BMJ Open

Enhancing dyadic outcomes of stroke survivors and caregivers: protocol for a randomised controlled trial

Yen-Nung Lin,[1,2] Shih-Pin Hsu,[1] Jiunn-Horng Kang,[3,4,5] Tsan-Hon Liou,[2,6] Der-Sheng Han,[7,8] Pengsheng Ni,[9] Valeria Chiu,[10] Juleen Rodakowski,[11] Feng-Hang Chang [1,2]

To cite: Lin Y-N, Hsu S-P, Kang J-H, *et al*. Enhancing dyadic outcomes of stroke survivors and caregivers: protocol for a randomised controlled trial. *BMJ Open* 2025;**15**:e090751. doi:10.1136/bmjopen-2024-090751

► Prepublication history for this paper is available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2024-090751).

Received 02 July 2024
Accepted 25 April 2025

For numbered affiliations see end of article.

Correspondence to
Dr Feng-Hang Chang;
fhchang@tmu.edu.tw

ABSTRACT

Introduction Stroke is a leading cause of death and disability worldwide. Stroke survivors and their caregivers often face profound social isolation and various participation restrictions, resulting in frustration and adverse health outcomes. Dyad-focused interventions, which address both survivor and caregiver needs, are essential during the transition process. However, few interventions equally prioritise the outcomes of both survivors and caregivers. This study aims to evaluate the efficacy of a newly developed dyad-focused strategy training intervention in enhancing participation among stroke survivors and their caregivers.

Methods and analysis This study employs a single-blind, parallel-group randomised controlled trial with allocation concealment and assessor blinding. We aim to enrol 138 stroke survivor-caregiver dyads, randomly assigned in a 1:1 ratio to either the experimental intervention group or the control group. Both groups will receive their usual rehabilitation plus 45–60 min sessions of the intervention twice weekly for a total of 12 sessions. Outcome measures, including the Participation Measure-3 Domains, 4 Dimensions, General Self-Efficacy Scale and Activity Measure for Post-Acute Care, will be collected at baseline, post-intervention and at 3-month, 6-month and 12-month follow-ups. Data will be analysed using multiple linear regression and mixed-effects regression models. Qualitative indepth interviews with participants, caregivers and therapists will be conducted post intervention, transcribed and thematically analysed.

Ethics and dissemination Ethics approval was obtained from the Ethics Committee of Taipei Medical University (approval number: N202203083), National Taiwan University Hospital (approval number: 202207096RINA) and Taipei Tzu Chi Hospital (approval number: 11 M-107). Findings will be disseminated through presentations at scientific conferences and publications in peer-reviewed journals.

Trial registration number NCT05571150; Preresults.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study is the first parallel-designed, multicentre, randomised controlled trial design with assessor blinding.
⇒ Both quantitative and qualitative data are collected at multiple time points.
⇒ Survivor-caregiver dyads are included only if the survivor had a first-time stroke within the past 2 years.
⇒ Intervention and control groups receive equal session frequency and duration to ensure comparability.

INTRODUCTION

Stroke is a leading cause of long-term disability.[1] According to the WHO, of the 15 million people who experience a stroke annually, 5 million die and another 5 million are left permanently disabled.[1] In Taiwan, approximately 230 people experience a stroke each day,[2] with a prevalence rate of about 19.3 per 1000 people.[3]

Participation is a primary recovery goal and health indicator for stroke survivors and their caregivers.[4 5] According to the International Classification of Functioning, Disability and Health, participation is defined as 'involvement in life situations' [6](p10), which encompasses engagement in various life domains such as productivity, social life and community involvement.[7] It also includes fulfilling social roles and cannot be separated from the context in which an individual lives.[6] Participation enhances recovery by increasing a person's motivation, competence and self-efficacy.[8] Challenges an individual faces in participation are termed 'participation restrictions', referring to limitations in life situations and roles that are important to the individual.[6] Restrictions in participation can contribute to a decreased quality of life and negative health outcomes.[9]

Both stroke survivors and their caregivers may face numerous restrictions in participation. Following a stroke, survivors and their caregivers must contend with challenges such as loss of employment, marital breakup and difficulties managing family care responsibilities following a stroke.[10] Most survivors give up leisure activities they enjoyed before

their stroke, spending more time on passive and solitary activities.[11 12] Similarly, family caregivers often sacrifice their personal time to care for the survivors, resulting in a substantial reduction in their participation in valued activities.[13] Consequently, both survivors and caregivers may experience a profound sense of social isolation and changes in their relationships,[14] potentially leading to severe physical and mental health conditions.[15–19]

Although participation outcomes are important to both stroke survivors and caregivers, the current healthcare system predominantly focuses on the needs of stroke survivors, often neglecting caregivers, who are commonly viewed merely as resources for the survivors.[20] As a result, caregivers frequently report stress, isolation, emotional distress and various physical and psychological health issues,[21–23] which negatively impact both caregiver and stroke survivor outcomes.[23–25] Therefore, services and programmes designed to address the needs of survivor-caregiver dyads during care transitions are essential.

Dyadic interventions are designed to target both the survivor and their family caregiver as active participants.[26] These interventions typically aim at dyadic outcomes, such as the health, quality of life, physical and psychological conditions, knowledge, service use and satisfaction of both survivors and caregivers.[27] Some studies also examine specific outcomes for survivors, such as physical functions, and for caregivers, such as preparedness, burden, stress and strain.[27] While the dyadic approach has been explored in stroke, dementia, oncology and other chronic conditions,[28–31] the body of literature remains limited.[28]

Three types of dyadic interventions are commonly found in the literature: psychoeducational (providing survivors and caregivers with knowledge and resources), support (focusing on peer interactions for support) and skill-building (training in problem-solving, goal-setting and functional skills such as mobility and activities of daily living).[26] Among these, skill-building interventions that emphasise goal-setting and problem-solving have shown potential in enhancing the quality of life and reducing depression and anxiety in both survivors and caregivers, as well as improving survivors' physical functions.[26 31] However, the evidence is still unclear and mixed.[27] Most of these interventions have been dyad-based (involving both survivors and caregivers in the intervention) rather than dyad-focused (targeting dyadic outcomes), often placing a majority of emphasis on either survivors or caregivers.[26 27 31] Very few interventions are designed to address the needs of both survivors and caregivers equally.[27] Without an equal emphasis on both individuals in a dyad, the needs of either survivors or caregivers can be neglected, potentially resulting in negative effects on dyadic outcomes.[26 31]

Strategy training is a complex intervention aimed at improving the occupational performance of individuals with specific needs.[32] This approach guides clients in identifying and analysing real-life problems and in generating and implementing problem-solving strategies.[33] While strategy training has shown promising effects in reducing disability among stroke survivors,[32 34 35] little is known about its effectiveness for caregivers. Given that strategy training aims to help individuals develop problem-solving strategies to address real-life challenges, it has the potential to meet the needs of both survivors and caregivers, facilitating their return to community life.

To address this research gap, our team developed a dyad-focused strategy training intervention. The feasibility of this intervention was tested in stroke survivor-caregiver dyads in Taiwan,[36] demonstrating that dyad-focused strategy training is feasible and potentially beneficial for both survivors and caregivers. Based on the findings from this feasibility study, we designed the present randomised controlled trial (RCT). The purpose of this trial is to examine the efficacy of the dyad-focused strategy training intervention in enhancing the participation of stroke survivors and their caregivers. The following hypotheses will be tested in this project:

1. Participation in the dyad-focused strategy training intervention will enhance both the survivor's and the caregiver's participation in productivity, social and community activities.
2. Improvement in the survivor's participation will be positively correlated with improvement in the caregiver's participation.
3. Improvement in both the survivor's and the caregiver's participation will be positively correlated with improvements in their quality of life.
4. Improvement in both the survivor's and the caregiver's participation will be positively correlated with improvements in their self-efficacy and the survivor's functional abilities.
5. The intervention effects on the survivor-caregiver dyad's participation will be sustained at 3 months and 6 months following the intervention.

METHODS AND ANALYSIS

Study design

This multicentre, parallel-group RCT employs allocation concealment and assessor blinding. Conducted in the rehabilitation departments of six hospitals in northern Taiwan (Taipei Medical University Hospital; Wan Fang Hospital, Taipei Medical University; Shuang Ho Hospital, Taipei Medical University; National Taiwan University Hospital; National Taiwan University Hospital Bei-Hu Branch; and Taipei Tzu Chi Hospital), data collection commenced on 5 October 2022 and is projected to continue until 31 July 2026.

Participants will be randomly allocated to either the experimental intervention group or the control group in a 1:1 ratio at each site. Assessments of outcomes will take place at baseline, and at 3 months and 6 months following the intervention. The study design is depicted in a flow diagram (figure 1). This protocol is prepared in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013. The

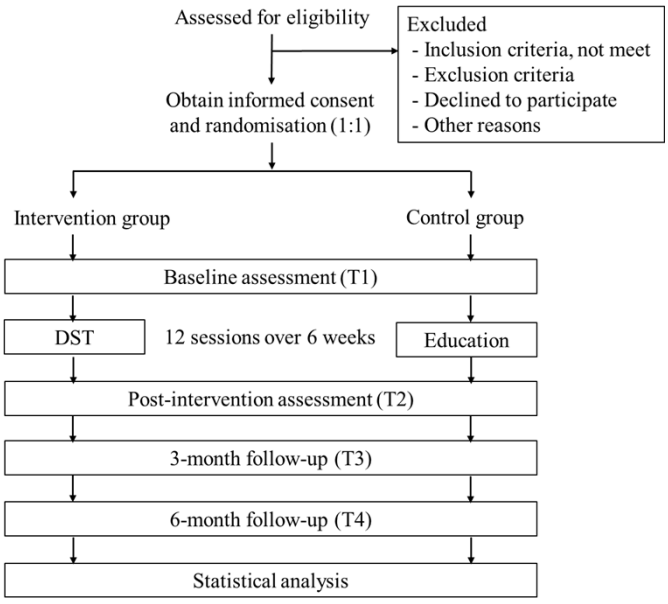

Figure 1 Standard Protocol Items: Recommendations for Intervention Trials 2013 flow diagram of the study design. DST, dyadic strategy training.

SPIRIT checklist, along with the schedule for enrolment, interventions and assessments, is available in the online supplemental additional file 1 and figure 2.

Participants

To participate in this study as a dyad, both the stroke survivor and their caregiver must meet specific inclusion criteria. The inclusion criteria for stroke survivors include: (1) age 20 years or older; (2) diagnosed with a first-time stroke within the past 2 years; (3) speaks Mandarin; (4) has an identified primary caregiver who provides care or assistance, and assumes responsibility for the survivor; and (5) is able to provide informed consent.

The inclusion criteria for family caregivers include: (1) age 20 years or older; (2) speaks Mandarin; (3) recognised as the primary caregiver by the survivor; (4) available to participate in the intervention sessions with the survivor; and (5) is able to provide informed consent.

The survivor-caregiver dyad will be excluded if any of them: (1) requires significant medical treatment (eg, chemotherapy, radiation therapy or haemodialysis/peritoneal dialysis) that may impede participation in the study; (2) has severe aphasia; (3) is unable to participate

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			
TIMEPOINT	$-t_1$	0	t_1	t_2	t_3	t_4
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
Intervention group (dyadic training)			←	→		
Control group (education)			←	→		
ASSESSMENTS:						
Primary outcome:						
Participation: Participation Measure-3 Domains, 4 Dimensions (PM-3D4D)			X	X	X	X
Secondary outcomes:						
Health-related quality of life: World Health Organization Quality of Life (WHOQOL-BREF)			X	X	X	X
Self efficacy: General Self-Efficacy Scale (GSES)			X	X	X	X
Activity function: Activity Measure for Post-Acute Care (AM-PAC)			X	X	X	X
Global cognition: Montreal Cognitive Assessment (MoCA)			X	X	X	X
Processing speed: Trail Making Test Part A (TMT A)			X	X	X	X
Executive functions: TMT Part B (TMT B) and Stroop Test			X	X	X	X
Additional variables:						
Demographic questionnaire			X			
National Institutes of Health Stroke Scale (NIHSS)			X	X	X	X
Modified Rankin Scale (mRS)			X	X	X	X
HEAL Positive Outlook questionnaire			X	X	X	X
Dyadic Relationship Scale			X	X	X	X
Hospital Anxiety and Depression Scale (HADS)			X	X	X	X
Pittsburgh Rehabilitation Participation Scale			←	→		
Strategy Training Fidelity Checklist			←	→		
Qualitative interviews				X		

Figure 2 Study schedule of enrolment, interventions and assessments. $-t_1$, −2 weeks; t_1, baseline; t_2, end of treatment; t_3, 3-month follow-up; t_4, 6-month follow-up.

in a 1-hour discussion session; and (4) has a diagnosis of dementia, major depressive disorder, substance use or other psychiatric disorders that may impede participation in the study.

Recruitment and screening

Based on the inclusion criteria, our trained research staff will regularly visit our collaborating clinical sites to screen for eligible participants through medical chart reviews and personal interviews. Additionally, the research staff will post advertisements for this study (eg, posters and flyers) at the collaborating sites and online, providing contact information. Informed consent will be obtained from all participants who agree to join the study.

Randomisation and allocation concealment

Eligible participants at each recruitment site will be randomly assigned to either the experimental intervention group or the control group using a computerised central randomisation scheme generated by a biostatistician. A minimisation randomisation technique will be employed to balance the number of dyads in the two intervention arms based on potential confounders such as survivors' disability level, sex, age, dyadic relationship and enrolment site. Each dyad will be randomised as a unit. The research staff will inform eligible participants of their group allocation by phone. Subsequently, the baseline assessment and intervention will be administered sequentially within a maximum of 4 weeks after randomisation.

Blinding

The nature of the intervention does not allow for blinding of participants or therapists to group assignment. However, outcome assessors, the statistician and the principal and coprincipal investigators will remain blinded to group assignment. The allocation results (intervention or control group) will be replaced with the Roman numerals 'I' or 'II' in the blind code. The grouping code will be revealed only after the completion of the statistical analyses.

Interventions

Experimental intervention group

The dyad-focused strategy training will be delivered to participants in the experimental intervention group. The intervention protocols were developed based on the strategy training guidelines outlined by Skidmore *et al*,[34] *Bodenmann's framework of dyadic coping*[37] and the *self-efficacy theory*,[38] with input from stroke survivors and their caregivers, ensuring the intervention addressed their real-world needs and priorities. Participants will engage in this intervention in addition to their routine outpatient rehabilitation. Trained research therapists will deliver the intervention to the survivor-caregiver dyads either at the participants' homes or in a quiet room at our collaborating hospitals, on a one-to-two basis.

The programme comprises five critical components: shared decision-making, shared goal-setting, shared self-evaluation of performance, strategy development and implementation, and therapeutic guided discovery. The therapist will ask the dyad to identify 3–5 participation goals using the Goal Attainment Scale and provide them with the global strategy (also called the guided discovery strategy),[39–41] which involves: (1) setting a goal to address the barriers, (2) developing a plan to achieve the goal, (3) executing the plan and (4) evaluating whether the plan worked or requires revision (see figure 3). This procedure will be repeated iteratively until the dyad's goal is met, and they can move on to the next goal. Each intervention session will last approximately 45 min, with participants receiving two sessions per week for a total of 12 sessions over 6 weeks.

Figure 3 The strategy training process.

Control intervention group

Participants in the control group will receive a dose-matched stroke education provided by a trained research therapist as an attention-control intervention. The therapist will deliver inperson education to the dyad using an illustrated manual developed based on the stroke rehabilitation guidelines recommended by the American Heart Association/American Stroke Association.[42] The educational topics will include: (1) secondary stroke prevention; (2) prevention and management of comorbidities; (3) managing emotions and behaviours; (4) medications and personal care; (5) finances and transportation; and (6) home and community-based participation. The frequency and duration of the control intervention sessions will match those of the experimental group sessions.

For both the experimental and control intervention groups, the same research therapists—serving as the intervention provider—will deliver all 12 sessions for each dyad to ensure consistency and continuity of the intervention. Each research therapist must complete training prior to delivering the dyad-focused strategy training and/or education. This training consists of reviewing standardised materials (eg, manuals, slides and demonstration videos) and participating in at least two discussions with experienced therapists who have previously implemented similar research interventions.

Withdrawal or drop-out criteria

Participation in the trial will be terminated under the following circumstances: (1) the participant is unwilling or unable to continue the trial, (2) the participant exhibits illness deterioration or any other physical or mental condition that may impede their continued participation or (3) the participant experiences serious adverse events (AEs).

Participant adherence and retention

Participant adherence to the intervention will be evaluated based on attendance rates, engagement in intervention sessions (measured using the Pittsburgh Rehabilitation Participation Scale,[43] a 6-point scale assessing effort and motivation of participating in the intervention) and adherence to the intervention protocol (measured using the Dyad-focused Strategy Training Fidelity Checklist, modified from the Strategy Training Fidelity Checklist[32] developed by Skidmore *et al*). To ensure fidelity, 20% of the sessions will be randomly selected for assessment by two trained independent raters. These raters will not be present during the sessions but will complete the fidelity checklist based on session records, including written notes, worksheets and audio recordings. The checklist is used to evaluate the therapists' adherence to intervention principles (yes or no) and their competence in delivery (rated as inadequate, adequate or exceptional).

During the intervention, research therapists will develop a rapport with the participants, encourage their continued participation and monitor their adherence to the study protocol. Following the intervention, our research staff will maintain monthly phone contact with the participants to sustain the relationship. Incentives will be provided to participants who complete all assessments and intervention sessions to encourage active participation.

Outcome assessment

Primary outcome

The primary outcome of this study is the change in participation performance, measured using the Participation Measure-3 Domains, 4 Dimensions (PM-3D4D).[44] This 24-item measure assesses three domains of participation: productivity, social and community.[44 45] For each domain, respondents rate items on four dimensions: (1) diversity, (2) frequency, (3) desire for change and (4) perceived difficulty.[44] For the purposes of this study, the frequency and difficulty dimensions will be used to reflect the objective and subjective participation performance of the dyad, respectively. The reliability, validity, and responsiveness of the PM-3D4D have been validated in a stroke population in Taiwan.[44–47]

Secondary outcomes

The quality of life for the dyads will be measured using the Taiwanese version of the The World Health Organization Quality of Life bref (WHOQOL-BREF).[48] This self-administered questionnaire includes two items related to overall quality of life (question 1) and general health (question 2), along with 26 items assessing satisfaction with quality of life across four domains: physical health (seven items), mental health (six items), social relationships (four items) and environmental health (nine items). Each item is scored on a 5-point Likert scale, with higher scores indicating a better quality of life.[48]

The self-efficacy of the dyads will be measured using the General Self-Efficacy Scale (GSES).[49] This 10-item measure evaluates the perceived self-efficacy of both survivors and caregivers on a 4-point scale, ranging from 1 ('not at all true') to 4 ('exactly true'). The total score of the GSES ranges from 10 to 40, with higher scores indicating greater self-efficacy.[49] The reliability of the GSES has been validated in Chinese-speaking populations.[50]

Survivors' functional independence will be evaluated using the Activity Measure for Post-Acute Care (AM-PAC) Generic Outpatient Short Forms.[51] The AM-PAC assesses difficulty in performing activities across three domains: basic mobility (18 items), daily activity (15 items) and applied cognitive (19 items). Each item is rated on a 4-point scale. Summary scores for each subscale are transformed into standardised scores on a t-score scale.[51] The Chinese version of the AM-PAC has demonstrated strong psychometric properties in patients undergoing rehabilitation in Taiwan.[52]

Survivors' general cognitive function will be assessed using the Montreal Cognitive Assessment (MoCA),[53] a 30-item tool that evaluates various cognitive domains. The MoCA has demonstrated promising reliability and

higher sensitivity compared with the Mini-Mental State Examination in detecting cognitive deficits in stroke survivors.[53 54] Executive function will be evaluated using the Stroop Test[55] and the Trail Making Test (TMT A and B).[56] The Stroop Test assesses inhibition, set-shifting and selective attention.[55] Participants will be asked to name the ink colour of a word as accurately and rapidly as possible, where the ink colour may be congruent or incongruent with the written colour name. The time taken to complete the task will be recorded.[57 58] The Stroop Test has shown validity in patients with traumatic brain injury.[59] The TMT A and B will measure sustained attention, sequencing, mental flexibility and visual tracking. In TMT A, participants link a series of 25 numbered circles on a test paper as quickly as possible. In TMT B, participants switch alternately between a set of numbers (1–13) and a set of letters (A–L).[56] The time taken to complete TMT A and B will be recorded, with longer completion times indicating poorer performance. This instrument has been validated in diverse populations.[60–62]

Additional data collection

At baseline, demographic characteristics of the dyad will be collected using a questionnaire developed by the research team. Clinical variables will be retrieved from medical charts. Stroke severity will be characterised using the National Institutes of Health Stroke Scale.[63] The modified Rankin Scale[64] will be used to assess the participant's disability level. The HEAL Positive Outlook questionnaire[65] will measure participants' positive attitudes. The Dyadic Relationship Scale[66] will describe the relationship between the survivor and the caregiver. The Hospital Anxiety and Depression Scale[67] will be used to measure the levels of anxiety and depression in both the survivor and the caregiver.

Qualitative data

Qualitative data will be collected through structured interviews with survivors, caregivers and research therapists to capture their experiences, satisfaction with the intervention and perceived effectiveness. Trained interviewers will conduct these interviews at the end of each participant's intervention programme. All interviews will be audio-recorded and transcribed verbatim. Additionally, field notes and research team meeting notes will be meticulously documented.

Safety evaluation

Any unexpected AEs that occur during the study period will be documented and reviewed by the study team to determine if they are related to the study. Serious AEs will be promptly reported to the research ethics committee.

Sample size

In our feasibility studies on strategy training for stroke survivors or survivor-caregiver dyads, the standard response means (SRMs) for the PM-3D4D's frequency and difficulty scales from baseline to the postintervention ranged from 0.58 to 1.25.[39 68] With a two-group *t*-test, different SRMs between T1 (preintervention) and T2 (postintervention) are expected in the intervention group, with no changes anticipated in the control group. A sample size of 48 dyads per group will provide 80% power to detect an SRM as low as 0.58.

For the second aim, a multiple regression model with 96 dyads (48 per group) will have 80% power to detect correlations of 0.3 or higher between score changes in secondary outcomes, assuming 10% variance explained by other characteristics. To detect a 0.4 difference in the correlation of change scores between survivors and caregivers (medium correlation of 0.6 in the intervention group vs small correlation of 0.2 in the control group), 55 dyads per group are needed. Allowing for a 20% loss to follow-up, 69 dyads per group are required.

Statistical analysis

Quantitative data will be analysed using SAS V.9.3 (SAS Institute, Cary, North Carolina, USA). All analyses will follow an intention-to-treat approach, meaning all participants will be analysed in their assigned groups regardless of compliance. Missing data will be handled using multiple imputation. We will make every effort to obtain follow-up assessments for all enrolled participants. Sensitivity analyses will be performed to examine differences between complete and incomplete data sets.

Descriptive statistics will be used to summarise the frequency, percentage distribution, mean and SD of all variables. Baseline differences between treatment and control groups will be assessed using the χ^2 test, the Mann–Whitney *U*-test or *t*-test, depending on the measurement scale and data distribution.

For our primary aim of evaluating the intervention's efficacy in improving participation for the dyads, changes in PM-3D4D scores from T1 to T2 will be compared between the experimental and control groups using a two-group t-test. Multiple linear regression models, akin to analysis of covariance, will adjust for background characteristics to examine group differences. Constrained longitudinal data analysis (cLDA) will further assess group differences in score changes from T1 to T2.

For our secondary aim, to determine if improvements in survivors' participation correlate with caregivers' participation, we will use correlation analysis followed by multiple regression to control for background characteristics and examine the relationship between changes in PM-3D4D scores.

For assessing whether changes in participation correlate with changes in survivors' functions and both survivors' and caregivers' self-efficacy and quality of life, we will calculate score changes from T1 to T2. Multiple linear regression models will analyse these associations, including interaction terms to assess differences between intervention and control groups.

To evaluate intervention effects over time, cLDA will model PM-3D4D, GSES, AM-PAC, MoCA, Stroop Test and TMT scores at T1 (preintervention), T2 (postintervention), T3 (3-month follow-up) and T4 (6-month

follow-up). Both baseline and follow-up outcomes will be treated as dependent variables. The model will include fixed effects of time, group, differences between study groups at each time point and background characteristics. An unstructured variance-covariance matrix will account for repeated measures. Mean differences and p values will be reported, with significance set at $p<0.05$.

Thematic analysis will be used to analyse qualitative data, combining inductive and deductive coding. Two independent coders will code the transcriptions, and a third researcher will review the coding for quality and consistency.

Patient and public involvement

The intervention protocols were developed with input from stroke survivors and their caregivers to ensure that the intervention addresses their real-world needs and priorities.

Data management and monitoring

The sponsor principal investigator (FHC) holds responsibility for securely storing and safeguarding all study data. Study documents will be securely stored and labelled with unique study identification numbers, which will be linked to subject identifiers through a master code. Access to the master code will be restricted to the principal investigator and a select number of research staff. This master code will be kept in an encrypted file separate from the study data.

Data entry will be conducted by research assistants using unique identification numbers, and the data will be stored in a secure, password-protected drive. Two research assistants will perform data checks and audits to ensure accuracy. All computers and electronic systems will be housed in locked offices, and access will be limited to Institutional Review Board (IRB)-approved study team members.

Given the minimal risks associated with this study and the absence of new drugs, biologics or devices, a data monitoring committee is deemed unnecessary. The Office of Human Research at Taipei Medical University, National Taiwan University Hospital and Taipei Tzu Chi Hospital will oversee data monitoring of each corresponding site and auditing for this study every 12 months. Following study completion, all pseudonymisation data will be archived for 10 years. Publications or presentations derived from this project will refrain from including identifying information about participants.

DISCUSSION

This study represents a pioneering effort in evaluating the efficacy of dyad-focused strategy training for enhancing the participation of stroke survivors and their caregivers. The methodologically rigorous approach of collecting both quantitative and qualitative data at various time points, along with the robust study design and close monitoring of fidelity, strengthens the validity and reliability of the findings.

While the strengths of the study are notable, it is essential to acknowledge potential limitations. As a single-blind RCT, blinding of participants and interventionists is not feasible, but efforts have been made to blind outcome assessors and data analysts to minimise bias. Additionally, longitudinal studies such as this one face challenges in participant recruitment and retention. Strategies to address these challenges, including collaboration with clinical staff and regular communication with participants, have been implemented.

Despite these limitations, this study is poised to determine the immediate and long-term effects of the intervention on participation outcomes for stroke survivors and their caregivers. The empirical evidence generated will contribute to the enhancement of stroke rehabilitation services and inform decision-making regarding payer coverage.

In conclusion, this research holds the potential to significantly impact the quality of care provided to stroke survivors and their caregivers. By elucidating the efficacy and treatment mechanisms of the intervention, this study will pave the way for improved rehabilitation practices and ultimately enhance the well-being of those affected by stroke.

Ethics and dissemination

This study protocol adheres to the principles outlined in the Declaration of Helsinki. Ethics approval for the study protocol and consent forms was granted by the Taipei Medical University-Joint Institutional Review Board (approval number: N202203083; protocol version/date: V1/2022.01.06), National Taiwan University Hospital Research Ethics Committee (approval number: 202207096RINA; protocol version/date: V5/2025.02.01) and Taipei Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation Institutional Review Board (approval number: 11-M-107; protocol version/date: V2/2022.08.23). Primary reason for amendments was personnel change. Prior to enrolment, participants will receive detailed explanations regarding the study background, objectives and potential benefits and risks. Informed consent will be obtained from all participants before their involvement in the study. The study protocol has been registered and is accessible on the Clinical Trial Registry website (trial registration number: NCT05571150). Any significant modifications to the protocol will necessitate approval from the ethics committee, with approved changes promptly updated on the Clinical Trial Registry website.

Study findings will be disseminated to participants and shared with researchers, healthcare providers and individuals with disabilities through presentations at scientific conferences, professional platforms and peer-reviewed journal publications.

Author affiliations
[1]Graduate Institute of Injury Prevention and Control, College of Public Health, Taipei Medical University, Taipei, Taiwan
[2]Department of Physical Medicine and Rehabilitation, Wan Fang Hospital, Taipei Medical University, Taipei, Taiwan
[3]Department of Physical Medicine and Rehabilitation, Taipei Medical University Hospital, Taipei, Taiwan
[4]Research Centre of Artificial Intelligence in Medicine, Taipei Medical University, Taipei, Taiwan
[5]Graduate Institute of Nanomedicine and Medical Engineering, College of Biomedical Engineering, Taipei Medical University, Taipei, Taiwan
[6]Department of Physical Medicine and Rehabilitation, School of Medicine, College of Medicine, Taipei Medical University, Taipei, Taiwan
[7]Department of Physical Medicine and Rehabilitation, College of Medicine, National Taiwan University, Taipei, Taiwan
[8]Department of Physical Medicine and Rehabilitation, National Taiwan University Hospital, Bei-Hu Branch, Taipei, Taiwan
[9]Health Law, Policy & Management, Boston University School of Public Health, Boston, MA, USA
[10]Department of Physical Medicine and Rehabilitation, Taipei Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation, Taipei, Taiwan
[11]Department of Occupational Therapy, University of Pittsburgh, Pittsburgh, Pennsylvania, USA

Acknowledgements We thank our collaborating therapists, including Yi-Hsuan Wu, OTR/L (National Taiwan University Hospital), Jui-Chi Lin, OTR/L (Shuang Ho Hospital), Ya-Ling Tseng (Shuang Ho Hospital), Shih-Shan Chen, OTR/L (Taipei Medical University Hospital), Yen-Ting Liu, OTR/L (Wan Fang Hospital), Chi-Tzu Feng, OTR/L (Taipei Tzu Chi Hospital) and Yi-Chun Lu, OTR/L (Taipei Tzu Chi Hospital).

Contributors FHC led the grant application. FHC, YNL, JHK, THL and JLR contributed to the development of the study protocol and were involved in the study's conception, design and funding acquisition. FHC, YNL and SPH led the drafting of the manuscript. PN was responsible for the statistical design and sample size estimation. VC, YNL, JHK, THL and DSH contributed to the implementation and coordination of the study. JLR made substantial contributions to the study design, manuscript development and critical review of its intellectual content. All authors contributed to revising the manuscript and approved the final version for submission. FHC is the guarantor of the study. Artificial intelligence technology (ChatGPT, developed by OpenAI) was used to assist with English language editing during the manuscript revision process, particularly for refining grammar and improving clarity. All content was critically reviewed, edited and approved by the authors to ensure accuracy and integrity. No AI-generated content was used to generate, analyse or interpret study data.

Funding This work is supported by the grants from the Ministry of Science and Technology of Taiwan (MOST 111-2628-B-038-015-MY3), the National Science and Technology Council of Taiwan (NSTC 113-2326-B-038-002-MY3), Taipei Medical University, Wan Fang Hospital (grant numbers: 112TMU-WFH-12 and 113TMU-WFH-05) and in part by the National Health Research Institutes of Taiwan (NHRI-EX114-11408PI). The funding source is not involved in the design of this study and will remain uninvolved throughout its execution, data analysis, interpretation and the decision to submit the results for publication.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD
Feng-Hang Chang http://orcid.org/0000-0002-0711-3644

REFERENCES

1 World Health Organization. The atlas of heart disease and stroke. 2015. Available: http://www.who.int/cardiovascular_diseases/resources/atlas/en/ [Accessed 23 Sep 2015].
2 Chen C-C, Chen C-S, Liu T-C, *et al*. Stock or stroke? Stock market movement and stroke incidence in Taiwan. *Soc Sci Med* 2012;75:1974–80.
3 Lin H-C, Lin Y-J, Liu T-C, *et al*. Urbanization and stroke prevalence in Taiwan: analysis of a nationwide survey. *J Urban Health* 2007;84:604–14.
4 Wade DT, de Jong BA. Recent advances in rehabilitation. *BMJ* 2000;320:1385–8.
5 Grigorovich A, Forde S, Levinson D, *et al*. Restricted participation in stroke caregivers: who is at risk? *Arch Phys Med Rehabil* 2015;96:1284–90.
6 World Health Organization. *International classification of functioning, disability and health (ICF)*. Geneva: World Health Organization, 2001.
7 Chang F-H, Coster WJ. Conceptualizing the construct of participation in adults with disabilities. *Arch Phys Med Rehabil* 2014;95:1791–8.
8 Baum CM. Fulfilling the promise: supporting participation in daily life. *Arch Phys Med Rehabil* 2011;92:169–75.
9 Lawan MM, Lawal IU, Yusuf AM. Correlates of participation restrictions and quality of life among Hausa women with post-stroke disabilities. *Bull Fac Phys Ther* 2022;27:48.
10 Teasell RW, McRae MP, Finestone HM. Social issues in the rehabilitation of younger stroke patients. *Arch Phys Med Rehabil* 2000;81:205–9.
11 Rochette A, Desrosiers J, Bravo G, *et al*. Changes in participation after a mild stroke: quantitative and qualitative perspectives. *Top Stroke Rehabil* 2007;14:59–68.
12 O'Sullivan C, Chard G. An exploration of participation in leisure activities post-stroke. *Aust Occup Ther J* 2010;57:159–66.
13 Losada A, Pérez-Peñaranda A, Rodriguez-Sanchez E, *et al*. Leisure and distress in caregivers for elderly patients. *Arch Gerontol Geriatr* 2010;50:347–50.
14 Woodman P, Riazi A, Pereira C, *et al*. Social participation post stroke: a meta-ethnographic review of the experiences and views of community-dwelling stroke survivors. *Disabil Rehabil* 2014;36:2031–43.
15 Ahern MM, Hendryx M. Community participation and the emergence of late-life depressive symptoms: differences between women and men. *J Womens Health (Larchmt)* 2008;17:1463–70.
16 Due P, Holstein B, Lund R. Social relations: network, support and relational strain. *Soc Sci Med* 1999;48:661–73.
17 Xia N, Li H. Loneliness, Social Isolation, and Cardiovascular Health. *Antioxid Redox Signal* 2018;28:837–51.
18 Yu B, Steptoe A, Niu K, *et al*. Prospective associations of social isolation and loneliness with poor sleep quality in older adults. *Qual Life Res* 2018;27:683–91.
19 Cameron JI, Stewart DE, Streiner DL, *et al*. What makes family caregivers happy during the first 2 years post stroke? *Stroke* 2014;45:1084–9.
20 Lutz BJ, Young ME, Cox KJ, *et al*. The crisis of stroke: experiences of patients and their family caregivers. *Top Stroke Rehabil* 2011;18:786–97.
21 Moon M. The Unprepared Caregiver. *Gerontologist* 2017;57:26–31.
22 Haley WE, Roth DL, Hovater M, *et al*. Long-term impact of stroke on family caregiver well-being: a population-based case-control study. *Neurology* 2015;84:1323–9.
23 van Exel NJA, Koopmanschap MA, van den Berg B, *et al*. Burden of informal caregiving for stroke patients. Identification of caregivers at risk of adverse health effects. *Cerebrovasc Dis* 2005;19:11–7.
24 Hayes J, Chapman P, Young LJ, *et al*. The prevalence of injury for stroke caregivers and associated risk factors. *Top Stroke Rehabil* 2009;16:300–7.
25 Perrin PB, Heesacker M, Hinojosa MS, *et al*. Identifying at-risk, ethnically diverse stroke caregivers for counseling: a longitudinal study of mental health. *Rehabil Psychol* 2009;54:138–49.

26 Bakas T, Clark PC, Kelly-Hayes M, *et al*. Evidence for Stroke Family Caregiver and Dyad Interventions. *Stroke* 2014;45:2836–52.
27 Pucciarelli G, Lommi M, Magwood GS, *et al*. Effectiveness of dyadic interventions to improve stroke patient–caregiver dyads' outcomes after discharge: A systematic review and meta-analysis study. *Eur J Cardiovasc Nurs* 2021;20:14–33.
28 Tierney MK, Tracy MF, Everson-Rose SA, *et al*. Challenges and Lessons Learned Tailoring a Behavioral Intervention for Stroke Survivor-Care Partner Dyads. *J Neurosci Nurs* 2020;52:239–44.
29 Buck HG, Stromberg A, Chung ML, *et al*. A systematic review of heart failure dyadic self-care interventions focusing on intervention components, contexts, and outcomes. *Int J Nurs Stud* 2018;77:232–42.
30 Laver K, Milte R, Dyer S, *et al*. A Systematic Review and Meta-Analysis Comparing Carer Focused and Dyadic Multicomponent Interventions for Carers of People With Dementia. *J Aging Health* 2017;29:1308–49.
31 Bakas T, McCarthy M, Miller ET. Update on the State of the Evidence for Stroke Family Caregiver and Dyad Interventions. *Stroke* 2017;48:e122–5.
32 Skidmore ER, Dawson DR, Whyte EM, *et al*. Developing complex interventions: lessons learned from a pilot study examining strategy training in acute stroke rehabilitation. *Clin Rehabil* 2014;28:378–87.
33 Skidmore ER, Holm MB, Whyte EM, *et al*. The feasibility of meta-cognitive strategy training in acute inpatient stroke rehabilitation: case report. *Neuropsychol Rehabil* 2011;21:208–23.
34 Skidmore ER, Dawson DR, Butters MA, *et al*. Strategy Training Shows Promise for Addressing Disability in the First 6 Months After Stroke. *Neurorehabil Neural Repair* 2015;29:668–76.
35 Skidmore ER, Butters M, Whyte E, *et al*. Guided Training Relative to Direct Skill Training for Individuals With Cognitive Impairments After Stroke: A Pilot Randomized Trial. *Arch Phys Med Rehabil* 2017;98:673–80.
36 Lin Y-N, Hung T-H, Rodakowski J, *et al*. Development of a Dyad-Focused Intervention for Stroke Survivors and Their Family Caregivers: A Feasibility Study. *Am J Occup Ther* 2024;78:7802180230.
37 Bodenmann G. A systemic-transactional conceptualization of stress and coping in couples. *Swiss J Psychol* 1995;54:34–49.
38 Bandura A. *Social foundations of thought and action: a social cognitive theory*. Englewood Cliffs, NJ: Prentice Hall, 1986.
39 Meichenbaum D. *Cognitive-behavior modification: an integrative approach*. New York: Plenum Press, 1977.
40 Wales CE, Nardi AH, Stager RA. Decision making: new paradigm for education. *Educ Leadersh* 1986;43:203–15.
41 Turner-Stokes L. Goal attainment scaling (GAS) in rehabilitation: a practical guide. *Clin Rehabil* 2009;23:362–70.
42 Gittler M, Davis AM. Guidelines for Adult Stroke Rehabilitation and Recovery. *JAMA* 2018;319:820–1.
43 Lenze EJ, Munin MC, Quear T, *et al*. The Pittsburgh Rehabilitation Participation Scale: reliability and validity of a clinician-rated measure of participation in acute rehabilitation. *Arch Phys Med Rehabil* 2004;85:380–4.
44 Chang F-H, Liou T-H, Ni P, *et al*. Development of the Participation Measure–3 Domains, 4 Dimensions (PM-3D4D): A New Outcome Measure for Rehabilitation. *Arch Phys Med Rehabil* 2017;98:286–94.
45 Chang F-H, Ni P. Responsiveness and Predictive Validity of the Participation Measure-3 Domains, 4 Dimensions in Survivors of Stroke. *Arch Phys Med Rehabil* 2019;100:2283–92.
46 Chang F-H. Measuring Participation of Rehabilitation Patients: Test-Retest Reliability and Mode of Administration Concordance of the Participation Measure-3 Domains, 4 Dimensions (PM-3D4D). *Arch Phys Med Rehabil* 2017;98:1622–7.
47 Chang F-H, Chang K-H, Liou T-H, *et al*. Validation of the Participation Measure-3 Domains, 4 Dimensions (PM-3D4D). *Arch Phys Med Rehabil* 2017;98:2498–506.
48 Yao G, Chung C-W, Yu C-F, *et al*. Development and verification of validity and reliability of the WHOQOL-BREF Taiwan version. *J Formos Med Assoc* 2002;101:342–51.
49 Schwarzer R, Jerusalem M. *Generalized self-efficacy scale. Measures in health psychology: a user's portfolio causal and control beliefs*. Windsor, UK: NFER-NELSON, 1995:35–7.
50 Liu L, Xu N, Wang L. Moderating role of self-efficacy on the associations of social support with depressive and anxiety symptoms in Chinese patients with rheumatoid arthritis. *Neuropsychiatr Dis Treat* 2017;13:2141–50.
51 Jette AM, Haley SM, Ni P, *et al*. Adaptive short forms for outpatient rehabilitation outcome assessment. *Am J Phys Med Rehabil* 2008;87:842–52.
52 Chang F-H, Liou T-H, Brodersen J, *et al*. Adaptation of the Activity Measure Post-Acute Care (AM-PAC) from English to Mandarin using the dual-panel translation approach. *Disabil Rehabil* 2018;40:2571–6.
53 Dong Y, Sharma VK, Chan BP-L, *et al*. The Montreal Cognitive Assessment (MoCA) is superior to the Mini-Mental State Examination (MMSE) for the detection of vascular cognitive impairment after acute stroke. *J Neurol Sci* 2010;299:15–8.
54 Nasreddine ZS, Phillips NA, Bédirian V, *et al*. The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. *J Am Geriatr Soc* 2005;53:695–9.
55 Stroop JR. Studies of interference in serial verbal reactions. *J Exp Psychol: General* 1992;121:15–23.
56 Bowie CR, Harvey PD. Administration and interpretation of the Trail Making Test. *Nat Protoc* 2006;1:2277–81.
57 Koss E, Ober BA, Delis DC, *et al*. The Stroop color-word test: indicator of dementia severity. *Int J Neurosci* 1984;24:53–61.
58 Ridley DR, Johnson DE, Braisted PD. The color-word connotative incongruity effect. *Percept Mot Skills* 1978;46:939–46.
59 Ponsford J, Kinsella G. Attentional deficits following closed-head injury. *J Clin Exp Neuropsychol* 1992;14:822–38.
60 Shum DHK, McFarland KA, Bain JD. Construct validity of eight tests of attention: Comparison of normal and closed head injured samples. *Clinical Neuropsychologist* 1990;4:151–62.
61 Lezak MD, Howieson DB, Bigler ED, *et al*. *Neuropsychological assessment*. 5th edn. Oxford, NY: Oxford University Press, 2012.
62 Zakzanis KK, Mraz R, Graham SJ. An fMRI study of the Trail Making Test. *Neuropsychologia* 2005;43:1878–86.
63 Cincura C, Pontes-Neto OM, Neville IS, *et al*. Validation of the National Institutes of Health Stroke Scale, modified Rankin Scale and Barthel Index in Brazil: the role of cultural adaptation and structured interviewing. *Cerebrovasc Dis* 2009;27:119–22.
64 Patel N, Rao VA, Heilman-Espinoza ER, *et al*. Simple and reliable determination of the modified rankin scale score in neurosurgical and neurological patients: the mRS-9Q. *Neurosurgery* 2012;71:971–5.
65 Greco CM, Yu L, Johnston KL, *et al*. Measuring nonspecific factors in treatment: item banks that assess the healthcare experience and attitudes from the patient's perspective. *Qual Life Res* 2016;25:1625–34.
66 Sebern MD, Whitlatch CJ. Dyadic relationship scale: a measure of the impact of the provision and receipt of family care. *Gerontologist* 2007;47:741–51.
67 Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67:361–70.
68 Lin Y-N, Wu C-Y, Yeh P-C, *et al*. Adapting Strategy Training for Adults With Acquired Brain Injury: A Feasibility Study in a Chinese Population. *Am J Occup Ther* 2020;74:7403205130p1–10.