

## **Study Protocol and Statistical Analysis Plan**

**Unique Protocol ID:** 17609417

**Brief Title:** Expressive Arts-based Intervention on Young and Pre-elderly Stroke Survivors

**Official Title:** The Psycho-physiological & Social-spiritual Effects of Expressive Arts-based Intervention on Young and Pre-elderly Stroke Survivors: A Randomized Controlled Study

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### **Overview of the research study**

Stroke is a devastating illness that induces numerous impairments of body function and structure, and limitations to activities in all aspects of life, thus imposing multi-faceted restrictions on one's participation in daily living [1]. It also has detrimental impacts on one's mental health, social relationship, and quality of life. Stroke survivors often face challenges arising from the illness and its disabilities [2], as well as the resulting deterioration of occupational functioning [3]. They also suffer from the psycho-spiritual sequels of loss in functioning, sense of worthlessness and hopelessness, and fear of relapse, all of which could result in mental health distress such as depression, anxiety, isolation, and impaired quality of life. Though the risk of stroke increases with age [4], statistics have documented an increasing trend of a younger age of onset [5, 6]. The issues faced by young and pre-elderly stroke survivors (<65 years old) will be even more severe due to longer term of survival, problems in resuming their occupations, and a lack of social welfare and resources for their pre-elderly age.

With an increasing survival rate following stroke and a younger age of onset, reducing morbidity and achieving better quality of life after stroke become a pressing aim during survivorship [7]. Along with regaining the ability to perform daily activities satisfactorily, literature highlights the importance of reestablishing connection with others and the ability to affirm life through a relationship with the deity, self, community, and environment that nurtures wholeness [8, 9]. Although ischemic stroke and hemorrhagic stroke differ in terms of risk factors, case fatality, recurrence rates, and treatment options, survivors of both types of stroke share common psychosocial consequences and similar coping trajectories [10-12]. Residual psychosocial-spiritual post-stroke consequence has been found to be decisive in survivors' compliance to rehabilitation and recovery outcomes [8]. To help younger stroke survivors cope with the bio-psychosocial-spiritual concerns, there is a need for holistic rehabilitation program, in particular, non-pharmacological, as adjuvant to conventional occupational rehabilitation regimens to buffer against mental health issues, reduce psychosocial stress, resume social connections, and reinstall hope [7, 13].

### **Understanding the application of expressive arts in stroke rehabilitation**

Evidence supporting the effectiveness of arts-based activities, such as drawing, music, dance, drama, and movement, in stroke rehabilitation has been proliferating over the past five years [14-17]. Our team has several completed and ongoing research projects using expressive arts-based intervention for diverse populations [18, 19]. Positive outcomes have been observed and intervention has been widely welcomed. Although studies on the effectiveness of interventions using single or two arts modalities (i.e. art, dance, movement, and music therapy) have shown promising results [19, 20], evidence for multi-model expressive arts-based intervention, bringing together the strengths of different art modalities is relatively limited locally and internationally. Expressive Arts-based Intervention utilizes all arts modalities such as visual art, music, movement, dance, drama, and writing [21]. It focuses not

on the artistic outcomes but on the process of creating and the capacity of arts to reflect and respond to human sufferings. Such variety of art forms multiplies the avenues by which a person in therapy may seek meaning, clarity, insight, and healing [21, 22]. Creating arts contributes to feelings of autonomy and dignity when other aspects of life seem out of control [23]. Through the creative self-expression, the person may uncover strengths, gain insight, and reclaim aspects of self-identity and worthiness of life [24].

## **Background of the study**

Stroke is a devastating illness that induces numerous impairments of body function and structure, and limitations to activities in all aspects of life, thus imposing multi-faceted restrictions on one's participation in normal daily living. The issues faced by young (<45 years old) [4] and pre-elderly stroke survivors (46-65 years old) [11] will be even more severe due to longer term of survival and possible problems in resuming their functioning for independent living. And this group of people will not be eligible for medical care services, social welfare and resources which are specifically designated to the elderly population (>65 years old). In Hong Kong, stroke is the fourth most common cause of mortality (accounting for 7.5% of all registered deaths) [25]. The illness is considered one of the health conditions with the highest burden of disease worldwide; about 60% of all strokes results in disability, physical dependency and impairments [5]. Despite a decreasing trend in annual stroke mortality rates, stroke remains a significant health concern in Hong Kong. The prevalence rate of stroke increased from 2.8% in 1988 to 4.9% in 2008, and will continue to increase following the global aging trend [4]. Local statistics showed an alarmingly younger age of onset (<65 years old) [4]; during 1999-2007, the incidence of stroke and its related risks have increased in the young age cohort (25-44 years) [5]. Although ischemic and hemorrhagic stroke have different etiology and treatment options, [26]; coping trajectories for survivors of both types of stroke might be similar in some ways [12]. All stroke survivors experience common irreversible psychosocial consequences among the survivors [3, 12]. In Hong Kong, post-stroke depression occurs in 17.2% of stroke survivors, and quality of life is reported to deteriorate steadily over the 12-month period post-stroke in spite of recovery in physical function [4], which results in increased dependency, life dissatisfaction, reduced confidence [7, 27], social isolation, and compromised quality of life 2 years following initial stroke onset [28].

### **Stroke rehabilitation and psychophysiological stress**

Management of psychosocial stress is an important aspect in post-stroke management. Prolonged psychosocial stress is an established risk factor of mortality and stroke-related complications [13]. Depression and psychosocial stress are risk factors for stroke; while stroke is known to be a strong risk factor for depression and stress [29]. Cortisol is a stress biomarker and an objective measure of psychological stress that reflects the hypothalamic-pituitary-adrenal (HPA) axis functioning. A previous study has showed that elevated cortisol is correlated with increased stroke severity; and such distortion in diurnal cortisol profile is linked with longer hospital stay for inpatients, higher dependency, greater risk of depression and delirium for outpatient stroke survivors [30]. Given the important implication of psychological distress and cortisol on stroke severity and rehabilitation outcome, it is important to examine the changes in psychological distress as well as cortisol profiles during the rehabilitation period.

### **The need for a holistic, arts-based approach to stroke rehabilitation**

With the increasing post-stroke survival rates and a younger age of onset, reduction of morbidity and achieving a better quality of life after stroke becomes a more pressing aim during survivorship [7]. Along with regaining the ability to perform daily activities properly, literature highlights the importance of reestablishing connection with others and the ability to affirm life through a rehabilitation with the deity, self, community, and environment that nurtures wholeness, which in turn improves compliance to rehabilitation and recovery outcomes [31].

Aligning with these needs, interdisciplinary rehabilitation programs addressing the psychosocial-spiritual dimensions of needs of stroke survivors have been accumulating in the field [2, 14, 41]. Among them, Arts-based interventions have drawn increasing attention due to its non-pharmacological, strength-based, positive orientation with an enjoyable and safe process in stroke rehabilitation [23]. Therapeutic use of arts has been found to be effective in facilitating emotion expression and improving mood, mobility, social relationship and quality of life of stroke survivors [32]. As opposed to a single modality intervention, an Expressive Arts-based Intervention utilizes all arts modalities such as visual art, music, movement, dance, drama, and writing [21]. Such variety multiplies the avenues by which a person in therapy may seek meaning, clarity, insight and healing [21, 22]. Creating arts contributes to feelings of autonomy and dignity when other aspects of life seem out of control [23]. Through the creative self-expression, the person may uncover strengths, gain insight, and reclaim aspects of self-identity and worthiness of life [24]. It also allows survivors to move away from illness-related preoccupations and derive greater satisfaction and self-esteem as they witness the quality of their artwork and gain positive feedback from others [34]. The non-verbal communication and symbolic expression through arts media during the process will further enhance engagement and help articulate feelings or thoughts that are difficult to be expressed through verbal means. The use of arts can be a joyful, engaging, and safe alternative to traditional therapies for management of stroke and its psychosocial-spiritual comorbidities.

Nevertheless, systematic study related to arts-based intervention has not yet been conducted, in particular for younger stroke survivors, who may face bigger and longer-term impacts in the psychophysiological and social-spiritual outcomes. The present study primarily examines the effectiveness of an Expressive Arts-based Intervention on bio-psychosocial-spiritual outcomes in younger Chinese stroke survivors as compared with the treatment-as-usual control group across different time points. It also aims to explore the associations between the psycho-social-spiritual variables and cortisol profiles as well as the changes of such association across time. Besides, this study also targets at understanding younger stroke survivors' first person body perception and the body-mind mechanism among them. Moreover, participants' nature of ischemic or hemorrhagic stroke will be accounted for using statistical methods to explore common and differential effects of Expressive Arts-based Intervention on both types of stroke.

## Study Aims

### Primary objectives:

To investigate the short and longer-term effects of an Expressive Arts-based Intervention on younger and pre-elderly Chinese stroke survivors on:

- (a) Depressive and anxiety symptoms
- (b) Perceived stress
- (c) Perceived social support
- (d) Self-esteem
- (e) Hope
- (f) Subjective and spiritual well-being
- (g) Stroke-related and general related quality of life
- (h) Salivary cortisol level

### Secondary objectives:

- (a) To examine the associations between cortisol levels, diurnal cortisol profiles and psycho-social-spiritual variables in participants
- (b) To examine the changes of the associations between cortisol levels, diurnal cortisol profiles and psycho-social-spiritual variables across the time points.

### Study hypotheses

1. Expressive Arts-based Intervention is more effective than treatment-as-usual control in
  - (a) reducing depressive and anxiety symptoms
  - (b) reducing stress
  - (c) enhancing perceived social support
  - (d) enhancing self-esteem
  - (e) fostering hope
  - (f) cultivating subjective and spiritual well-being
  - (g) enhancing stroke-related and general quality of life
2. Expressive Arts-based Intervention group will be different from control group in altering salivary cortisol levels and profiles
3. The associations between cortisol profiles and psychosocial-spiritual variables and the changes of such associations across the time points are exploratory in this study.

## Methodology

### Research design

The study will adopt a 2-arm randomized controlled design with treatment-as-usual control. *Appendix A* depicts the conceptual model of the study. Upon screening for inclusion-exclusion criteria, baseline data will be collected; and eligible participants will be randomized into either an 8-week Expressive Arts-based intervention group or Treatment-As-Usual control group. The control group will continue with routine rehabilitation service and have the option to participate in the Expressive Arts-based Intervention Group upon study completion. Participants will be assessed 3 times at baseline ( $T_0$ ), post-intervention (8th week,  $T_1$ ), and 6-month post-intervention ( $T_2$ ). The participants will complete the study in about 8 months.

### Sample size determination, participant eligibility and recruitment

To achieve a statistical power of 80% with a medium effect size (Cohen  $d = 0.63$ ) at a significance level of 0.05 in regression modeling (latent growth modeling) under the proposed 2-arm, 3-time point design, a sample size of 116 is needed according to Monte Carlo simulation. Assuming an attrition rate of 25%, based on prior trials on stroke survivors using arts-based therapies [14], a total of 154 participants are required (i.e. 77 per arm). Eligible participants are Chinese, aged 18 to 64, having an acute stroke episode no more than 120 months before by the time of group participation; both ischemic and hemorrhage stroke survivors will be recruited. Since stroke survivors who are under 65 years old are not qualified to receive any elderly services and welfare, there is a lack of resources and support for these individuals. The targeted age range of 18 to below 65 years old in the present study is specifically set for filling the service gap in local situation as well as for practical reason to ensure recruitment of sufficient participants for the study sample.

Recruitment information will be delivered via posters, pamphlets, newsletters, and website of the Community Rehabilitation Network of the Hong Kong Society for Rehabilitation, Department of Social Work and Social Administration, Centre on Behavioral Health of the University of Hong Kong, and Department of Rehabilitation Sciences, The Hong Kong Polytechnic University. The recruitment process will also take part in Queen Mary Hospital and Tung Wah Hospital. Once the stroke cases discharged from the hospitals, responsible research assistant will contact and invite them to participate in this research study. Screening will be performed after recruitment by a trained research assistant based on the inclusion-exclusion criteria (*Appendix B*).

### Intervention group(s)

The Expressive Arts-based Intervention group will consist of 8 weekly 90-minute sessions, with a total of 12 contact hours. The intervention will be delivered in small group format with 6-8 participants each and led by a registered Expressive Arts Therapist and an expressive arts therapy trainee/student helper. The program follows the structure of a typical arts-based intervention program which has been

applied to Chinese populations with various ages, abilities, and conditions [20]. The content of the program also takes reference from previous expressive arts-based intervention programs which have been used for adults with trauma, mental health issues, and chronic illness [20, 37, 43] to suit the needs of stroke survivors and the purposes of the intervention (*Appendix C*). The program includes gentle movement warm-up with the body parts, simple musical rhythm improvisation to encourage creativity and social interactions, arts-making process with themes of strength, stress coping, care and love, piece of joy, exploration of hope and meaning, and followed by sharing of arts-making experiences to enhance intrapersonal and interpersonal connections. To cater to different conditions of the participants, activities can be done in standing or sitting positions, or in a wheelchair. The structure and schedule of each session will be kept similar while the content can be appropriately adjusted to suit the immediate needs and dynamics of the group. The program has been tested with a group of stroke survivors and demonstrated to be feasible and well-received.

The Treatment-As-Usual Control group will continue with routine healthcare and rehabilitation services. They would be given the option to participate in the Expressive Arts-based Intervention after the 8-month study period.

### **Ethical consideration**

The study is reviewed by the Human Research Ethics Committee (HREC) and the Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB). Written informed consent will be obtained from the participants before screening, assessment and randomization. To ensure confidentiality, participant codes will be assigned to represent the participants. All data collected will be stored in locked storage and destroyed 3 years upon study completion.

### **Outcome measurements**

Assessments pertain to areas of psycho-social-spiritual well-being of stroke survivors, including (a) emotional distress, (b) psychosocial functioning, (c) quality of life, (d) physiological biomarkers, and (e) demographics and clinical details. Self-related questionnaires and salivary cortisol are administered by the participants while blood pressure, heart rate, will be measured by a trained research assistant blinded to the randomization. All measurements are taken at all study time points except for demographics and clinical details. Since the impairment levels of stroke survivors vary and may affect rehabilitation progress and intervention outcomes, a disability assessment will be used as a screening tool to understand the physical condition of the participants and for recruitment of the participants into the trial.



## **Screening**

*Disability.* The Modified Rankin Scale is a clinician-reported rating scale for measuring the degree of disability of the stroke participants. The scale is rated on an ordinal scale of 0 to 6, with a higher score denoting higher level of disability post-stroke [47].

## **Outcome measures**

### Emotional distress

*Depression and anxiety.* The Chinese version of the Hospital Anxiety and Depression Scale [48] captures anxiety and depressive symptoms. The 14-item, 4-point scale measures anxiety (7-item) and depression (7-item) subscales. The measure will be used as an outcome measure on mental health distress.

*Perceived stress.* Perceived stress will be assessed by the Chinese Perceived Stress Scale [49]. Using a 5-point Likert scale (0-4), the scale consists of 10 items about the degree to which life events are appraised as stressful.

### Psychosocial functioning

*Perceived social support.* Perceived social support is captured by the Chinese version of the Multidimensional Scale of Perceived Social Support [50]. The 12-item scale composes of subscales for perceived social support from the family, friends, and significant others, rated on a 7-point Likert scale.

*Self-Esteem.* Self-esteem is documented by the Chinese version of the Rosenberg Self-esteem Scale [51]. The 10-item scale, rated on an 4-point scale, yields a total score of self-esteem.

*Hope.* The Chinese version of the Adult State Hope Scale [52] is used to measure hope. The 6-item scale, rated on an 8-point scale, yields an aggregate score of hope, as well as the agency and pathway subscales.

*Spiritual well-being.* Participants' intention to find peace and to take care of their own spiritual needs will be measured by the 3-item spiritual care subscale of the Body-Mind-Spirit Holistic Well-being Scale, rated on an 11-point anchored scale. The scale measures different dimensions of subjective well-being in the context of afflictions and equanimity [53].

### Quality of life

*Stroke-specific quality of life.* The Chinese version of the Stroke-specific Quality of Life (SS-QoL-CH), Short Form is a 12-item disease-specific health-related quality of life measure widely applied in stroke research. The scale yields 2 QoL subscales in physical and psychosocial components rated on a 5-point scale.

*Health-related quality of life.* The Chinese 12-item Short Form (SF-12) Health Survey [54] is used to measure the health-related quality of life on the dimensions of physical and emotional well-being.

### Psychophysiological biomarkers

*Salivary Cortisol.* Saliva samples will be collected by the participants at five prescribed time points (awakening, 45-minute post-awakening, 12 noon, 5pm, and 9pm) on two consecutive days using the collection device package, Salivette, which includes a cotton swab to place under the tongue. A trained research assistant with prior experience in using the Salivette kit will explain the collection procedures to the participants in details. A record sheet will also be included in the package to document the participants' health behaviors and activities on the day of saliva collection that might affect the diurnal cortisol rhythm, including (a) smoking habit, (b) consumption of alcohol/coffee drinking on that day, and (c) subjective evaluation of sleep quality, total sleep duration, stress levels on a scale of 1 to 10. All of these measures may affect the diurnal cortisol rhythm and will be controlled in the analysis.

### Demographics and clinical details

*Demographics.* Socio-demographic, such as age, gender, education level, employment and financial status, and marital status will be documented based on self-report questionnaires.

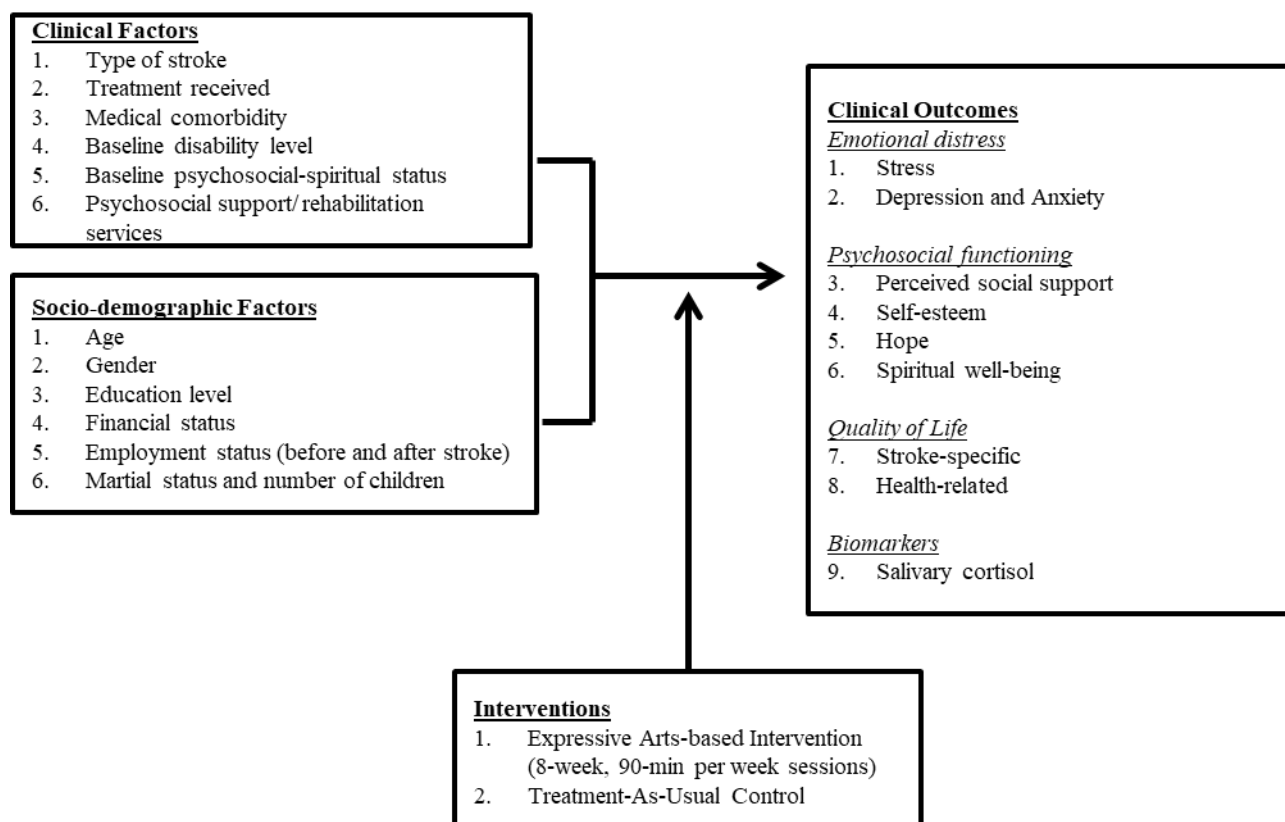
*Clinical data.* Participants' clinical profile including the type of stroke, time lapse from first occurrence, onset and history of psychiatric disturbance, presence of comorbidity if any (such as physical disabilities, hypertension, diabetes mellitus, or any other form of vascular disease), treatment and medication record, and psychosocial support and/ or rehabilitation service utilization will be documented.

### **Data analyses**

Effectiveness of Expressive Arts-based Intervention group: Analysis of variance and chi-square independence tests will be carried out using SPSS to compare the demographic profile of the two groups. Latent growth modeling in Mplus will be used to explore the effectiveness of the intervention over the assessment points in comparison with the control group. All variables including the demographic variables (e.g. age, gender, education etc.) will be accounted for in the analysis.

Analysis of Salivary Cortisol Data: Saliva sample will be centrifuged at 3,000 rpm for 10 minutes at room temperature. Cortisol level will be determined with an enzyme-linked immunoabsorbent assay kit (EIA, Salimetrics, Inc). The assay sensitivity is 0.193 nmol/l and the intra-assay and inter-assay coefficients of variation are 3% and 10% respectively. The mean cortisol level across the day, total cortisol level indexed by the area under the curve, and the diurnal cortisol slope will be calculated. To explore individual trajectories of changes in cortisol level over time and the complex relationships between different variables, a two-level individual growth curve model using Mplus software will be adopted since cortisol measures at 5 daily time points are nested within participants. The method is an appropriate variant of multiple regression modeling for the nested structure of cortisol data.

## APPENDIX A: A Conceptual Model of the Proposed Study



## APPENDIX B: Inclusion-Exclusion Criteria

<b>Inclusion Criteria</b>	
1.	Presence of a single-lesion stroke in the left or right, temporal, frontal, parietal, or subcortical brain regions;
2.	Being in the early-phase of stroke (i.e. not more than 120 months after an initial stroke) at the time of group participation;
3.	Diagnosis of either (a) ischemic or (b) hemorrhage stroke;
4.	Disability grade 1 or 4 on Modified Rankin Scale;
5.	With residual functions of the affected extremity;
6.	The ability to understand instructions, both verbal and written in Chinese, and;
7.	Ages between 18 and <65
<b>Exclusion Criteria</b>	
1.	Concurrent diagnosis of major medical or psychiatric disorders other than stroke (except depression)
2.	Currently receiving hospital treatment and care
3.	Presence of hearing or visual deficits, even with aids
4.	Total paralysis of the upper limbs
5.	Amputation of one of the limbs

### APPENDIX C: Session content of Expressive Arts-based Intervention

<b>Details of the Expressive Arts-based Intervention Program</b>		
<b>Time</b>	<b>Program Schedule</b>	<b>Purposes</b>
15minutes	Greetings and general warm-up	Building relationships, trust, checking-in, warming-up physically and psychologically
20 minutes	Group activities such as movement games, sounding, drumming, use of props etc.	For joy, energy and mood elevation; also help facilitate interactions among group members
10 minutes	Introduction of the theme of the session (i.e. positive mood, stress, strength, love, care, hope etc.)	Understanding of the topics, collecting ideas about the topics, introducing concepts like positive orientation, strength, stress, coping etc.
20 minutes	Arts-making process, can be individual, with partner or in group depending on the dynamics of the group	Creative process with different arts forms, facilitating interactions between group members and the arts, as well as among the group members
15 minutes	Sharing of the arts-making experiences or arts products and discussion, encouraging mutual support and positive interactions	Facilitating self-understanding through articulating the arts and the creative process with coping with real life situation, promoting mutual care and support
10 minutes	Ending with communal activities i.e. group movement or sounding; summary of the session	Fostering connections and cohesion of the group, consolidating the experiences, saying goodbye

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