived and designed the study, coordinated project administration, and was responsible for data collection, statistical analysis, and drafting of the manuscript. Jingtian Xue contributed to the study design and theoretical framework, supervised the intervention implementation, critically revised the manuscript for important intellectual content, and served as the corresponding author. Xiaoya Li contributed to study conceptualization, data interpretation, and substantive manuscript revision. All authors read and approved the final version of the manuscript.

### **Funding**

This work was supported by the National Social Science Foundation in China under Grant [number 21CRK002].

### **Availability of data and materials**

The datasets generated and analyzed during the current study are not publicly available due to the identity information contained in the data but they can be obtained from the first author on reasonable request by deleting this information.

### **Declarations**

Not Applicable.

### **Ethics approval and consent to participate**

This trial has been registered with the Chinese Clinical Trial Register (ChiCTR), under the registration number ChiCTR2500105602, with the registration date of July 7, 2025.

### Consent for publication

Not Applicable.

### Competing interests

The authors declare no competing interests.

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