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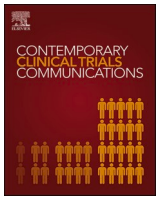

A three-arm randomized controlled trial protocol: Effects of telephone-based, layperson-delivered wisdom-enhancement narrative therapy and empathy-focused interventions on loneliness, social, and mental health in older adults

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ABSTRACT

Background: Loneliness is an increasingly widespread issue among older adults globally, with significant implications on physical, social, and mental health. While various interventions exist to address this challenge, their long-term effects remain unclear. Using a 3-arm randomized controlled trial, this study aims to evaluate the efficacy of a telephone-based and layperson-delivered wisdom-enhancement narrative therapy (Tele-NT) and empathy-focused program (Tele-EP) against an active control group (ACG) in reducing loneliness.

Methods: 282 community-dwelling lonely older adults will be recruited and randomly allocated into 1 of the 3 interventions. Older adults will receive two 30-min intervention per week, over the course of 4 weeks, delivered over the phone by a layperson. Assessments will be conducted in-person at baseline (T0), 1-month (T1), 6-month (T2), and 12-month (T3) post-intervention. The primary outcome will be assessed using the Chinese validated 6-item De Jong Gierveld Loneliness Scale and the Revised UCLA Loneliness Scale. The secondary outcomes will include sleep quality, perceived social support, and depressive symptoms. Potential mediators and moderators will also be explored. The data will be analysed using linear mixed models on an intention-to-treat basis.

Discussion: This RCT is effective, Tele-NT and/or Tele-EP could serve as a model for broader implementation in the community, offering practical solutions to mitigate loneliness and its associated health burdens in the aging populations.

Trial registration: This trial is registered with the Chinese Clinical Trial Registry; ChiCTR2300070179 on April 4, 2024.

1. Background

1.1. Importance of loneliness in older adults

The COVID-19 pandemic has highlighted the critical importance of addressing loneliness, a growing global concern exacerbated by physical distancing measures. In 2019, the World Health Organization declared loneliness as a major public health issue worldwide [1]. Loneliness is distress due to a perceived discrepancy between desired and current social relationship [2]. Loneliness is alarmingly prevalent among Hong Kong's aging population. A longitudinal survey in Hong Kong revealed that 35.8 % and 10.1 % of 1686 older adults felt lonely sometimes and always, respectively in 2018 [3]. It is well-established that loneliness is linked to a wide range of detrimental effects on physical and mental health. Specifically, loneliness is associated with increased blood pressure [4], impaired immune reactions [5], higher risk of cardiovascular disorder [6], breast cancer [7], depression [8], cognitive functioning [9], dementia [10], suicide attempt [11], and greater mortality [12].

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Given the profound impact of loneliness, it is imperative to develop therapeutic and preventive interventions that are innovative, cost-effective, and scalable to tackle the challenge we face due to this behavioral pandemic of loneliness. To fill this research gap, we aim to evaluate the effectiveness of two innovative and scalable psycho-social interventions for reducing loneliness in older adults using a 3-arm randomized controlled trial (RCT).

1.2. Effects of wisdom-enhancement narrative therapy intervention on loneliness

Although numerous intervention studies have been conducted to address loneliness in older adults, there remains a lack of consensus in the literature regarding the most effective intervention [13,14]. Recent research has consistently demonstrated a strong inverse relationship between wisdom and loneliness [8,15]. In contrast, wisdom is considered a complex human trait with multiple components (i.e. prosocial behaviors, emotional regulation, spirituality, self-reflection, social decision making, acceptance of uncertainty and decisiveness) [16]. Notably, empirical evidence suggests that wisdom can be enhanced through psychosocial interventions [17,18]. A recent meta-analysis revealed three components of wisdom; prosocial behaviors (e.g., empathy, compassion, and altruism), emotional regulation, and spirituality can be improved through interventions with a modest, medium-sized and large-sized effect, respectively [17]. Narrative therapy, in particular, offers older adults an opportunity to reflect on life experiences, including losses, strengths, and challenges, which can enhance their wisdom [19]. A recent RCT demonstrated that an 8-hour group-based narrative therapy intervention significantly improved overall wisdom [20]. These findings align with a pilot study showing that a life-review intervention benefited the overall wisdom of ten Vietnam veterans [21]. Thus, in this study, we will adopt and modify the wisdom-enhancement narrative therapy intervention developed by Chow and Fung [20], which will be individual-based and delivered by laypersons over the phone.

1.3. Effects of a layperson-delivered, empathy-focused program of telephone calls

Besides wisdom, another risk or causal factor contributing to loneliness is the level of empathy individuals receive from their social network. Loneliness is positively associated with the lack of empathy from loved ones [22,23] and empathy is what lonely individuals desire [24]. Empathetic listening is often identified as a key mechanism underlying the effectiveness of befriending interventions in qualitative studies [14,25]. This is not surprising, as empathy involves: 1) being affected by and sharing another person's emotional state; 2) understanding the reasons behind their emotional state; and 3) relating to them by adopting their perspective [26]. A recent RCT demonstrated that a layperson-delivered program of empathetic telephone calls significantly reduced loneliness, with an effect size of 0.48 compared to a passive control group [27]. However, the study had three major limitations: 1) the long-term benefits of the program beyond four weeks were unknown; 2) it was unclear whether the empathetic nature of the engagement itself contributed to the outcomes, as opposed to the simple act of being called; and 3) the sample was not randomly selected. To address these limitations, our study aims to use a household survey to randomly select participants, ensuring a sample more representative of the target population, comparing the intervention with a telephone-based befriending program, and examining a longer-term impact through follow-up assessments at six and twelve months.

1.4. Secondary outcomes and mediators underlying the mechanism

According to the biopsychosocial pathways (BPS-P) model of loneliness, loneliness is associated with a wide range of psychological and social factors. Empirical evidence links loneliness to poor sleep quality [28], depressive symptoms [22], and cognitive functioning [9]. Furthermore, the relationship between loneliness and social factors is often conceptualized as reciprocal. Therefore, a reduction in loneliness may lead to more engagement in social networks in terms of the size of the social network [29] and the availability of social support [30]. In light of this evidence, we will examine the impact of these psychological and social factors directly or indirectly through their impact on loneliness and investigate the mechanism underlying the effect of our interventions on loneliness.

1.5. Tailoring intervention

Due to the variability inherent in each older adult's situations, interventions are often designed to allow for tailoring to meet individual needs. However, it is still largely unknown whether such matching between an individual's profile and a specific intervention leads to better outcomes. The interaction effect between specific interventions and their corresponding individual characteristics has not been systematically examined. A recent review identified several significant risk factors for loneliness, including female gender, advanced age, social isolation, poor financial conditions, and lower self-rated health status [31]. To address this gap, one approach would be to examine the moderating effects of these risk factors, along with baseline scores of potential mediators, on the relationship between intervention components and reductions in loneliness.

2. The present study

The present study is a three-arm RCT designed to evaluate the effectiveness of two innovative, scalable psychosocial interventions aimed at reducing loneliness among older adults in Hong Kong. The first intervention is a telephone-based layperson-delivered wisdom-enhancement narrative therapy (Tele-NT), adapted from Chow and Fung's [20] group-based approach, but modified to be delivered individually by laypersons over the phone. This intervention leverages the strong inverse relationship between wisdom and loneliness, targeting components such as emotional regulation, prosocial behaviors, and self-reflection through life-review techniques. The second intervention is a telephone-based layperson-delivered, empathy-focused telephone call program (Tele-EP), which builds on evidence that empathetic engagement significantly reduces loneliness [27]. This intervention addresses the lack of received empathy, a key factor contributing to loneliness, by fostering emotional connection and understanding. Both interventions are compared to an active control group (ACG) that receives regular phone calls. While the term *therapy* is typically associated with interventions delivered by trained mental health professionals, the interventions in this study are delivered by trained volunteers. We retained the term narrative therapy to adhere to the original terminology of the program, ensuring consistency with its fundamental framework [20]. Narrative therapy centers on individuals' personal experiences and facilitates decision-making processes [54], whereas empathy-focused program emphasizes understanding and acknowledging individuals' emotions while fostering emotional connections [55]. Both approaches have gained significant recognition in the field of psychotherapy. The inclusion of these two experimental conditions is justified by their complementary mechanisms: while the wisdom-enhancement intervention focuses on internal psychological growth, the empathy-focused program emphasizes external social connection. We hypothesize that participants in the Tele-NT and Tele-EP groups will report lower levels of loneliness compared to those in the ACG. However, we do not hypothesize differences between Tele-NT and Tele-EP, as the two programs target different mechanisms for reducing loneliness.

3. Method

3.1. Study objectives and hypothesis

The objective of this study is to develop and evaluate the effects of two telephone-delivered psychosocial interventions (Tele-NT and Tele-EP) against an ACG in reducing loneliness among Hong Kong older adults. The study design, randomization procedures, and conditions are detailed in Fig. 1, while the study schedule and measurements, aligned with the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) guidelines, are outlined in Table 1 [32]. We hypothesize the following.

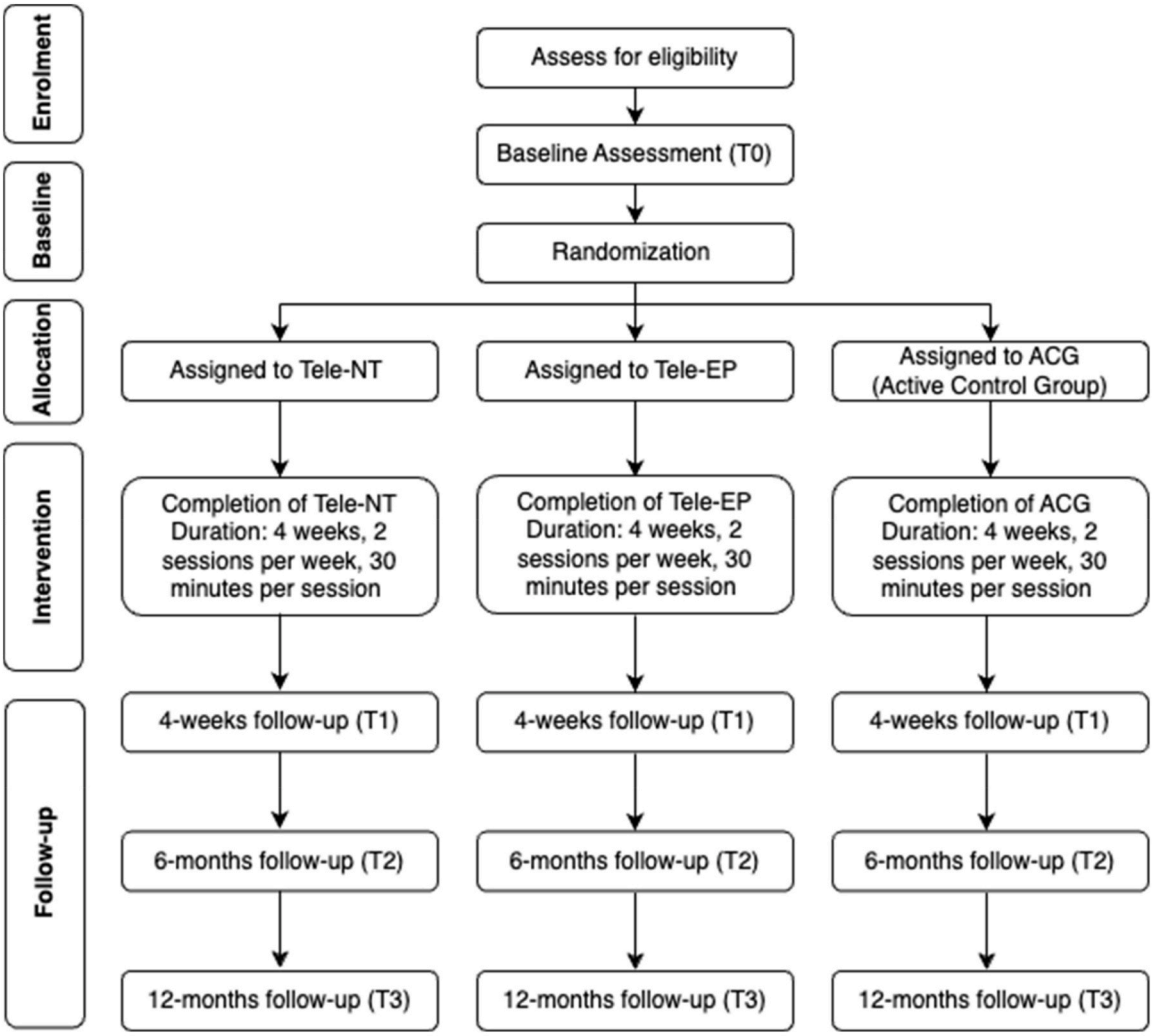
- Tele-NT and Tele-EP will be more effective than ACG in reducing loneliness at 1-month, 6-month, and 12-month follow-up assessments.
- Tele-NT and Tele-EP will be more effective than ACG on secondary outcomes (i.e., sleep quality, depression symptoms, size of social network, perceived social support) measured at 1-month, 6-month, and 12-month follow-up assessments.
- Perceived received wisdom and empathy could mediate the effects of Tele-NT and Tele-EP in reducing loneliness.
- The effects of Tele-NT and Tele-EP on loneliness could be moderated by gender, age, social isolation, poor financial situation, self-rated health, and baseline levels of social isolation.

3.2. Research integrity

This RCT study was approved by the Human Research Ethics Committee of The Education University of Hong Kong (Reference Number: 2021-2022-0100) and prospectively registered in the Chinese Clinical Trial Registry, which is part of the World Health Organization Registry Network (Registration Number: ChiCTR2300070179).

3.3. Eligibility and participant recruitment

In this 3-arm RCT study, community-dwelling Chinese older adults in Hong Kong will be recruited based on the following inclusion criteria: 1) aged 65 or older; 2) able to communicate in Cantonese over the telephone; 3) no cognitive impairments; 4) no history of psychiatric disorders, learning disabilities, or suicidal ideation; 5) not currently participating in any befriending services, narrative therapy, or life review programs; and 6) a score of $\geq$6 on the 3-item UCLA Loneliness Scale. These criteria were established to ensure that participants can



Notes. Tele-NT = Telephone-delivered wisdom enhancement narrative therapy-based intervention; Tele-EP = Telephone-delivered empathy-focused intervention; ACG = Active Control Group

Fig. 1. Flowchart illustrating the 3-arm randomized controlled trial. *Notes.* Tele-NT = Telephone-delivered wisdom enhancement narrative therapy-based intervention; Tele-EP = Telephone-delivered empathy-focused intervention; ACG = Active Control Group.

Table 1
SPIRIT schedule of enrolment, interventions, and assessments.

Timepoint:	Study Period					
	Enrolment	Allocation		Post-Allocation		
	$-t_1$	T_0	*Intervention*	T_1	T_2	T_3
Enrolment:						
•Eligibility screen	✓					
•Informed consent	✓					
Interventions:						
•Tele-NT			✓			
•Tele-EP			✓			
•ACG			✓			
Assessments:						
Sociodemographic & Covariates						
•Age, gender, number of children, living arrangements, education level		✓				
•Marital status		✓		✓	✓	✓
•Employment status, household income, financial status		✓		✓	✓	✓
•Utilization of social and healthcare services		✓		✓	✓	✓
•Self-rated health, vision, and hearing		✓		✓	✓	✓
Primary Outcome: Loneliness						
•De Jong Gierveld 6-item Loneliness Scale [33,34]		✓		✓	✓	✓
•Revised UCLA Loneliness Scale [35,36]		✓		✓	✓	✓
Secondary Outcomes/ Mediators						
•Sleep Condition Indicator [37,38]		✓		✓	✓	✓
•Perceived Social Support [39,40]		✓		✓	✓	✓
•Patient Health Questionnaire-9 [41,42]						
•Lubben Social Network Scale [43, 44]		✓		✓	✓	✓
•Brief Self-Assessed Wisdom Scale [45]		✓		✓	✓	✓
•Meaning in Life Scale [46,47]		✓		✓	✓	✓
•The Consultation and Relational Empathy [48]		✓		✓		

Notes. Tele-NT = Telephone-delivered wisdom enhancement narrative therapy-based intervention; Tele-EP = Telephone-delivered empathy-focused intervention; ACG = Active Control Group.

successfully receive the intervention, while preventing the effects from being confounded by cognitive or psychiatric conditions, learning disabilities, or concurrent participation in similar programs. Recruitment will be carried out through senior community centers, housing complexes, non-governmental organizations, and word-of-mouth referrals.

3.4. Sample size

According to Kahlon and colleagues [27], Tele-EP has an effect size of 0.48 on reducing loneliness using the UCLA Loneliness Scale. Hence, to be conservative, a-priori power analysis assuming a smaller effect size of 0.4, with an alpha error rate of 0.05, and a power of 90%, requires a sample size of 238 participants. With an anticipated drop-out rate of 15% over 12 months, the target sample size is 282 at baseline, with 94 participants in each intervention group.

3.5. Study design, randomization, and procedure

All interested participants will be provided with detailed information about the study, including its purpose, time commitment, inclusion criteria, and their right to withdraw at any time without negative consequences. To ensure informed consent, participants will have to pass a quiz to test their understanding that the study is voluntary. Eligibility will then be established, and consent will be obtained. Assessments will take place at baseline; prior to intervention, and at 1-, 6-, and 12-months post-intervention. Unless alternative arrangements are requested, all assessments will be conducted face-to-face. After completing the baseline assessment, participants will be randomly assigned to one of three groups: Tele-NT, Tele-EP, or the ACG. Randomization will be stratified by gender (female, male), age (65–74, 75–84, 85+), and baseline loneliness scores to ensure balanced representation across groups. An independent research assistant will perform the randomization using an online number generator and inform participants of their assigned group. Each intervention will involve a 4-week program delivered by trained laypersons, consisting of two 30-minutes telephone sessions per week. Follow-up assessments will be conducted by research assistants who will be blinded to participants' intervention assignments to minimize bias. As a token of appreciation, participants will receive HK$300 supermarket vouchers upon completing the intervention and all assessments.

3.6. Interventions

All interventions will be delivered by volunteers who are retirees aged 50 and 70. They will be recruited through various sources like elderly centers and elder academies at The Education University of Hong Kong, Lingnan University, City University of Hong Kong and The Hong Kong Polytechnic University. Retirees who are willing to volunteer for up to 5 hours per week for a minimum of two months will be invited to participate. Each volunteer will deliver the intervention to one or two participants at a time, and will be paid a stipend of HK$300 for each participant.

3.6.1. Wisdom-enhancement narrative therapy (Tele-NT)

The Tele-NT will be adapted based on a group-based, face-to-face narrative therapy intervention designed to enhance wisdom in older adults, evaluated and developed by Chow and colleagues [20]. This study will standardize into a 4-week telephone-based layperson-delivered narrative therapy intervention. Each participant will engage in two 30-minutes sessions per week, over 4 weeks, structured around the metaphor of the *Tree of Life*, which covers four areas: tree of life, forest of life, storms of life, and celebration of life. This metaphor is a sound, integrative, and respectful approach to facilitate participants to express and reflect on different aspects and stages of their lives. This is also suitable for understanding how wisdom could accumulate over the lifespan, and we will facilitate participants to examine their past and present, to reflect on their self-identity, and address the ups and downs, as well as loss and achievements in their lives [19]. In the first session, participants will explore the *Tree of Life*, with each part representing aspects of their lives (e.g. roots, ground, trunk, branches, leaves, flowers, fruits, and seeds) and they will be asked to draw their tree. For example, trunk represents their strengths, skills, talents, and personality while branches represent their hopes, dreams, and wishes. In the second session, participants will reflect on the *Forest of Life,* describing how their trees grew and how the context affect the growth of their trees. The third session focuses on *Storms of Life,* where participants will be asked to describe how their trees grew despite storms and fire or how they responded to challenges in their lives. The final session is on *Celebration of Life*, where participants' achievements will be celebrated, and their

Tree of Life will be shared with their family and friends via a Zoom ceremony. Volunteers delivering the intervention will undergo two 2-hours training sessions, including lectures, group discussion, role-play, and feedback to ensure the program is effectively implemented.

3.6.2. Empathy-focused program (Tele-EP)

The Tele-EP will be adapted from a brief 4-week, layperson-delivered empathy-focused program of telephone calls developed and evaluated by Kahlon and colleagues [27]. The program was designed to maximize participants' perceived benefits, with volunteers conducting phone calls at times chose by the participants. Participants will receive two calls a week, each lasting up to 30 minutes, over a four-week period. During the calls, volunteers will record any concerns about participants' safety, food security, and financial issues. They will also record details of their interactions, such as whether participants answer the call, any follow-up issues on the next call, and any concerns raised by the volunteers. Volunteers will receive peer feedback and support through weekly Zoom-based sessions. Additionally, a research assistant will hold weekly session with volunteers for quality control, providing a list of important conversational topics to participants, guidance on handling situations, and mechanism to escalate any problems. Volunteers training will consist of three 3-hours sessions via Zoom. The training will focus on teaching volunteers how to ask specific questions about topics raised by participants. They will learn strategies to draw participants out in conversation by following the clues (e.g. asking the obvious questions participants are guiding volunteers to ask), asking follow-up questions in open-ended form one by one, and being real and simple by sharing an authentic sentiment. Training materials will include a short role-play video, handouts, and videotaped demonstrations to reinforce techniques.

3.6.3. Active control group (ACG)

The four-week telephone-based volunteer friendly visit program will be administered as the active control condition. Participants will be paired up with a volunteer, who will call participants two times per week [49]. Each call will have a minimum duration of 10 minutes and volunteers will be provided with useful tips on communicating with the participants focusing on healthy ageing without teaching any skills. A "best practice" manual will be developed to support volunteers, and it will include guidelines for developing a relationship, introducing, and orienting a client to befriending and how to manage participants' distress. The volunteers will undergo 2 hours of training, including boundaries of the role, listening skills, problems faced by older adults during the pandemic, managing distress of older adults, health and safety risk assessment and confidentiality.

3.7. Fidelity training, intervention and program implementation

Attendance and feedback from the training sessions and intervention will be systematically recorded. The research team will observe and monitor at least 20% of these sessions, particularly during the initial phase of the study. Feedback will be assessed by the 6-item Credibility/Expectancy Questionnaire to assess their beliefs about the efficacy of the intervention.

3.8. Measures

3.8.1. Primary outcome

Loneliness. Loneliness will be assessed using the Chinese-validated version of the 6-item De Jong Gierveld Loneliness Scale [33,34]. Participants will rate their level of agreement for each statement using a 3-point Likert Scale (1 = Yes; 2 = More or less; 3 = No). Statements include "There are many people I can trust completely", "I miss having people around", and "I often feel rejected". Some statements will be reverse-coded, and the total score will range from 0 to 6, with higher score indicating greater loneliness. Furthermore, the 20-item Revised UCLA Loneliness Scale validated among Chinese adolescents will be utilized [35,36]. Each item in the scale begins with "How often do you feel …", participants will rate how they feel for each statement on a 4-point Likert scale (1 = never to 4 = always). Total scores will range from 20 to 80, with higher scores indicating a greater level of loneliness.

3.8.2. Secondary outcomes

Sleep Quality. Using the Chinese validated eight-item Sleep Condition Indicator [37,38], participants will be asked to indicate different aspects of their sleep (e.g., quality, duration, satisfaction, insomnia episode) on a 5-point Likert Scale ranging from 0 to 4. Scores will be summed ranging from 0 to 32, with high scores indicating better sleep quality.

Perceived Social Support. The Chinese version of the 12-item Multidimensional Scale of Perceived Social Support will be used to evaluate perceived social support [39,40]. Participants will rate their level of agreement on a 7-point scale (1 = strongly disagree to 7 = strongly agree) towards perceived social support by family, friends, and a significant other. Statements include "My family really tries to help me.", "I can count on my friends when things go wrong", and "There is a special person in my life who cares about my feelings." The total score will be calculated, with higher scores reflecting greater perceived social support.

Depressive Symptoms. Depressive symptoms will be measured using the Chinese version of the 9-item Patient Health Questionnaire [41,42]. Participants will be asked to report the frequency of different symptoms (e.g., cognitive, physical, affective) of depression in the past two weeks on a 4-point Likert scale (0 = Not at all to 3 = Nearly every day). The total score will range from 0 to 27, with higher scores indicating greater severity of depression.

3.9. Mediators

Wisdom. Participants' wisdom will be measured using the Chinese validated nine-item Brief Self-Assessed Wisdom Scale [45], designed to measure five dimensions; emotion regulation, reminiscence, openness, experience, and humor. Participants will rate their agreement for each statement on a 6-point scale (1 = Strongly Disagree to 6 = Strongly Agree), with higher scores will reflecting a greater level of wisdom.

Meaning in Life. The 15-item Chinese version of the Meaning in Life Scale [46,47] will evaluate participants' perceived sense of life's worth. Participants will rate each statement on a 5-point Likert scale, ranging from 1 (low negative meaning) to 5 (high positive meaning). Sample statements include: "I feel that my life is (a) useful and worthwhile or (b) useless and worthless.", "Doing things for myself is (a) of no importance to me whatsoever or (b) very important to me.", and "My life has been (a) disappointing or (b) full of good things.". Total scores will range from 15 to 75, with higher scores indicating a greater sense of meaning in life.

Empathy. Empathy will be assessed using the 10-item Consultation and Relational Empathy tool [48], designed to measure empathy within the context of a therapeutic relationship during one-on-one sessions. Participants will rate the intervention provided by the trained layperson on a scale from 1 (poor) to 5 (outstanding). The total score will range from 10 to 50, with higher scores indicating greater satisfaction with the intervention.

3.10. Moderators

Demographics. Participants will be asked to provide demographic information, including their age, gender, marital status, educational attainment, household size, and number of children.

Physical Health. Participants will assess their perceived health using a 5-point scale ranging from 1 (Very Poor) to 5 (Very Good). For analysis, reverse-scoring will be applied, with higher scores indicating better health status. Additionally, participants will be asked whether

they have any chronic diseases and, if applicable, to list them.

Financial Strain. Participants will be asked about their financial situation by indicating whether they have sufficient money to cover daily expenses and their concern about handling unexpected expenses.

Poverty. The 28-item Hong Kong version of the Material Deprivation Index will be utilized to assess the poverty status of the participants [50,51]. This scale examines five domains of essential items: accommodation, food and clothing, medical care, social connections, and basic amenities. Participants will indicate whether they possess or lack each item due to financial constraints. Material deprivation will be identified if participants report lacking at least five essential items because of financial limitations.

Social Network. Social networks will be measured using the 6-item Chinese version of the Lubben Social Network Scale [43,44]. Participants will respond to two sets of three questions, one focusing on family and the other on friends, rating their level of engagement on a six-point Likert scale ranging from 0 (less engaged) to 5 (more engaged). Total scores range from 0 to 30, with higher scores reflecting greater social engagement.

3.11. Statistical analysis plan

Linear mixed modelling for repeated measures conditional growth model analysis with an unstructured covariance matrix will be conducted using a Condition (two intervention groups and one control group; Tele-NT vs ACG and Tele-EP vs ACG) x Time (baseline, 4-week, 6-month and 12-month follow-ups) interaction as an indicator of intervention effects. For sensitivity analysis, a similar mixed model for repeated measures, but using the analysis of variance model, with an unstructured covariance matrix will be conducted. Covariates in these analyses will be the demographic information showing significant differences across conditions at the baseline. Additionally, an intention-to-treat analysis will be performed to account for participants who drop out of the study, using maximum likelihood methods to manage missing data from follow-up losses. The Bonferroni correction will adjust for multiplicity in follow-up assessments among the three intervention groups [52]. All intention-to-treat and per-protocol analyses will be conducted using SPSS 29. To assess mediation and moderation effects, Model 1 and Model 4 from Hayes' Process macro v4.2 will be employed, using 95 % confidence intervals and bootstrapping with 5000 samples, while controlling for potential covariates [53]. This approach will help determine how each intervention is mediated by potential factors such as wisdom and empathy, and how moderating factors influence the effect of the intervention on loneliness.

4. Discussion

This study is a randomized controlled trial, which will evaluate the effect of two psychosocial interventions: wisdom-enhancing narrative therapy (Tele-NT) and empathy-focused program (Tele-EP) against an active control group (ACG) in addressing loneliness among older adults at 1-month, 6-month, and 12-month post intervention. These interventions are strategically designed to tackle loneliness's psychological and social determinants using innovative and accessible methodologies. Tele-NT applies narrative therapy principles to enhance wisdom by guiding participants to reflect on and reinterpret their life experiences [19]. At the same time, Tele-EP emphasizes empathy-focused conversation and strengthening interpersonal relationships [27].

The unique aspect of our RCT lies in an innovative approach using layperson-delivered and telephone-based methods. By leveraging existing community resources, these interventions offer a scalable and cost-effective approach to addressing loneliness among older adults. The telephone-based design ensures accessibility for individuals who may encounter barriers to in-person interactions, such as physical limitations or logistical challenges, while facilitating broader implementation across diverse populations without incurring significant costs. The use of laypersons as intervention providers further enhances the feasibility and sustainability of the approach, allowing the intervention to be integrated into local community networks and ensuring a more inclusive and easily replicable model. This design not only makes the intervention accessible to a broader population (e.g., older adults in the housing estate) but also ensures that it can be applied on a large scale to reach as many individuals as possible.

However, a possible limitation of this RCT could be participant attrition. Given that older adults are often managing health issues or facing significant life changes, some participants may drop out due to factors such as declining health, difficulty in maintaining contact, or changes in personal circumstances. High attrition rates may introduce bias and limit the generalizability of the findings. To mitigate this risk, regular calls between follow-up assessments and flexible scheduling of the mode of follow-up assessment will be implemented to encourage continued participation and maintain engagement throughout the study period. In addition, while our exclusion criteria serve to maintain a focused and specific research sample, we recognize that this approach may limit the generalizability of our findings. Future research could consider including a more diverse group of individuals with varying cognitive and mental health profiles to better understand the effects of loneliness interventions among older adults.

As such, the findings from this RCT are expected to contribute to the growing body of research on loneliness interventions and their impact on the overall well-being for older adults. If proven effective, these interventions could provide practical solutions for alleviating loneliness, reducing depressive symptoms, enhancing social support, and improving sleep quality among older adults. These outcomes would represent a significant step forward in addressing the pressing issue of loneliness among older adults, with the potential to influence future interventions and public health strategies promoting healthy aging and improving quality of life.

CRediT authorship contribution statement

Vivien Foong Yee Tang: Writing – original draft, Formal analysis. **Da Jiang:** Writing – review & editing, Validation, Supervision, Resources, Project administration, Methodology, Formal analysis, Conceptualization. **Maninder Kahlon:** Writing – review & editing, Validation, Supervision, Resources, Project administration, Methodology, Conceptualization. **Esther Oi-wah Chow:** Writing – review & editing, Validation, Supervision, Resources, Project administration, Methodology, Conceptualization. **Dannii Yuen-lan Yeung:** Writing – review & editing, Validation, Supervision, Resources, Project administration, Methodology, Conceptualization. **Rhonda Aubrey:** Writing – review & editing, Validation, Supervision, Resources, Project administration, Methodology, Conceptualization. **Kee-Lee Chou:** Writing – review & editing, Validation, Supervision, Resources, Project administration, Methodology, Funding acquisition, Conceptualization.

Ethics approval and consent to participate

The Human Research Ethics Committee at The Education University of Hong Kong approved the study (Reference Number: 2021-2022-0100). The study was prospectively registered in the Chinese Clinical Trial Registry within the World Health Organization Registry Network (Registration Number: ChiCTR2300070179). Detailed verbal and written information about the study will be provided, and participants will have to provide written informed consent to participate.

Availability of data

The data are available when requests are sent to Kee Lee Chou (The Education University of Hong Kong, Hong Kong, klchou@eduhk.hk) or Da Jiang (The Education University of Hong Kong, Hong Kong, djiang

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Abbreviations

ACG	Active Control Group
BSP-P:	Biopsychosocial-Pathway
RCT	Randomized Controlled Trial
Tele-NT	Telephone-delivered, Wisdom-enhancement Narrative Therapy
Tele-EP	Telephone-delivered, Empathy-focused Program

Data availability

Data will be made available on reasonable request.

References

[1] World Health Organization, Global Health and Aging, 2018.
[2] D. Perlman, L.A. Peplau, Towards a social psychology of loneliness, in: M. Duck, R. Gilmour (Eds.), Personal Relationships in Disorder, Academic Press, London, 1981.
[3] K.L. Chou, Social exclusion in old age: a validation study in Hong Kong, Aging Ment. Health 22 (8) (2018) 1072–1079.
[4] L.C. Hawkley, et al., Loneliness predicts increased blood pressure: 5-year cross-lagged analyses in middle-aged and older adults, Psychol. Aging 25 (1) (2010) 132–141.
[5] S.D. Pressman, et al., Loneliness, social network size, and immune response to influenza vaccination in college freshmen, Health Psychol. 24 (3) (2005) 297.
[6] N.K. Valtorta, et al., Loneliness and social isolation as risk factors for coronary heart disease and stroke: systematic review and meta-analysis of longitudinal observational studies, Heart 102 (13) (2016) 1009–1016.
[7] C.M. Fox, et al., Loneliness, emotional repression, marital quality, and major life events in women who develop breast cancer, J. Community Health 19 (6) (1994) 467–482.
[8] E.E. Lee, et al., High prevalence and adverse health effects of loneliness in community-dwelling adults across the lifespan: role of wisdom as a protective factor, Int. Psychogeriatr. 31 (10) (2019) 1447–1462.
[9] L. Boss, D.-H. Kang, S. Branson, Loneliness and cognitive function in the older adult: a systematic review, Int. Psychogeriatr. 27 (4) (2015) 541–553.
[10] J.S. Kuiper, et al., Social relationships and risk of dementia: a systematic review and meta-analysis of longitudinal cohort studies, Ageing Res. Rev. 22 (2015) 39–57.
[11] Q. Chang, C.H. Chan, P.S.F. Yip, A meta-analytic review on social relationships and suicidal ideation among older adults, Soc. Sci. Med. 191 (2017) 65–76.
[12] L.A. Rico-Uribe, et al., Association of loneliness with all-cause mortality: a meta-analysis, PLoS One 13 (1) (2018) e0190033.
[13] J. Cohen-Mansfield, R. Perach, Interventions for alleviating loneliness among older persons: a critical review, Am. J. Health Promot. 29 (3) (2015) e109–e125.
[14] O.A. Fakoya, N.K. McCorry, M. Donnelly, Loneliness and social isolation interventions for older adults: a scoping review of reviews, BMC Public Health 20 (1) (2020) 129.
[15] T.T. Nguyen, et al., Association of loneliness and wisdom with gut microbial diversity and composition: an exploratory study, Front. Psychiatr. 12 (2021) 648475.
[16] D.V. Jeste, et al., Expert consensus on characteristics of wisdom: a Delphi method study, Gerontol. 50 (5) (2010) 668–680.
[17] E.E. Lee, et al., Outcomes of randomized clinical trials of interventions to enhance social, emotional, and spiritual components of wisdom: a systematic review and meta-analysis, JAMA Psychiatry 77 (9) (2020) 925–935.
[18] E.B.H. Treichler, et al., A pragmatic trial of a group intervention in senior housing communities to increase resilience, Int. Psychogeriatr. 32 (2) (2020) 173–182.
[19] E.O. Chow, H. Nelson-Becker, Spiritual distress to spiritual transformation: stroke survivor narratives from Hong Kong, J. Aging Stud. 24 (4) (2010) 313–324.
[20] E.O.W. Chow, S.F. Fung, Narrative group intervention to rediscover life wisdom among Hong Kong Chinese older adults: a single-blind randomized waitlist-controlled trial, Innovation in Aging 5 (3) (2021) igab027.
[21] L.R. Daniels, J. Boehnlein, P. McCallion, Aging, depression, and wisdom: a pilot study of life-review intervention and PTSD treatment with two groups of Vietnam veterans, J. Gerontol. Soc. Work 58 (4) (2015) 420–436.
[22] K. Lee, K. Vasileiou, J. Barnett, 'Lonely within the mother': an exploratory study of first-time mothers' experiences of loneliness, J. Health Psychol. 24 (10) (2019) 1334–1344.
[23] A.H. Tejada, M. Montero, R. Dunbar, Being unempathic will make your loved ones feel lonelier: loneliness in an evolutionary perspective, Pers. Indiv. Differ. 116 (2017) 223–232.
[24] T. Hu, X. Zheng, M. Huang, Absence and presence of human interaction: the relationship between loneliness and empathy, Front. Psychol. 11 (2020) 768.
[25] C. Preston, S. Moore, Ringing the changes: the role of telephone communication in a helpline and befriending service targeting loneliness in older people, Ageing Soc. 39 (7) (2019) 1528–1551.
[26] F.B. De Waal, Putting the altruism back into altruism: the evolution of empathy, Annu. Rev. Psychol. 59 (2008) 279–300.
[27] M.K. Kahlon, et al., Effect of layperson-delivered, empathy-focused program of telephone calls on loneliness, depression, and anxiety among adults during the COVID-19 pandemic: a randomized clinical trial, JAMA Psychiatry 78 (6) (2021) 616–622.
[28] J.E. McHugh, B.A. Lawlor, Perceived stress mediates the relationship between emotional loneliness and sleep quality over time in older adults, Br. J. Health Psychol. 18 (3) (2013) 546–555.
[29] L.C. Hawkley, M. Kocherginsky, Transitions in loneliness among older adults: a 5-year follow-up in the national social life, health, and aging Project, Res. Aging 40 (4) (2018) 365–387.
[30] J. De Jong Gierveld, T. Van Tilburg, The De Jong Gierveld short scales for emotional and social loneliness: tested on data from 7 countries in the UN generations and gender surveys, Eur. J. Ageing 7 (2) (2010) 121–130.
[31] L. Dahlberg, et al., A systematic review of longitudinal risk factors for loneliness in older adults, Aging Ment. Health 26 (2) (2022) 225–249.
[32] A.-W. Chan, et al., SPIRIT 2013 statement: defining standard protocol items for clinical trials, Ann. Intern. Med. 158 (3) (2013) 200–207.
[33] J. De Jong Gierveld, T. van Tilburg, A 6-item scale for overall, emotional, and social loneliness, Res. Aging 28 (5) (2006) 582–598.
[34] G.T. Leung, J. de Jong Gierveld, L.C. Lam, Validation of the Chinese translation of the 6-item De Jong Gierveld loneliness scale in elderly Chinese, Int. Psychogeriatr. 20 (6) (2008) 1262–1272.
[35] D. Russell, L.A. Peplau, C.E. Cutrona, The revised UCLA Loneliness Scale: concurrent and discriminant validity evidence, Journal of Personality and Social Psychology 39 (3) (1980) 472–480.
[36] K.L. Chou, L.W. Jun, I. Chi, Assessing Chinese older adults' suicidal ideation: Chinese version of the Geriatric Suicide Ideation Scale, Aging Ment. Health 9 (2) (2005) 167–171.
[37] C.A. Espie, et al., The Sleep Condition Indicator: a clinical screening tool to evaluate insomnia disorder, BMJ Open 4 (3) (2014) e004183.
[38] M.L. Wong, et al., Psychometric properties of the sleep condition indicator and insomnia severity Index in the evaluation of insomnia disorder, Sleep Med. 33 (2017) 76–81.
[39] K.L. Chou, Assessing Chinese adolescents' social support: the multidimensional scale of perceived social support, Pers. Indiv. Differ. 28 (2) (2000) 299–307.
[40] G.D. Zimet, et al., The multidimensional scale of perceived social support, J. Pers. Assess. 52 (1) (1988) 30–41.
[41] X. Yu, et al., The Patient Health Questionnaire-9 for measuring depressive symptoms among the general population in Hong Kong, Compr. Psychiatry 53 (1) (2012) 95–102.
[42] R.L. Spitzer, et al., Validation and utility of a self-report version of PRIME-MD: the PHQ primary care study, JAMA 282 (18) (1999) 1737–1744.
[43] S.C.Y. Chan, et al., The psychometric properties of the Lubben Social Network Scale (LSNS-6) and its associations with well-being indicators in Hong Kong older adults, Australas. J. Ageing 42 (4) (2023) 683–689.
[44] J.E. Lubben, Assessing social networks among elderly populations, Fam. Community Health 11 (3) (1988) 42–52.
[45] S.F. Fung, E.O. Chow, C.K. Cheung, Development and validation of a brief self-assessed wisdom scale, BMC Geriatr. 20 (1) (2020) 54.
[46] E.O. Chow, The role of meaning in life: mediating the effects of perceived knowledge of stroke on depression and life satisfaction among stroke survivors, Clin. Rehabil. 31 (12) (2017) 1664–1673.
[47] S.C. Warner, J.I. Williams, The meaning in life scale: determining the reliability and validity of a measure, J. Chron. Dis. 40 (6) (1987) 503–512.
[48] K. Wong, Tips on Healthy Ageing: Psychological, The Open University of Hong Kong, 2009.

[49] N.G. Choi, et al., Improving social connectedness for homebound older adults: randomized controlled trial of tele-delivered behavioral activation versus tele-delivered friendly visits, Am. J. Geriatr. Psychiatr. 28 (7) (2020) 698–708.
[50] P. Townsend, Poverty in the United Kingdom: A Survey of Household Resources and Standards of Living, Penguin Books, London, 1979.
[51] K.L. Chou, S.Y. Lee, Superimpose material deprivation study on poverty old age people in Hong Kong study, Soc. Indic. Res. 139 (3) (2018) 1015–1036.
[52] G. Li, et al., An introduction to multiplicity issues in clinical trials: the what, why, when and how, Int. J. Epidemiol. 46 (2) (2017) 746–755.
[53] A.F. Hayes, Introduction to mediation, moderation, and conditional process analysis : a regression-based approach. Methodology in the Social Sciences, third ed., The Guilford Press, New York, 2022.
[54] C.C. Danner, et al., Running from the demon: culturally specific group therapy for depressed Hmong women in a family medicine residency clinic, Women Ther. 30 (1–2) (2007) 151–176.
[55] A.J. Clark, Empathy in Counseling and Psychotherapy: Perspectives and Practices, Routledge, 2014.