



## Preparing Family Members of Older Adults with Multi-Morbidity for Advance Care Discussion: Protocol of a Pilot RCT

<sup>[1]</sup>Doris YP Leung, <sup>[2]</sup>Joyce OK Chung, <sup>[3]</sup>Sau Fong Leung

<sup>[1]</sup><sup>[2]</sup><sup>[3]</sup>School of Nursing, The Hong Kong Polytechnic University

<sup>[1]</sup> [doris.yip.leung@polyu.edu.hk](mailto:doris.yip.leung@polyu.edu.hk), <sup>[2]</sup> [okjoyce.chung.polyu.edu.hk](mailto:okjoyce.chung.polyu.edu.hk), <sup>[3]</sup> [sau.fong.leung@polyu.edu.hk](mailto:sau.fong.leung@polyu.edu.hk)

### Article History

Volume 6, Issue 12, 2024

Received: 02 Jun 2024

Accepted: 25 Jun 2024

doi:

[10.48047/AFJBS.6.12.2024.3929-3934](https://doi.org/10.48047/AFJBS.6.12.2024.3929-3934)

*Abstract—Family involvement has been identified as an important facilitator to advance care planning (ACP) implementation. Some older adults clearly indicated to relinquish their right to plan for EOL care and preferred to allow their doctor or their family or the two parties together to make the decision for them in ACP conversations. Given longer life expectancies, many adult children will sooner or later become family caregivers who will be called upon to support older relatives. The study aims to assess the preliminary efficacy of a community-based ACP-related intervention for raising awareness of the importance of engaging in ACP discussions and enhancing knowledge to support their older relatives to engage in ACP conversations. This is a pilot 2-arm parallel group randomized controlled trial with follow-ups at Week 2 and Week 4 after enrolment. Sixty family members of older adults with multi-morbidity in the community will be recruited, and randomized to either the ACP group to receive one 2.5-hour educational session or the wait-list control group. Outcomes of the two groups will be compared using generalized estimating equations. This study will provide information for designing a full-scale trial to shed light in developing guidelines in promoting ACP in the community*

**Index Terms—**Advance care planning, Family members, Multi-morbidity, Older adults.

## I. INTRODUCTION

The global world faces rapid changes in medical technology, demographics and disease patterns, resulting in a huge number of older adults who live with chronic diseases. Multi-morbidity is defined as the co-existence of two or more chronic conditions in an individual [1] and is prevalent in older adults. Globally, it is present in 70% in people aged  $\geq 75$  years and close to 90% of those aged  $\geq 85$  years [2],[3]. Multi-morbidity is associated with disability [4] and greater disability and mortality were observed in individuals having three or more chronic illnesses across different bodily systems [5],[6]. Hong Kong is no exception, with 1.32 million (18.4%) were older adults in 2019 and the number will be double, reaching 2.52 million in 2039 [7]. About 41.8% people aged  $\geq 60$  were living with multi-morbidity [8]. Advance care planning (ACP) is a process of communication aimed at helping individuals to proactively make decisions on their end-of-life (EOL) care when they are mentally competent through effective communication among the individuals, their family or carers, and healthcare providers [9]. Having ACP could result in many benefits including increasing documentation of EOL care decisions and improving patient-surrogate congruence in relevant decision-making; decreased caregiver burden, better

bereavement processes and more positive psychological outcomes for family members; and reduced healthcare cost and improving quality of care [10]–[13]. Given the vulnerability of older people with multi-morbidity, ACP is particularly relevant to this population. However, low engagement in ACP poses national and international challenges, preventing maximization of these potential benefits [14],[15]. Inadequate knowledge of ACP is a commonly reported barrier affecting readiness to ACP conversations and hence could lead to the low participation [16]–[18].

Family involvement on the other hand has been identified as an important facilitator to ACP implementation. In both Western and non-Western populations, older adults want to consider the opinions of family members to support them in making decisions regarding EOL care and treatment options [19],[20]. Our recent study found that some older adults even clearly indicated to relinquish their right to plan for EOL care and preferred to allow their doctor or their family or the two parties together to make the decision for them in ACP conversations [21]. Given longer life expectancies, many adult children will sooner or later become family caregivers who will be called upon to support older relatives. Preparing young adults for discussing EOL care with their older relatives is thus very important, as the discussion will inevitably involve sensitive issues on death/dying, medical knowledge and the use of technical terms when describing the EOL situation and the related treatment options.

Therefore, we have developed and plan to examine the potential efficacy of a community-based educational programme to introduce the ACP-related concepts to family members using a caregiver's perspective for raising awareness of the importance of engaging in ACP discussions and enhancing knowledge to support their older relatives to engage in ACP conversations. We hypothesize that family members receiving the educational programme will have greater improvements in ACP engagement with their older relatives with multi-morbidity and ACP-related knowledge than family members not receiving the educational programme.

## II. METHODS

### A. Study Design

This is a 2-arm parallel waitlist group randomized controlled trial (RCT) with two follow-ups at Week 2 and Week 4 after enrolment. The methodology of the study was developed according to the CONSORT checklist to ensure the quality of the study [22].

### B. Participants

Family members will be eligible if they are (1) aged  $\geq 18$ ; (2) have an older relative who aged 60 or above and lives with at least two chronic diseases such as cancer, dementia, lung, heart, liver, and renal disease; (3) perceive themselves will take part in taking care of their relatives in the near future; (4) able to communicate in Cantonese; and (5) self-reported as cognitively intact. Caregivers will be excluded if their older relatives have been referred to palliative care service before the study.

### C. Treatment Conditions

*Intervention group:* Family members in the intervention group will receive the community-based educational programme, which consists of one 2.5-hour face-to-face session to be delivered within two weeks after enrolment by a trained nurse with more than three-year experience in delivering ACP. The educational session covers five major areas, including (1) serious illness in older adults; (2) Realities of caring and dying from a caregiver's perspective, (3) introduction of the importance of advance care planning for individuals and communities, (4) effective communication between older adults, family members, and healthcare professionals in ACP conversations, and (5) audience participations and clarification including questions, answers and concerns. Special attention has been given to the topics on palliative and EOL care that are important to the Chinese such as food, pain-free, and being a burden to the family as the same time being with the family [23]–[25].

*Waitlist Control group:* Family members in the control group will receive the educational programme to be delivered by the trained nurse after the follow-up at Week 4.

### D. Procedure

Randomization and masking: Caregivers will be randomized into the two arms using a 1:1 allocation. Before subject recruitment, a separate sequence of group identifies based on computer-generated random

codes will be prepared and placed in serially numbered opaque sealed envelopes by an independent person who is blinded to the conditions and will not have contact with potential participants.

Recruitment, baseline assessment, and allocation: Files and posters will be placed in the board in community centres and churches for subject recruitment. In addition, persons who in-charge of community centres and churches will be approached to seek for the opportunity to include the community-based educational programme as one of their activities in the centres/churches. Research assistant of the project (RA1) will approach family members who are interested in the project and screen for their eligibility and explain the study details including aims and procedure to eligible subjects. After obtaining informed written consent, the caregivers will self-complete the baseline questionnaire (T0) independently. RA1 then will randomly assign the family members to either the intervention or the waitlist control group using the pre-prepared envelopes. The participants then will be informed about the venue and scheduled timeslots of the group they are allocated. To avoid contamination between groups, the participants will be asked not to share the content of the intervention beyond the members in their groups.

*Follow-ups:* Another RA (RA2), blinded to the allocation, will conduct the two follow-ups at Week 2 (T1) and Week 4 (T2) with the family members by telephone or WhatsApp.

*Ethical consideration:* The study will comply with the Declaration of Helsinki to ensure confidentiality, anonymity in result dissemination and there will be no interference with the patient's treatment in the study. If family members experience negative emotions caused by the sensitive topics, they will be disjoined the session and counselling will be provided by the research team to acknowledge their reactions. Family members have every right to withdraw from the study at any time without reprisal.

#### E. Measures

##### Primary outcome

1) ACP engagement as a family caregiver: The validated Chinese version of ACP Engagement Survey – Surrogate Decision Maker [26],[27] will be used to measure the extent of engagement in the ACP process in the role of surrogate decision-makers. The Chinese version of the scale has 17 items covering four dimensions: role cognition, contemplation, self-efficacy, and readiness. The questionnaire used a 5-point Likert scale to gather response. The total score can range between 17 and 85, with higher score indicating higher level of ACP engagement.

##### Secondary outcomes

2) Knowledge of ACP: The Knowledge Questionnaire is an instrument to measure ACP-related knowledge with 5 items addressing the purpose of advance directives, EOL discussion, and issues related to ACP. The scale has good content validity (CVI>0.9) and internal consistency (0.84) [28].

3) Demographics: We will collect information regarding participant's demographic characteristics and participants' self-reported of health status of their older relatives. The items for the participants will include: sex, age, marital status, religious, educational level, perceived health status, and the relationship with their older relatives. The items for the older relatives will include: type of current diseases and perceived health status.

#### F. Data Analysis Plan

1) *Sample size determination:* As recommended by Hertzog, a sample size of 30-40 subjects per treatment arm is typically recommended for pilot interventional studies [29]. Therefore, we target to recruit 60 family members in this pilot study.

2) *Preliminary efficacy and effect size estimation:* Intention-to-treat will be applied in all the analyses whenever applicable. Descriptive statistics will summarize the characteristics of the sample. Independent t-tests for continuous variables and chi-square tests for categorical variables examine comparability of groups produced by randomization. Between-group Cohen's d will estimate the effect sizes of the community-based educational programme on the two studied outcomes separately. Generalized estimating equations (GEE) models will assess the preliminary efficacy of the educational programme, and a significant "Time x Group" interaction term in GEE models support there is an effect of the educational programme. All statistical analyses will be performed using SPSS with a significant level at 5%.

### III. DISCUSSION

Due to the established benefits and the relevant legislation of advance directives, ACP interventions have been recently extended from hospitals to the community for reaching out to a wider coverage including both the healthy and the sick at all age groups. The proposed intervention of using a caregiver's perspective is a novel idea to create relevance of ACP to young adults who are healthy. It is because under the current medical model, individual autonomy is fundamental to Western notions of ACP, causing the development of current community-based ACP interventions using the first-person angle (i.e., patient's perspective). It will be too early for young adults, especially those who are healthy, to consider ACP for themselves, even it has been argued that ACP discussions should be started as early as possible. Furthermore, preparing family members in ACP conversations with their older relatives is also important because many older adults wanted to take account of family members' opinions for their decision making. Thus, introducing ACP using a caregiver's perspective is a possible way to create relevance to engage young adults in their older relatives' ACP conversations. There is also a longer-term impact on the younger adults themselves because they are prepared and equipped with ACP knowledge and hence, they should be more ready to have ACP for their own when they are getting older.

We proposed a pilot randomized controlled trial to investigate the preliminary efficacy of a community-based educational programme to promote ACP conversations in the community by arising awareness of the importance of such conversations and ACP-related knowledge among family members of older adults with multi-morbidity. If this pilot RCT demonstrates potential efficacy of the educational programme as an intervention to improve their engagement in ACP discussions as a family member and their ACP-related knowledge, such findings will support for a proposal on a main RCT. The study will, hopefully, provide directions for promoting ACP discussions in the community.

### REFERENCES

- [1] The Academy of Medical Sciences. (2018, April). Multi-morbidity: a priority for global health research [Online]. Available: <https://acmedsci.ac.uk/file-download/82222577>
- [2] Centre for Medicare and Medicaid Service (2012, January). Chronic conditions overview. Available: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions>
- [3] H. Nguyen, G. Manolova, C. Daskalopoulou, S. Vitoratou, M. Prince, and A. M. Prina, "Prevalence of multi-morbidity in community settings: A systematic review and meta-analysis of observational studies," *Journal of Comorbidity*, 2019, Article 9.
- [4] A. Cassell, D. Edwards, A. Harshfield, K. Rhodes, J. Brimicombe, R. Payne, and S. Griffin, "The epidemiology of multimorbidity in primary care: A retrospective cohort study," *British Journal of General Practice*, vol. 68, no. 669, pp. e245–e251, 2018.
- [5] C. Harrison, H. Britt, G. Miller, and J. Henderson, "Examining different measures of multimorbidity, using a large prospective cross-sectional study in Australian general practice," *BMJ Open*, vol. 4, e004694, 2014.
- [6] R. E. Mujica-Mota, M. Roberts, G. Abel, M. Elliott, G. Lyratzopoulos, M. Roland, and J. Campbell, "Common patterns of morbidity and multi-morbidity and their impact on health-related quality of life: evidence from a national survey," *Quality of Life Research*, vol. 24, no. 4, pp. 909–918, 2015.
- [7] Census and Statistics Department, Hong Kong SAR Government, (2020). Hong Kong population projections 2020–2069. Available: <https://www.statistics.gov.hk/pub/B1120015082020XXXXB0100.pdf>
- [8] J. T. K. Cheung, R. Yu, Z. Wu, S. Y. S. Wong, and J. Woo, "Geriatric syndromes, multimorbidity, and disability overlap and increase healthcare use among older Chinese," *BMC Geriatrics*, vol. 18, no. 1, Article 147, 2018.
- [9] *Palliative care for older people: better practices*. World Health Organization Regional Office for Europe. Denmark: WHO regional office for Europe, 2011.

- [10] G. Jimenez, W. S. Tan, A. K. Virk, C. K. Low, J. Car, and A. H. Y. Ho, "Overview of systematic reviews of advance care planning: Summary of evidence and global lessons," *J. Pain Symptom. Manag.*, vol. 56, pp. 436–459, 2018.
- [11] M. A. MacKenzie, E. Smith-Howell, P. A. Bomba, and S. H. Meghani, "Respecting choices and related models of advance care planning: A systematic review of published evidence," *Am. J. Hosp. Palliat. Care*, vol. 35, pp. 897–907, 2018.
- [12] J. Myers, R. Cosby, D. Gzik, I. Harle, D. Harrold, N. Incardona, and T. Walton, "Provider tools for advance care planning and goals of care discussions: A systematic review", *Am. J. Hosp. Palliat. Care*, vol. 35, pp. 1123–1132, 2018.
- [13] J. C. Fahner, A. J. M. Beunders, A. van der Heide, J. A. C. Rietjens, M. M. Vanderschuren, J. J. M. van Delden, and M. C. Kars, "Interventions guiding advance care planning conversations: A systematic review," *J. Am. Med. Dir. Assoc.*, vol. 20, pp. 227–248, 2019.
- [14] D. K. Heyland, D. Barwich, D. Pichora, P. Dodek, F. Lamontagne, J. J. You, C. Tayler, P. Porterfield, T. Sinuff, J. Simon, ACCEPT (Advance Care Planning Evaluation in Elderly Patients) Study Team and the Canadian Researchers at the End of Life Network (CARENET), "Failure to engage hospitalized elderly patients and their families in advance care planning," *JAMA Intern. Med.*, vol. 173, no. 9, pp. 778–787, 2013.
- [15] K. L. Harrison, E. R. Adrion, C. S. Ritchie, R. L. Sudore, and A. K. Smith, "Low completion and disparities in advance care planning activities among older medicare beneficiaries," *JAMA Intern. Med.*, vol. 176, pp. 1872–1875, 2016.
- [16] C. W. H. Chan, M. M. H. Wong, K. C. Choi, H. Y. L. Chan, A. Y. M. Chow, R. S. K. Lo, and M. M. K. Sham, "What patients, families, health professionals and hospital volunteers told us about advance directives," *Asia Pac J Oncol. Nurs.*, vol. 6, pp. 72–77, 2019.
- [17] J. T. K. Cheung, D. Au, A. H. F. Ip, J. Chan, K. Ng, L. Cheung, J. Yuen, E. Hui, J. Lee, R. Lo, and J. Woo, "Barriers to advance care planning: A qualitative study of seriously ill Chinese patients and their families," *BMC Palliat. Care*, vol. 19, article 80, 2020.
- [18] D. Martina, O. P. Geerse, C. P. Lin, M. S. Kristanti, W. M. Bramer, M. Mori, I. J. Korfage, A. van der Heide, J. A. Rietjens, and C. C. van der Rijt, "Asian patients' perspectives on advance care planning: A mixed-method systematic review and conceptual framework," *Palliat. Med.*, vol. 35, pp. 1776–1792, 2021.
- [19] A. Hall, C. Rowland, and G. Grande, "How should end-of-life advance care planning discussions be conducted according to patients and informal carers? a qualitative review of reviews," *J Pain Symptom Manage.*, vol. 58, no. 2, pp. 311–335, 2019.
- [20] S. Y. Cheng, C. P. Lin, H. Y. Chan, D. Martina, M. Mori, S. H. Kim and R. Ng, "Advance care planning in Asian culture," *Jpn. J. Clin. Oncol.*, vol. 50, pp. 976–989, 2020.
- [21] Z. Wan, H. Y. L. Chan, P. K. C. Chiu, R. S. K. Lo, H. L. Cheng, and D. Y. P. Leung DYP, "Experiences of older adults with frailty not completing an advance directive: A qualitative study of ACP conversations," *Int. J. Environ. Res. Public Health*, vol. 19, no. 9, article 5358, 2022.
- [22] K. F. Schulz, D. G. Altman, and D. Moher, "CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trial," *BMC Med.*, vol. 8, article 18, 2010.
- [23] Centers for Disease Control and Prevention (CDC). Advance care planning and chronic disease management / alzheimer's disease and healthy aging [Online]. Available <https://www.cdc.gov/aging/advancecareplanning/index.htm>
- [24] H. L. Cheng, D. Y. P. Leung, P. S. Ko, M. W. Chung, W. M. Lam, P. T. Lam, A. L. Luk, and S. C. Lam, "Reliability, validity and acceptability of the traditional Chinese version of the carer support needs assessment tool in Hong Kong palliative care settings," *BMC Palliat. Care*, vol. 20, no. 1, article 152, 2021.
- [25] M. C. Lee, K. A. Hinderer, and C. S. Alexander, "What matters most at the end-of-life for Chinese Americans?" *Gerontology & Geriatric Medicine*, vol. 4, pp. 1–7, 2018.

- [26] L. J. Van Scoy, A. G. Day, M. Howard, R. Sudore, and D. K. Heyland, "Adaptation and preliminary validation of the Advance Care Planning Engagement Survey for Surrogate Decision Makers," *J Pain Symptom Manage*, vol. 57, no. 5, pp. 980–988.e9, 2019.
- [27] X. B. Liu, H. Chen, and D. L. Liu, "Translation and validation of the Advance Care Planning Engagement Survey for Surrogate Decision Makers [in Chinese]," *Hu Li Xue Za Zhi*, vol. 36, no. 17, pp. 97–100, 2021.
- [28] H. Y. L. Chan, J. S. Ng, K. S. Chan, P. S. Ko, D. Y. P. Leung, C. W. H. Chan, L. N. Chan, I. F. K. Lee, and D. T. F. Lee, "Effects of a nurse-led post-discharge advance care planning programme for community-dwelling patients nearing the end of life and their family members: A randomised controlled trial," *Int. J. Nurs. Stud.*, vol. 87, pp. 26–33, 2018.
- [29] M. Hertzog, "Considerations in determining sample size for pilot studies," *Res Nurs Health*, vol. 31, no. 2, pp. 180–191, 2008.