Title: Physical Literacy-based Intervention (PLBI) for Older Adults: A Cluster Randomized Controlled Trial Study Protocol

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Study Protocol and Statistical Analysis Plan

Physical literacy-based intervention (PLBI)

Because people are in different stages of life and diverse settings, there should be a variety of physical literacy programs conducted by sports, educational, or social security systems throughout the physical literacy journey. Researchers have made great efforts in PLBI targeting adolescents within school settings (1). The efficacy and effectiveness of other interventions (e.g., family, community, public health, sport) have yet to be proven (2). As a result, older adults have been neglected in previous PLBI. Currently, there is no common framework or model to measure physical literacy in older adults. Canada has set up a guiding model in order to enhance the physical literacy of older Canadians. This model consists of five components, namely policy, community, organizational, interpersonal, and intrapersonal (3). The draft Australian Sports Commission Physical Literacy Standard has been used as a PLBI guideline with four domains (physical, psychological, social and cognitive), which could be applied throughout the course of an individual's life (4). Since little is known about the development of physical literacy among the older adults of Hong Kong and elsewhere in the world, the present study proposes to use a PLBI for developing physical literacy and to chart the physical literacy level among older adults in Hong Kong. In this connection, the following PLBI program and activities have been designed in the intervention of this proposed study.

Part 1: Weekly-based functional fitness training (WBFFT)

Functional fitness is focused on building a body capable of doing real-life activities in real-life situations, which is in line with the actual needs of the elderly. Physical function declines up to 4% per year after the age of 65, and research has shown the positive effect of a 20-week intervention to increase functional fitness among older adults (5). Another study implemented a 12-week comprehensive golf training program for older adults (6), which also stressed the importance of the functional fitness improvement program. Hagströmer et al. (7) examined the effects of twice-weekly (12 weeks in total) intensive aerobic exercise on physical function and quality of life after a subacute stroke, which showed improved aerobic capacity, walking, balance, health-related quality of life, and patient-reported recovery (8). Yang et al. (9) identified strong evidence supporting a program of combined exercises (e.g., resistance, cardiovascular, and functional training) to effectively improve mobility in older adults. Weekly-based exercise programs have therefore been widely adopted by fitnessrelated interventions to promote health.

In this proposed study, participants will receive a 12-week duration of functional fitness training in daycare centers, which will be implemented twice a week (one during the week, another one at the weekend). The 60-minute per session training series will be delivered and guided by qualified elderly health and fitness instructors recruited from the professional national association in Hong Kong, who will be provided with a workshop (3 - 6 hours, 2 sessions) before this intervention. The workshop will be designed and

delivered by the research team. The first session will focus on the physical literacy of older adults and the second session will focus on how to lead functional fitness training under the FITT principle (Frequency, Intensity, Time, Type; and how they relate to cardio, strength, stretching and injury prevention) for older adults. A further important issue that will be mentioned is related to ensuring the safety of older adults during the whole intervention, which will emphasize the process-oriented outcomes and encouragement to participation, rather than the product oriented assessments. Meanwhile, the main goal of functional training is to improve the range of joint motion, increase muscle strength and flexibility, and boost blood circulation in a safe and acceptable manner. Therefore, symmetry training together with cardiovascular training is the core of the training program. Examples of the main training activities include cardio-fullbody exercises (e.g. move adherence to the music training, including running, jogging, dancing movements, etc.), upper body exercises (e.g. bench press, rowing and lifting), lower body exercises (e.g. squatting and lateral hurdle jumps with tap-sensitive pods) and sensory integrative training (e.g. shooting training with an electronic sensory wall).

Part 2: Mastering physical literacy class (MPLC)

A 30-minute MPLC program will be conducted by experienced elderly health and fitness instructors after WBFFT. This MPLC program aims to enhance the knowledge and understanding of physical literacy. Referring to the newly developed consensus statement (10), the MPLC includes the following five domains related to the relationship with movement and physical activity throughout life:

i. Why physical literacy matters – improves health, well-being and quality of life.
ii. Understanding physical literacy – value, enjoy and engage in physical activity for life.
iii. Everyone's physical literacy is different – their individual needs and experiences of movement and physical activity.
iv. Building physical literacy – think, feel, move and connect with others.
v. How experience affects physical literacy – people, places and spaces around us.

Part 3: Daily-based reflective writing (DBRW)

Daily-based reflective writing or keeping a journal has been widely used in interventions targeted at older adults, especially within the affective domain. Life review through writing, which includes written or verbal prompts to encourage writing about one's life in a systematic, chronological way irrespective of emotional content is a valuable intervention that can be used in occupational therapy practices with the elderly. Previous randomized controlled trials have shown support for the therapeutic benefits of emotional disclosure through writing in not only adults with chronic illness but also in healthy adults (11).

At the end of the baseline stage of this proposed study, each participant of the intervention group will receive a template notebook for daily-based reflective writing. The required columns consist of the daily diet, physical activity, mood and sleep quality. Participants will be required to write down their behavior in this notebook daily. In each week's functional training course, there will be a life-sharing session, where the

participants will be reminded to bring their notebooks and share their daily activities with others. They will receive feedback, advice and encouragement from the instructor and each other. The notebook will be collected during the last week of the intervention.

Part 4: Buddy peers support group (BPSG)

Providing strong social support for older people in Hong Kong may lead to a high level of relatedness that may increase well-being and better physical health (12). The BPSG introduced in this program may greatly increase social support which will be shown to be a key determinant of adherence to the exercise programs and create a commitment to achieve specified levels of physical activity (13).

In this proposed study, peer-support groups with buddy members will be arranged in each daycare center. Three pairs of buddies and hence about 6 participants will be formed per group. A total of 6 buddy pairs and 2 groups will be formed per daycare center. Buddy peers will encourage each other to do functional exercises regularly or to perform functional exercises together. The time and place for the practice will be decided among buddy members. A member in each group will be nominated as the leader to assist in the liaison and coordination of group activities. The group will perform weekly group-based functional exercises, and the time and place for the practice will be decided among group members. The group will be encouraged to hold monthly gatherings with their fitness instructor in order to strengthen social support.

Study design

A two-arm cluster randomized controlled trial will be employed in this proposed study (see details in Fig 1). According to the Social Welfare Department of Hong Kong, there are 98 daycare centers for the elderly in 2023 (14). Daycare centers for the elderly located in 3 regions in Hong Kong will be invited to participate in the intervention. The PLBI will be conducted for twelve weeks.

Sample size and participants

The required sample size is calculated based on the hypothesized effect sizes, and the likely rates of participant drop-out for the outcomes. The estimated sample size is 198 with an effect size of 0.25, α of 0.05 and power of 0.95 (15). With the anticipation of a 20% participant drop-out rate, this led to a required number of 120 participants per group. Therefore, 10 daycare centers for the elderly in Hong Kong will be invited to participate in this study.

Physical literacy-based intervention group (PLBI)

Inclusion criteria will be: 1) those aged 65 to 74 years old who are registered in a daycare center/unit for the elderly in Hong Kong, 2) the ability to walk eight meters without assistance (16), and 3) able to read and write. Exclusion criteria will include 1) neurological disease which impairs mobility, cardiovascular disease which results in shortness of breath or angina on walking up one flight of stairs, and 2) cognitive impairment. Participants' cognitive function will be screened by the Chinese Mini-Mental State Examination (17, 18), and those who score below 24 will be excluded.

The research team will randomly send a series of email messages and invitation letters to daycare centers in accordance with their district via a computer-generated

randomization sequence (GraphPad Software, Inc.) by a statistician who is blinded to the allocation of participating daycare centers. After the daycare centers agree to participate, a leaflet package, which describes the theoretical background, timeframe, and main objectives/learning goals, will be delivered to the staff of daycare centers. Then an introductory meeting with staff will be held to illustrate practical details related to the intervention. The proposed program will be publicized in the participating elderly daycare centers through posters and pamphlets, where the efficacy and benefits of PLBI will be briefly outlined. Recruitment will follow by setting up counters supported by the staff in the participating centers. Those who express interest will have their eligibility screened through a short questionnaire based on the inclusion and exclusion criteria. More detailed information about the study will be given to the eligible participants. Written informed consent will be obtained.

Control group

Participants will follow the inclusion and exclusion criteria of the PLBI group. Participants will not receive PLBI intervention treatment. However, participants in the control group will be given the same treatment (program and activities) after all data has been collected.

Outcome measures

Assessment or charting progress in relation to physical literacy is essential, as this will help clarify policymakers' understanding of the concept as well as individuals' appreciation of their physical literacy journeys, and how they might develop physical literacy through a lifespan (2). Physical literacy is an individualized personal journey so any assessment trying to support this journey should be relative to the individual and their progress and must reflect the changes over time (19). Therefore, this study will adopt both objective and self-reported measures to cover the elements and domains of physical literacy. Participants will be evaluated at baseline (week 0), post-intervention (week 12), and at a 6-week follow-up (week 18). All of them will be conducted at daycare centers for the elderly. The self-reported measurements will be administered by research assistants while the objective measurements will be performed by certified physical fitness assessors and health professionals who are blinded to the randomization for avoiding bias.

Objective measure (primary outcomes)

<u>Physical competence</u>

The Short Physical Performance Battery (SPPB) will be used to measure the physical competence within the physical literacy of older adults (16). Huang et al. (18) suggested using a combined and comprehensive kit of assessment tools to measure physical competence, and the SPPB was reported to be able to measure complex capabilities with excellent test-retest reliability, especially in community-dwelling older adults. It is a group of measures that combines the results of the gait speed, chair stand and balance tests, which consist of balance, a timed eight-foot walk and chair stands. The scores range from zero (worst performance) to 12 (best performance). It has been used as a predictive tool for possible disability and can aid in monitoring function in older people. The reliability of SPPB has been reported as ICC = 0.75 – 0.89 for all measures.

Daily behavior

Accelerometers (Actigraph wGT3X-BT) will be used to measure the physical activity engagement levels of participants, and are categorized as sedentary, light, moderate and vigorous. Data was collected in 60 s epochs to account for elderly people's natural activity levels, as it was shown to present the most acceptable classification accuracy for accelerometer use among older adults (20). The cut-points developed by Aguilar-Farías et al. was applied to identifying intensity levels (20). Participants will wear accelerometers at the waist to measure their physical activity engagement levels for at least 8 hours per day, for seven consecutive days.

Self-report measures (secondary outcomes)

Demographic information

Demographic information including age, gender, BMI (height and weight), education, and socio-economic status will be included in the starting part of the questionnaire set, in order to acquire personal characteristics for further analysis.

Daily behavior

International Physical Activity Questionnaire – short form is the short version of the International Physical Activity Questionnaire used to measure self-reported physical activity levels. They will be required to report on the total duration of different types of physical activity which lasted at least 10 uninterrupted minutes in the last 7 days. Example item included: During the last 7 days, how many days did you do vigorous physical activities?

Knowledge and understanding

Montreal Cognitive Assessment (MoCA) is a 30-question brief and sensitive test used for detecting Alzheimer's disease and measuring executive functions and multiple cognitive domains. It is widely adopted for older adults and will be used to assess knowledge and understanding of physical literacy among the elderly. MoCA-B is a revised MoCA test. The Chinese Version of MoCA-B tests nine cognitive domains (executive function, language, orientation, calculation, conceptual thinking, memory, visual perception, attention, and concentration), and has been reported as a reliable cognitive screening test across all education levels in Chinese elderly adults (21), with high acceptance and good reliability.

Physical literacy

The perceived Physical Literacy Instrument (PPLI) is a 9-item instrument which is used to measure the perceived physical literacy of different individuals (22, 23). Three subscales are "sense of self and self-confidence", "self-expression and communication with others" and "knowledge and understanding" which were identified as key attributes of physical literacy (4). Participants responded to the instrument on a 1 to 5 Likert scale (1 = strongly disagree and 5 = strongly agree). Sum et al. (22) confirmed that the three-factor validity (RMSEA = 0.08; CFI = 0.94 and SRMR = 0.04) and convergent validity (CR = 0.72 - 0.78; AVE = 0.43 - 0.54) of the PPLI was satisfactory.

Motivation and confidence

Perceived Well-being Scale (PWB) contains 14 items with 7 points which will be used to measure participants' motivation and confidence (24). It is a short and convenient measure for use with community-based and institutionalized elderly. Example items include: (a) I am often bored (psychological well-being); (b) I am in good shape physically (physical wellbeing). The validity of PWB is sufficiently high to justify being used with the elderly, in particular in longitudinal and intervention studies.

Buddy Peers Support

A 5-item Friend Support for Exercise Habit Subscale of the validated Social Support for Diet and Exercise Behavior Scale will be used (25). Five questions are "exercise with me", "offered to exercise with me", "gave me reminder to exercise", "gave me encouragement to stick with my exercise program", and "changed their schedule so we could exercise together". Participants responded to the instrument on a 1 (none) to 5 (very often) Likert scale. Sallis et al. (25) confirmed that the sub-scales are with high acceptance and good reliability.

Data analysis

SPSS version 28 for Windows will be used for data analysis. Internal consistency reliability coefficients (Cronbach alpha) will be calculated for all sub-scales within the psychometric questionnaires. A cut-off score of 0.7 will be used to determine acceptable reliability. Descriptive statistics (means and standard deviations) will be calculated for participants' primary and secondary outcomes (objective and self-reported) at three-time points. Multilevel modeling methods were used to account for the clustered nature of the data. Specifically, we used three-level (time within older adults within daycare center) regression analyses to examine the effects of group (experimental vs control), time (baseline, post-test and follow-up), and the group–time interaction (i.e., "intervention effect") on the primary and secondary outcomes. Covariates such as age, gender, BMI, education, and socioeconomic status will be included in the analysis. Bonferroni post hoc analyses will be conducted to determine contributing factors to the significance of F values, and the confidence level will be set at 95% to maintain statistical reliability for all the analyses.

Evaluation plan

At post-intervention, in-depth interviews of a group of 8 - 12 participants will be conducted to explore their experiences in participating in the intervention, the level of satisfaction with the intervention, and the barriers and expediters in performing the PLBI as instructed. DBRW will also be material for evaluation analysis. The reasons why participants dropped out of the study will also be recorded. Additionally, participants will be invited to fill in a process evaluation survey which assesses their level of involvement and level of satisfaction with the intervention.

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