

**Investigation of the Effect of Acceptance and Commitment Therapy and Exercise in
Older Adults with Chronic Pain: A Randomized Controlled Trial**

IDENTIFIERS: NCT05528536

UNIQUE PROTOCOL ID: EA200132

PROTOCOL DATE: February 7th, 2022

INVESTIGATORS

Terry YS Lum (Principal Investigator)

Department of Social Work and Social Administration, HKU

Gloria HY Wong (Co-Principal Investigator)

Department of Social Work and Social Administration, HKU

Dr. Tianyin Liu

Department of Social Work and Social Administration, HKU

Dr. Dara KY Leung

Department of Social Work and Social Administration, HKU

Ms. Wai Wai Kwok

Department of Social Work and Social Administration, HKU

Ms. Angie Shum

Department of Social Work and Social Administration, HKU

Ms. Annabelle PC Fong

Department of Social Work and Social Administration, HKU

PARTNERING ORGANIZATIONS

The Hong Kong Jockey Club Charities Trust

Aberdeen Kai-fong Welfare Association

Caritas Medical Centre, Hong Kong

Hong Kong Sheng Kung Hui Welfare Council Limited

Hong Kong Young Women's Christian Association

The Neighbourhood Advice-Action Council

BACKGROUND

Chronic pain is one of the common problems in older adults, affecting their physical ability, treatment satisfaction, quality of life and psychosocial functioning. Various types of exercises have shown to have a positive impact on physical well-being, but more improvements on pain outcomes is observed with psychological interventions. Among the different behavioural therapies, Acceptance and Commitment Therapy (ACT) holds the key behaviours in the adaption and prolonged effect in chronic pain. Previous study has shown benefits of combining ACT and Exercise, but the effectiveness is yet unknown. We aim to examine the effectiveness of this method with the intention of enhancing the overall well-being of older adults with chronic pain.

OBJECTIVES

The objective is to establish evidence of Acceptance and Commitment Therapy (ACT) in combination with exercise in:

Primary Outcomes

- 1) Reducing pain intensity and interference;
- 2) Reducing depression;

Secondary Outcomes

- 3) Reducing anxiety;
- 4) Increasing psychological flexibility;
- 5) Increasing pain-related self-efficacy;
- 6) Increasing quality of life;
- 7) Increasing physical functioning

METHODS

Design

This study adopts a cluster randomized trial design comparing older adults with chronic pain receiving ACT and exercise intervention to two arms: 1) art and exercise; and 2) treatment as usual (control group). 15-20 elderly from 10 different mental health service centres will be randomized to the experimental, sham, or active control group.

Participants

The effect size from previous literature and pilot data (0.25), an $\alpha=0.05$, and power=0.8 was used to derive the total sample size of 135 participants. Assuming 10% attrition, total sample size = 150. Older adults with chronic pain (n=150) recruited from collaborating NGOs will be randomized into 3 different arms: 1) ACT and exercise; 2) art and exercise; and 3) treatment as usual.

Inclusion criteria are:

- age 60 years or above; and
- have depressive symptoms of mild level or above (PHQ > 5)
- have chronic pain (>3 months)
- able to give informed consent to participate

Exclusion Criteria:

- known history of autism, intellectual disability, schizophrenia-spectrum disorder, bipolar disorder, Parkinson's disease, or dementia
- (temporary exclusion criteria) imminent suicidal risk difficulty in communication
- have had stroke, fracture, cardiovascular disease, cardiovascular surgery, artery disease, surgery on vertebrae, and knee replacement in the past 6 months
- physical activity prohibited by a medical professional

Assessment Procedures

After basic screening, assessments will be conducted by trained social services staff and trained research assistants employed by the University of Hong Kong for the intervention group.

Assessments will be conducted for all 3 arms at baseline (T0/Intake), completion of intervention (2 months, depending on individual condition) or drop-out (T1/Exit), and follow-up at 3 months (T2/FU) from discharge. Assessment will last for around 60 minutes for all participants.

Intervention

ACT and Exercise:

Participants with chronic pain will participate in an intervention program given twice a week for 8 weeks. ACT designed for chronic pain will be conducted by register Clinical Psychologist, and co-facilitated by registered social workers who are trained by this project and employed by the NGOs. The trained peer supporters will be matched to individual older adults to walk them through the process with regular follow-up. Exercise training program would be designed and instructed by an Exercise Specialist and trained exercise coach.

Art and Exercise:

Similar to the experimental group, participants with chronic pain will participate in the sham program twice a week for 8 weeks. The Art program, conducted by an art therapist and research assistants, and will be co-facilitated by the project officers who are trained by this project and employed by the NGOs. Trained peer supporters will be matched to individual older adults to walk them through the process with regular follow-up if necessary. Exercise training program would be designed and instructed by an Exercise Specialist and trained exercise coach.

Measurements

Basic demographics including age, gender will be collected.

Primary Outcomes

1. Feeling and Function in existence of pain: Brief Pain Inventory (BPI) (Cleeland, 1994) aims to evaluate the individual's pain experience and its effect on physical function on daily activities. The tool consists of 11 items, using an 11-point rating, of which 0 indicates not interference and 10 as interferes completely. The Cronbach's alpha coefficients for interference and severity subscales were .88 and 0.80 respectively (Cleeland, 1991). A validation on the Taiwanese population of BPI (BPI-T) was done by Ger et al in 1999.
2. Depression: The Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer, & Williams, 2001): a 9-item instrument that incorporates depression diagnostic criteria with other leading major depressive symptoms, and rates the frequency of the symptoms which factors into the scoring severity index. PHQ-9 scores of 5-9,

10-14, 15-19, 20 and above represent mild, moderate, moderately severe, and severe depression. The Cronbach's alpha coefficients for Primary Care Study and Ob-Gyn Study were .89 and 0.86 respectively. A validation on the Chinese version of PHQ- 9 was done by Yeung, Y. in 2010.

Secondary Outcomes

3. Anxiety: Generalized anxiety disorder scale (GAD-2) (Plummer et al., 2016; Seo & Park, 2015): a 2-items self-report to determine the person's level of anxiety. Each item is rated on a 4-point scale ranging from 0 (not at all) to 3 (nearly everyday), where higher scores indicate higher anxiety levels. This scale has a Cronbrach's alpha of 0.82 (Seo & Park, 2015). A validated Chinese version was done by Luo et al in 2019.
4. Psychological Flexibility: CompACT-SF (Morris, 2019), also known as CompACT-8 aims to evaluate the individual's psychological flexibility. The tool consists of 8 items, using a 7-point rating of which 0 represents strongly disagree and 6 as strongly agree, of which higher score represents higher psychological flexibility. The scale demonstrated internal reliability of ($\alpha > .73$).
5. Pain Self-Efficacy-2 (PSEQ-2) (Nicholas et al., 2015): a 2-items self-report to evaluate the individual's confidence level in performing each of the activities despite of their pain. Each item is rated on a 7-point scale ranging from 0 (not at all confident) to 6 (completely confident), of which higher scores indicate stronger self-efficacy. This instrument has a Cronbach's alpha coefficient of 0.76. A validation on the Chinese version of PSEQ-2 was done by Yang et al. in 2019.
6. Quality of life: SF-12 Health Survey (Luo, 2003): a 12-items self-report to evaluate the person's quality of life based on the scores of 2 subscales: Physical component score (PCS) and Mental component score (MCS). The scale has a Cronbach alpha coefficient of 0.77 for PCS-12 and 0.80 for MCS. A validation on Hong Kong Chinese was done by Lam et al in 2005.

Physical Assessment

The purpose of a physical assessment of physical functioning of the elderly prior entering an exercise program is to identify the individuals at risk and effectiveness of the program design.

1. The participant will have their heart rate and blood pressured measured to determine if they are at risk of high blood pressure, of which was one of the leading cause of death and disability in 2010 usually due to unhealthy diet habits, higher percentage of body fat, and physical inactivity (Whelton, P.K. et al, 2018). This can further be supported by the measurements from the Bioelectrical Impedance Analysis (BIA) scale (Kabiri et al, 2015) to determine the individuals body composition.
2. As mentioned previously, risk of falling is closely associated with physical disability and chronic pain. Hence the participant will be assessed on mobility, lower body muscle strength, and balance ability to determine the effectiveness of the intervention:
 - a. Timed Up and Go (TUG) (Podsiadlo and Richardson 1991): a chair with handle is placed 3m away from an obstacle. The individual is instructed to rise from the chair without touching the handles, walk to the point then return to the chair in a seated position as quickly as possible. The rating is based on the number of seconds it takes for the individual to return to initial position where: less than 10 sec. is normal, less than 20 sec. is independent and can displace without aid, and lastly, less than 30 sec. demonstrates that that individual has difficulty walking and requires assistance with daily activity.
 - b. 4-Stage Balance Test “modified” (Phelan et al, 2015): requires the individual to stand in 4 different positions progressively for 10 sec. each. The 4 positions include: stand with feet side-by-side, place the instep of one foot next to the other foot’s big toe, tandem stand, and stand with one foot. If the tandem stand cannot be held for 10 sec. indicates that the elderly is at risk of falling.
 - c. 30 seconds sit to stand test (Rikli, R.E. & Jones, C.J., 2001): the

individual is instructed to sit in the middle of the chair (17 inches from the ground) with hand across the chest and both feet flat on the ground. With back straight, the individual is to rise from the chair to a standing position then return to sitting position for 30 seconds. The score is compared with the norm to evaluate on the risk of fall. This test is chosen over other sit to stand tests because of its ability to differentiate the lower strength ability among wider range of older adults with a intraclass correlation coefficient and valid measurement for lower body strength is 0.89 and 0.77 respectively (Rikli, R.E. & Jones, C.J., 1999).

3. Physical functioning is also assessed to determine their capability in performing daily activities involving the upper body:
 - a. Grip strength (Lino et al, 2016) is commonly used as a biomarker for elderly's health status (Bohannon, 2019): The individual is asked to sit with their back straight arms straight on the side. The dynamometer set at the second handle will be squeezed as hard as possible alternating hands after trial. 2 trials will be taken on each hand and the sum of it will be calculated.
4. Aerobic is assessed using the 2-Minute Step Test (Johnston et al, 1999) : The individual is instructed to lift their knee to the height halfway between iliac crest to patella for a total of 2 minutes. The score is the number achieved with the right knee throughout 2 minutes at the given height.

Data Analysis

Data will be analysed using a pre-post analysis based on different time points. For the main outcome measures of depressive symptoms/risks, wellbeing, and personal recovery, mixed ANOVA will be used to assess changes from T0/Intake to T1/exit between the two groups. To test for sustained effect after completion of intervention, mixed ANOVA will be used to assess depressive symptoms/risks, wellbeing, pain acceptance, physical ability, and symptoms of pain from T1/Exit to T2/FU within- and between- subjects. All results will be reported with the appropriate effect sizes, along with statistical significance and confidence intervals.

References

- Bohannon, R. W. (2019). Grip strength: an indispensable biomarker for older adults. *Clinical interventions in aging*, 14, 1681.
- Cleeland, C. S., & Ryan, K. M. (1991). The brief pain inventory. *Pain Research Group*, 143-7. Cleeland, C. S., & Ryan, K. M. (1994). Pain assessment: global use of the Brief Pain Inventory. *Ann Acad Med*;23:129–38.
- Ger, L. P., Ho, S. T., Sun, W. Z., Wang, M. S., & Cleeland, C. S. (1999). Validation of the Brief Pain Inventory in a Taiwanese population. *Journal of pain and symptom management*, 18(5), 316-322.
- Johnston, Jeff, and Adams, Gene. *The Validation of a 2-minute Step Test in Older Adults* (1999): ProQuest Dissertations and Theses. Web.
- Kabiri, L. S., Hernandez, D. C., & Mitchell, K. (2015). Reliability, validity, and diagnostic value of a pediatric bioelectrical impedance analysis scale. *Childhood Obesity*, 11(5), 650-655.
- Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The Phq-9. *Journal of general internal medicine*, 16(9), 606-613.
- Lam, C. L., Tse, E. Y., & Gandek, B. (2005). Is the standard SF-12 health survey valid and equivalent for a Chinese population?. *Quality of life Research*, 14(2), 539-547.
- Lino, V. T. S., Rodrigues, N. C. P., O'Dwyer, G., de Noronha Andrade, M. K., Mattos, I. E., & Portela, M. C. (2016). Handgrip strength and factors associated in poor elderly assisted at a primary care unit in Rio de Janeiro, Brazil. *PloS one*, 11(11).
- Luo, X., George, M. L., Kakouras, I., Edwards, C. L., Pietrobon, R., Richardson, W., & Hey, L. (2003). Reliability, validity, and responsiveness of the short form 12-item survey (SF-12) in patients with back pain. *Spine*, 28(15), 1739-1745.
- Luo, Z., Li, Y., Hou, Y., Zhang, H., Liu, X., Qian, X., ... & Wang, C. (2019). Adaptation of the two-item generalized anxiety disorder scale (GAD-2) to Chinese rural population: A validation study and meta-analysis. *General Hospital Psychiatry*, 60, 50-56.
- Morris, J. (2019). *Development and validation of a short form of the Comprehensive assessment of Acceptance and Commitment Therapy processes (CompACT- SF)* (Doctoral dissertation, University of Nottingham).
- Nicholas, M. K., McGuire, B. E., & Asghari, A. (2015). A 2-item short form of the

- Pain Self-efficacy Questionnaire: development and psychometric evaluation of PSEQ-2. *The Journal of Pain*, 16(2), 153-163.
- Phelan, E. A., Mahoney, J. E., Voit, J. C., & Stevens, J. A. (2015). Assessment and management of fall risk in primary care settings. *Medical Clinics*, 99(2), 281-293.
- Plummer, F., Manea, L., Trepel, D., & McMillan, D. (2016). Screening for anxiety disorders with the GAD-7 and GAD-2: a systematic review and diagnostic metaanalysis. *General hospital psychiatry*, 39, 24-31.
- Podsiadlo, D., & Richardson, S. (1991). The timed "Up & Go": a test of basic functional mobility for frail elderly persons. *Journal of the American geriatrics Society*, 39(2), 142- 148.
- Rikli, R. E., & Jones, C. J. (1999). Development and validation of a functional fitness test for community-residing older adults. *Journal of aging and physical activity*, 7(2), 129-161.
- Rikli, R. E., & Jones, C. J. (2001). *Senior fitness test manual*. Human kinetics.
- Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Himmelfarb, C. D., ... & MacLaughlin, E. J. (2018). ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Journal of the American College of Cardiology*, 71(19), e127- e248.
- Yang, Y., Yang, M., Bai, J., Zhao, J., Chen, K., Zhou, X., ... & Li, M. (2019). Validation of simplified Chinese version of the Pain Self-Efficacy Questionnaire (SC-PSEQ) and SC- PSEQ-2 for patients with nonspecific low back pain in Mainland China. *Spine*, 44(20), E1219-E1226.
- Yeung, Y. H. (2010). Validation of the patient health questionnaire-9 (PHQ-9) Hong Kong Chinese version in the elderly population in Hong Kong. *HKU Theses Online (HKUTO)*.