

Official Title: Enhancing physical activity levels of community-dwelling older people with frailty through an exercise intervention with or without a wearable activity tracker (WAT)-based intervention: a feasibility and pilot study

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A. Background

The current prevalence of frailty among community-dwelling older people is as high as 27%; this figure is expected to rise dramatically in the next decades due to the rapid growth in the aged population globally (Dent et al., 2017). The common adverse outcomes due to frailty include fatigue, increased risk of falls, unintentional weight loss, reduced levels of physical activity, and sarcopenia (Clegg, Barber, Young, Forster, & Iliffe, 2012). Frailty is also associated with depressed moods (Mezuk, Edwards, Lohman, Choi, & Lapane, 2012), restricted social participation (Liu, 2017), and a poorer quality of life (Strawbridge, Deleger, Roberts, & Kaplan, 2002). Frailty is an age-related state characterized by reduced strength and physiological malfunctioning that increases an individual's susceptibility to dependency, vulnerability, and death (Clegg, Young, Iliffe, Rikkert, & Rockwood, 2013; Morley et al., 2013). Frailty also raises the risk of institutionalization, hospitalization, and mortality (Woo, Chan, Leung, & Wong, 2010). These adverse outcomes lead to considerable healthcare expenditures, and it is known that reducing such adverse outcomes could lead to reductions in medical costs (Cutler, 2001). Fortunately, the evidence shows that frailty is a modifiable dynamic process characterized by frequent transitions between states (i.e., robust, pre-frail, and frail) over time. This suggests that specific intervention and health strategies should be developed and evaluated to provide evidence-based practices to prevent, postpone, or even reverse the phenomenon of frailty (Gill, Gahbauer, Allore, & Han, 2006). Thus, it is indeed a worthy cause to test interventions that can mitigate the effects of frailty or reverse its progress, to prevent or reduce the socioeconomic burden associated with this condition.

Limitations of the current exercise programme for frail older adults

Several recent systematic reviews and meta-analyses have found preliminary evidence of the exercise programme's effectiveness in maintaining and improving the physical strength, function, and mobility of older adults with frailty (Chou, Hwang, & Wu, 2012; de Labra, Guimaraes-Pinheiro, Maseda, Lorenzo, & Millan-Calenti, 2015; Theou et al., 2011). For example, a systematic review of nine RCTs concluded that exercise interventions led to improvements in different physical outcomes, including falls, mobility, balance, functional ability, muscle strength, and mass. Among all of these studies, however, only one demonstrated that frailty status could be reversed after a 3-month exercise programme (Kim et al., 2015).

To achieve long-term beneficial effects, it is recommended that older adults accumulate at least 30 minutes of moderate-to-vigorous intensity physical activity (MVPA) on most, preferably all, days of the week (Nelson et al., 2007). Promotions of physical activity in older adults should emphasize moderate-intensity aerobic activity, muscle strengthening exercises, balance exercises, and reducing sedentary behaviour (Nelson et al., 2007). It has been suggested that an exercise programme with multiple components is an effective intervention to improve the overall health status and functional capacity of frail older people (Cadore et al., 2014; Villareal, Smith, Sinacore, Shah, & Mittendorfer, 2011). However, improvements in physical strength evidenced through laboratory assessments do not necessarily transfer to increased daily physical activity levels. The limitations of the exercise programmes in those clinical trials include the relatively short nature of the programme, no monitoring of daily physical activity levels, and a lack of strategies to encourage the participants to adopt a physically active lifestyle after the completion of the programme.

Therefore, whether old people with frailty can adopt a physically active lifestyle after clinical trials with an exercise alone programme is still a major concern. The major obstacles to adopting a physically active lifestyle include a lack of self-belief, low self-efficacy, and poor coping strategies (Dent et al., 2017).

In view of the limitations of an exercise alone programme, a pilot study was conducted to evaluate the preliminary effects of using an exercise programme plus the implementation of face-to-face behavioural change techniques (BCT). Eighty-five frail older people were randomly assigned to either the exercise

combined with BCT intervention (COMB), exercise only (EXER), or usual care (control) groups (Liu et al., 2017). Feasibility was achievable with high recruitment (87.2%) and low overall attrition (7.1%) rates. With the exception of the attendance rate and the self-perceived exercise compliance scores, we found no statistically significant differences in the other outcome assessments due to the small sample size in the pilot study. However, participants in the COMB group reported that ‘goal setting’ and ‘obtaining encouragement and suggestions from the BCT facilitator’ were the most effective ways of increasing their confidence in adhering to the exercise regimen. This pilot study showed that the combined exercise training and face-to-face BCT programme has the potential to strengthen the participants’ engagement in daily exercises, as reflected by their significantly higher self-reported exercise compliance and higher attendance rate in all of the training sessions during the 12-week programme [$F(2,76) = 5.64, p < 0.01$] when compared with the other two groups. Not surprisingly then, a trend of greater improvement in physical endurance was observed in the COMB group than in the other two groups, although the figures did not reach statistical significance because of the small sample size. However, one drawback is that the effects of implementing face-to-face BCT are likely to gradually fade after the programme.

Rationale for combining exercise training with a wearable activity tracker (WAT)-based intervention to increase physical activity levels in frail older people

Wearable fitness trackers (WAT) are activity monitors that track daily activity levels and synchronize the data (such as step counts, time spent on MVPA, heart rate, calories burned) to smartphone applications. WAT technologies are increasingly accessible and offer the potential to support lifestyle interventions targeted at enhancing physical activity. It is believed that the mechanism that makes WATs effective at increasing the physical activity of older people relates to increasing their self-efficacy. Previous systematic reviews have identified a significant correlation between physical activity self-efficacy and different BCTs (French et al., 2014). Some of these effective BCTs have already been incorporated into the design of the WATs, such as “prompting a review of behavioural goals”, “providing rewards contingent upon successful behaviour”, “alerting self-monitoring of behaviour”, “encouraging a focus on past successes”, and “giving cues to action” (Mercer et al., 2016). For instance, “cues to action” are important if sedentary behaviour is to be replaced with physical activity, as they provide real-time prompts to alert the participants of the need to avoid sedentary behaviour. In addition, the capacity for the user’s behaviour to be shared via the connectivity capabilities of smartphone applications can promote social support, feedback, and competition via social networking platforms (Nakhisi, 2014). Another systematic review has shown that activity monitors can positively influence multiple health behaviours, including physical activity (Fanning, 2012). These are important elements in changing and maintaining the change in behaviour (French et al., 2014).

Before the availability of this technology, to implement these BCTs required well-trained instructors to continually conduct face-to-face or telephone sessions with the participants. It was highly likely that these elements would gradually fade out after the completion of the face-to-face or telephone programme. With advancements in technology, these important BCT elements are already embedded in the WATs. It is believed that even after the completion of the programme, users of WATs have a greater chance of adopting the BCTs and of maintaining a physically active lifestyle over the long term.

Several previous studies have demonstrated that activity tracker-based interventions can effectively increase physical activity among adolescents and young adults with or without chronic illnesses (Choi, Lee, Vittinghoff, & Fukuoka, 2016; Lyons, Swartz, Lewis, Martinez, & Jennings, 2017; Mendoza et al., 2017; Partridge, McGeechan, Bauman, Phongsavan, & Allman-Farinelli, 2017). For example, an RCT involving 51 inactive postmenopausal women showed that a 16-week wearable activity tracker-based intervention contributed to significantly increased MVPA and step counts when compared to the standard behavioural intervention

(Cadmus-Bertram, Marcus, Patterson, Parker, & Morey, 2015). However, evidence of the feasibility and acceptability of using WAT among older people remains scant.

A recent survey of 127 older people evaluated WAT positively in terms of comfort, ease of installation, and usefulness (Kekade et al., 2018). Another trial invited 32 older people (mean age: 64) to evaluate the usefulness of six types of trackers after wearing each for 3 days. WATs, in general, were perceived as useful and acceptable, and 70% of the participants planned to purchase a WAT in the future to focus on improving their physical activity levels (Mercer et al., 2016). Although promising, these initial studies assessed the experiences of older people who were relatively young, and over short durations, which may not represent long-term experiences or the experiences of frail older people.

Another study aimed to examine the short and long-term experiences of 95 older people using a WAT throughout the 8-month study. Their experiences were assessed after two main phases of the RCT: an intervention phase and a follow-up phase. During the 10-week intervention phase, the participants had regular contact with intervention staff and structured technical support for using their WAT. During the 6-month follow-up phase, the participants were left to use their own WAT independently. All ratings of the participants' experience of using WAT, which included "ease-of-use", "usefulness", and "acceptance", showed a downward trend between the intervention and follow-up phases. These findings indicate that older people may need more support to continue to use the WAT to the point of achieving increased MVPA (McMahon et al., 2016).

In addition, there may still be several challenges when using WATs with frail older people. First, there is no guarantee that the users will encounter the BCTs, even if they are present in the WATs (Mercer et al., 2016). This is particularly true for frail older people, as some studies have shown that older people may be fearful of new technology and reluctant to use it (Jen & Hung, 2010; Deng, Mo & Liu, 2013). Second, the WAT still lacks several important BCTs, which are essential to increasing the self-efficacy and motivation of older people to engage in exercise and to take up new physical activities (French, Olander, Chisholm, & Mc Sharry, 2014; van Stralen, De Vries, Mudde, Bolman, & Lechner, 2009). Those BCTs that are lacking include action planning, problem solving, and the modelling of the desired health-related behaviour (Mercer et al., 2016).

To further strengthen the use of WATs among frail older people, it is suggested that some additional measures should be implemented. First, they should be provided with structured technical training, support, and reassurance on using the WATs and their related mobile applications, especially during the early stages of the programme. Second, more support, focusing on action planning, problem solving (i.e., both exercise-related and IT-related problems), and the modeling of health-related behaviour should be delivered in person alongside the WAT intervention and exercise training (Cramp & Byron-Daniel, 2012; Edmonds, McGuire, & Price, 2004; Neill, Belan, & Ried, 2006; Pinto, Frierson, Rabin, Trunzo, & Marcus, 2005). Third, these forms of support should be gradually withdrawn to see if the older people can use the WATs on their own.

Although the ultimate goal of using WATs should be increased MVPA, such data was not reported in previous studies on older people. Moreover, the suggested additional measures for facilitating the adoption of WATs by older people have not previously been tested. It is worth testing the efficacy of a combined intervention of exercise training plus WAT intervention in which BCTs have been incorporated. Little is presently known about the efficacy of using a WAT intervention among older people with frailty. The main hypothesis is that the WAT intervention plus exercise training programme will increase physical activity levels compared to an exercise programme alone. If we are successful in proving the hypothesis, we will propose studying the long-term effects (i.e., increased daily MVPA and the adoption of a physically active lifestyle) of this intervention in the main study with a larger sample size with a longer follow-up period.

B. Research plan and methodology (Appendix 1: Consort Research Flowchart)

Aim: A single-blinded, repeated-measures, two-arm pilot cluster RCT is proposed to examine the feasibility and preliminary effects of an exercise programme with or without a WAT intervention for promoting physical activity levels among community-dwelling older people with frailty. To explore the acceptability of the WAT intervention, a focus group with all participants in the experimental group (4-6 people per group) will be interviewed by JS (the Co-I).

Subjects and Settings: A district community health centre will be viewed as one unit/cluster. Eligibility criteria for district community health centres are those that are funded by the Hong Kong (HK) government and under the supervision of the Social and Welfare Department of HK, and thus that meet a specific set of standard regulations and criteria on environment and practices. Six community centres, which provide similar types of community care and social support services for community-dwelling older people, will be invited by a convenience method to work as collaborators in this study. The target population of this study are community-dwelling older people with frailty who will be recruited through the community centres.

Sample size: Teare et al., 2014 recommended that a pilot study is required a total number of participants between 60 and 100 when estimating the effect size for a continuous outcome. Thus, sixty participants will be recruited from six community centres. We estimate that about 25-50% of the members of these centres will be eligible to participate (Schultz-Larsen et al., 2007; Liu, 2017). We will target moderate to large centres with the total number of centre members around 800. Given that we can screen 200 older people (50 in each centre) per 4 to 6 weeks, and based on our previous study in similar centres (Liu et al., 2017), we believe that we will need about 3 to 4 months to recruit 60 participants (with 30 subjects recruited per 4 to 6 weeks in two-three centres) for this study. Given the difficulty of obtaining details of the backgrounds of all potential participants in these community settings, a properly random sample cannot be implemented. Thus, convenience sampling will be used to recruit participants among the collaborative community centres. Using computer-generated random numbers, a biostatistician not affiliated with this study will randomize the centres in a 1:1 ratio into either: the control or the experimental groups. Participants from each centre will be placed in their centre's corresponding group to avoid 'contamination' effects across participants. To avoid selection biases, the allocation to the study groups will be concealed from the researchers until sample recruitment and baseline measurements have been completed. Appendices 1 and 2 show the CONSORT research flow chart and the timeline of this study.

The Inclusion Criteria are: 1) community-dwelling older people aged ≥ 65 years; 2) able to communicate in Cantonese to ensure that they understand our instructions; 3) able to walk with or without an assistive device and able to complete the Time Up and Go (TUG) test with no specific cutoff point to ensure that their mobility and balance is good enough to join the exercise training; 4) able to use a smartphone; and 5) in a pre-frail or frail state as determined using the Fried Frailty Index^[1]; including: i) having experienced an unintentional loss of 10% of body weight in the past year; ii) exhaustion: by answering 'Yes' to either 'I felt that everything I did was an effort', or 'I could not get going in the last week'; iii) a slow walk time: with an average walking speed in the lowest quintile stratified by median body height; iv) reduced grip strength: with maximal grip strength in the lowest quintile stratified by the body mass index quartile; and v) a Physical Activity Scale for Elderly-Chinese (PASE-C) score in the lowest quartile (i.e., < 30 for men and < 27.7 for women). The presence of 1-2 indicates pre-frailty, ≥ 3 items indicates frailty.

The Exclusion Criteria are older people who: 1) have any physical conditions that hamper their performance of the exercise programme or use of the WAT, such as visual or hearing problems. 2) regularly engage in moderately intense exercise (such as hiking, Tai Chi) for ≥ 3 hours per week.

Interventions: A 3-month exercise programme plus WAT intervention will be arranged for the participants in the experimental group. They will receive a weekly centre-based exercise programme for 3 months. Meanwhile, two face-to-face sessions followed by weekly to monthly telephone sessions offering support on dealing with technical issues and BCTs will be arranged for the experimental group (see Figure 1: Intervention components for the experimental group). The additional technical support given alongside the WAT intervention will be gradually withdrawn from the participants. Eventually, all additional measures to support the use of WATs among participants will be stopped. Participants will be left to use the WAT on their own for 3 months during the follow-up period. Another 3-month exercise programme with face-to-face, and telephone-delivered BCTs follow-up sessions will be arranged for the control group, with the number and timing of all sessions similar to that in the experimental group. All face-to-face sessions and exercise training sessions will have ≤ 10 participants to maintain good interactions between the participants and the physical trainer / facilitator.

Wearable activity tracker (WAT)-based intervention for the experimental group: The aim is to strengthen the participants' motivation to develop the intention to gradually increase their physical activity levels to eventually meet the level recommended for older people by the American Heart Association (AHA)^[2]. The intervention consists of two face-to-face group-based sessions followed by a weekly to monthly telephone sessions offering support on technical issues and behavioural change techniques.

Supervision of face-to-face sessions and telephone follow up: JL (the PI), has successfully conducted many psychosocial intervention trials to enhance behavioural changes in older people with different health problems, and RK, who has experience in using WAT with older people. They will be responsible for implementing the face-to-face sessions and training an RA as a facilitator to deliver telephone BCTs support. A protocol for the face-to-face sessions and a script for telephone behavioral support will be developed and validated by the experts in BCTs and WAT. The initial calls by the RA will be observed by JL and feedback will be provided to maintain quality. Throughout the study, the telephone support will be supervised by JL and RK.

Physical training in the experimental and control groups A weekly 45-60 minute structured exercise programme, designed according to the AHA's recommendations on exercise for older people^[2] will be conducted for 12 weeks in the community centres. The exercise sessions will begin with a brief warm-up, followed by 30 minutes of moderate-intensity walking, 30 minutes of light upper and lower body resistance training, balance, and flexibility exercises. All of the participants will receive circuit training with set exercises, but the dosage of different components will be tailor-made for each participant based on his/her physical condition. Exercise intensity will be individually monitored using a subjective 0-10 scale for physical exertion (Borg CR10 scale). The participants will be initially instructed to walk at a moderate intensity, equivalent to 5-6 on the CR 10 scale. They will then be encouraged to gradually incorporate periods of vigorous walking (7-8 CR10) towards the end of the programme. They will be asked to take around 5000 steps per day at the beginning of the programme, gradually increasing to > 7000 steps towards the end of the programme, depending on their physical condition.^[3]

Demonstrations and return demonstrations will be performed during the training to ensure that the participants are able to do the exercises properly. A YouTube video/pamphlet demonstrating the exercises used in this programme will be disseminated to all of the participants to encourage them to continually practice their exercises at home for at least 30 minutes at least 3 times per week. The participants will also be encouraged to perform 30–60 minutes of walking exercise at least 3 times per week. The intensity of the walking exercise should gradually increase from moderate to vigorous according to the CR10 scale. Information on exercising safely (Appendix 2) will be discussed with all of the participants prior to the beginning of the physical training.

Supervision of the physical training: Physical training will be conducted by a well-trained research assistant who will work as a physical trainer under the supervision of JL and RK. JL has successfully conducted many intervention studies using exercise to address different health problems among older people. JL and RK will also work closely with the physical trainer, to monitor the progress of each participant.

The Control Condition: The same physical training and BCTs support will be arranged for the control group.

Instruments and Measures:

Participants will be assessed on a variety of outcomes (described below) at 1 week and at 1 and 3 months (T1 – T3) after the programme, which will be compared with the baseline assessment (T0). The participants will be asked to wear an ActiGraph Wgt3x accelerometer on their non-dominant wrist for 7 days before the commencement of any intervention, as well as during each outcome assessment time point.

Socio-demographic data: The following data will be collected: 1) data on age, gender, marital status, exercise habits, living conditions, and level of education, 2) the participants' health-related information, including their morbidities, cognitive status, medications, and number of hospital and out-patient clinic visits in the past 12 months.

Feasibility:

To understand the feasibility of this intervention, the frequency with which the participants in the experimental group use the tracker over the time of the study (i.e., 112 days), the recruitment rate, the attrition rate, the participants' adherence to the exercise regimen, and reports of adverse effects will be monitored.

Primary outcome measurement: Activity levels

The participants' physical activities and sedentary time will be objectively measured using a ActiGraph wGT3X accelerometer.

Secondary outcome measurements

Fitbit Data (only participants in the experimental group): The total steps per week, total walking distance per week, and time spent in different heart rate zones (50-69%, 70-84%, and >85% of the maximum heart rate) of an individual will be collected.

Physical Endurance: This will be evaluated using different physical tests:

1. The participants' lower-limb muscle and upper-limb strength will be assessed using a 30-second chair stand test and a handheld Jamar Hydraulic Hand Dynamometer, respectively.
2. Mobility will be assessed through the Timed-up-and-Go (TUG) test and by their gait speed (2-m walk). These two tests assess the overall performance of the lower limbs and walking speed, which can reflect the effect of exercise in enhancing the participants' overall physical endurance.

Exercise Self-efficacy: The participants' self-confidence in their ability to exercise in a variety of circumstances (e.g., even when they were feeling tired) will be assessed using the Chinese Self-Efficacy for Exercise scale (CSEE).

Frailty status: This will be assessed based on Fried's frailty five phenotypes as mentioned in the sample inclusion criteria. **Physical activity level** is one criterion of frailty that will be assessed using the 10-item PASE-C to measure self-reported occupational, household, and leisure activities for the last week.

Self-reported sedentary behavioral and physical activity: This will be assessed using the Global Physical Activity Questionnaire-Chinese version (C-GPAQ), which comprises 16 questions designed to estimate an individual's self-perceived level of physical activity in three domains (occupational, transport-related and discretionary or leisure time).

Motivation to engage in physical activity: This will be assessed by the 19-item Chinese version of the Behavioral Regulation in Exercise Questionnaire-2 (C-BREQ-2). The C-BREQ-2 is a 19-item questionnaire assessing five dimensions: amotivation, external regulation, introjected regulation, identified regulation, and intrinsic regulation. Each item is rated on a 5-point scale ranging from 0 = "not true for me" to 4 = "very true for me", with higher scores indicative of higher motivation.

Procedures: Ethical and access approval will be obtained from the Ethics Review Committee of The University and study venues, respectively. Potential participants will be referred to the research team by the community centres. An RA will screen all potential participants for their eligibility to participate in this study. Written informed consent will then be obtained from all of the participants, to whom all aspects of the study will be explained and questions answered. They will then be interviewed to obtain their demographic data, and baseline assessment. After that, the participating community centres will be randomized to either the control or experimental group. Participants from each centre will be placed into their centre's corresponding group to avoid 'contamination' effects across participants. At 1 week, 1 month, and 3 months post-intervention, an independent assessor who is blinded to the group allocations will assess the participants' outcomes, which will be compared with the baseline assessment. Another RA will collect all "Fitbit activity-related data" from the participants in the experimental group every week. All of the participants in the experimental group will be invited to attend the focus group interviews, which will be conducted by JS after the first post-test T1 and T3.

Intervention fidelity and RA training: User guidelines for each instrument will be obtained by the developers of the instrument or through a literature review. The PI (JL) will train an RA on how to use all of the outcome instruments, so that the RA can serve as an independent outcome assessor. He/she will practise using all of the instruments with various clinical vignettes and on-site practice. The PI will evaluate the assessor on his/her use of all of the instruments to ensure that quality assessments are performed as intended prior to the start of the study, and on a monthly basis throughout the data collection period. In addition, intra-class correlations (ICC) will be used to test the intra-rater reliabilities. Acceptable levels of reliability (ICC ≥ 0.9) will be established by comparing the scores rated by the assessor and the PI prior to the start of the study, and checking them on a monthly basis throughout the data collection period.

Exercise, WAT intervention protocols, and a scripted telephone support guideline will be developed and used to guide the implementation of all interventions involving participants in the experimental and control groups to ensure standardization of the intervention/study procedure. All physical training and face-to-face sessions must follow the protocol and will be run by the same facilitator/physical trainer to ensure consistency. To reduce the expectation bias from the physical trainer as well as the BCT facilitator, he/she will be instructed to use the same approach of encouraging all participants to adherence to their recommended exercise regimen. After receiving training on behavioural change techniques, an RA will conduct the telephone support based on the guideline under the supervision of JL and RK to the experimental and control groups.

Intervention fidelity checking will be conducted in the training period and then monthly to bi-monthly during the intervention period, based on the face-to-face facilitation / physical training checklists / telephone scripted guideline. Achieving a fidelity rate of $>90\%$ will be considered acceptable, based on the recommendations of

the NIH Behaviour Change Consortium (Bellg et al., 2004). This is to ensure that all of the interventions are executed by the physical trainer and the psychoeducation facilitator as intended. Monthly to bi-monthly quality-control meetings will be arranged with all research personnel in this study to evaluate their instruction/facilitation skills.

Ethical Considerations: Ethical approval will be obtained from the Ethics Review Committee of The Hong Kong Polytechnic University. The participants will be informed of the study before it begins; anonymity will be guaranteed. All eligible participants will be asked for their informed written consent. A letter clearly explaining the nature of the study will be provided to all. The nature, conduct, and potential risks and benefits of the study will be fully explained to the participants. The participants will be made aware that their participation is entirely voluntary and that refusing to take part will not have a negative impact on the usual care provided by the service. They will be given assurances throughout the study that their data will be kept confidential in accordance with the Privacy Ordinance. The research personnel involved will work closely with the clinical team to monitor the occurrence of any untoward effects on the participants. Standard guidelines for the management of, for example, symptoms of intolerance, will be used. The involvement of a multi-disciplinary team and the aforementioned monitoring and safety procedures have been specifically designed to minimise any potential risks to the physical health of the participants.

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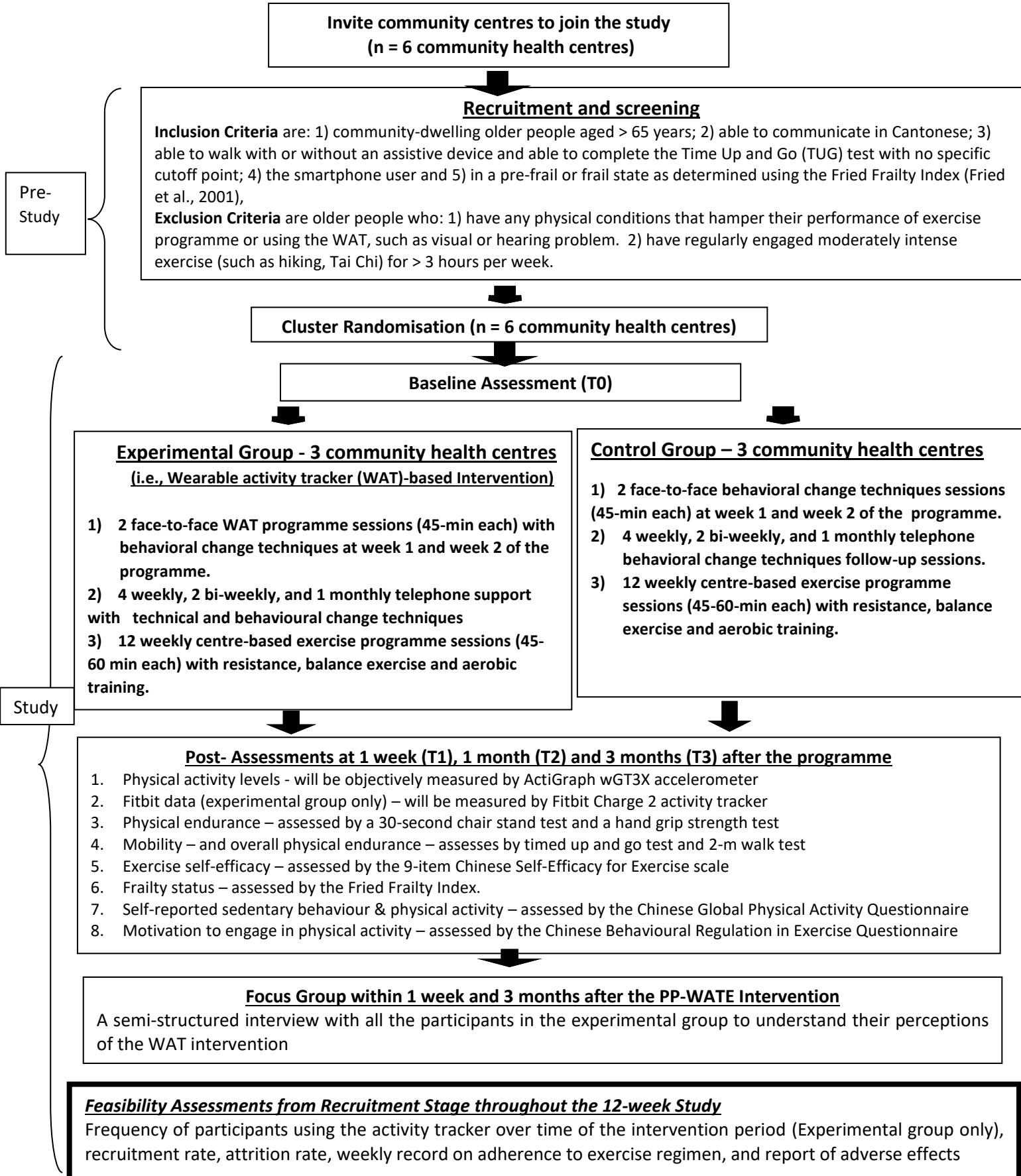
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Appendix 1: Consort Research Flowchart



Appendix 2: Example of lecture notes about tips of exercise safety

Example of lecture notes about tips of exercise safety

Centre for Gerontological Nursing 運動安全小貼士



戶外運動-
預防熱衰竭與中暑






空氣質素健康指數