Featured Article

The My Active and Healthy Aging (My-AHA) ICT platform to detect and prevent frailty in older adults: Randomized control trial design and protocol

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Abstract

Introduction: Frailty increases the risk of poor health outcomes, disability, hospitalization, and death in older adults and affects 7%–12% of the aging population. Secondary impacts of frailty on psychological health and socialization are significant negative contributors to poor outcomes for frail older adults.

Method: The My Active and Healthy Aging (My-AHA) consortium has developed an information and communications technology–based platform to support active and healthy aging through early detection of prefrailty and provision of individually tailored interventions, targeting multidomain risks for frailty across physical activity, cognitive activity, diet and nutrition, sleep, and psychosocial activities. Six hundred adults aged 60 years and older will be recruited to participate in a multinational, multisite 18-month randomized controlled trial to test the efficacy of the My-AHA platform to detect prefrailty and the efficacy of individually tailored interventions to prevent development of clinical frailty in this cohort. A total of 10 centers from Italy, Germany, Austria, Spain, United Kingdom, Belgium, Sweden, Japan, South Korea, and Australia will participate in the randomized controlled trial.

Results: Pilot testing (Alpha Wave) of the My-AHA platform and all ancillary systems has been completed with a small group of older adults in Europe with the full randomized controlled trial scheduled to commence in 2018.

Discussion: The My-AHA study will expand the understanding of antecedent risk factors for clinical frailty so as to deliver targeted interventions to adults with prefrailty. Through the use of an information and communications technology platform that can connect with multiple devices within the older adult's own home, the My-AHA platform is designed to measure an individual's risk factors for frailty across multiple domains and then deliver personalized domain-specific interventions to

the individual. The My-AHA platform is technology-agnostic, enabling the integration of new devices and sensor platforms as they emerge.

1. Introduction

Frailty is a precursor of and contributor to age-related diseases [1–5] affecting 7%–12% of the adults aged 65 years and older [5], with the occurrence of frailty increasing with age and potentially reaching a prevalence of 45% in those aged older than 85 years [6,7]. It has been suggested that frailty develops when age-associated degenerative processes overwhelm reserve capacity and plasticity processes that maintain function of the nervous system and other physiologic systems [5,8,9]. Overall, frailty represents the vulnerability of aged population to adverse events as the result of the subtle and progressive metabolic and physical changes. Frailty confers a significantly increased risk for poor health outcomes, incident disability, hospitalization, and mortality [7,10–14]. Older adults experiencing frailty are not acutely medically ill but are in a state of compromised function and capacity arising from a reduction in reserve capacity across multiple systems [15]. This loss of reserve capacity places the individual in a state that is approaching the physiological threshold for symptomatic clinical failure [15]. Therefore, frailty refers to a state of reduced physiological function and capacity rather than to a disease or clinical condition. An older adult in a state of frailty is at increased risk of developing secondary diseases, which then in turn exacerbate the level of frailty experienced [4]. A frail older adult can be conceived of as continually performing at his/her maximum capacity without additional reserves to cope with additional stressors. At the highest level of frailty, the person is increasingly dependent on caregivers, highlighting the social impact of frailty as the person progressively loses autonomy. This loss of autonomy is associated with increased need for assistance with mobility, self-care, and activities of daily living, with an associated progressive loss of self-confidence, leading to social isolation, reduced physical activity, progressive isolation, and decreased social interaction, further exacerbating the level of frailty experienced by the individual. Therefore, early identification and intervention of frailty is essential to prevent this deterioration.

The clinical diagnosis of frailty is based on the presence of symptoms of physical weakness (including weak muscle strength, slow gait speed, unintentional weight loss, malnutrition or comorbidity, exhaustion, and low physical activity). The diagnosis of frailty requires the presence of three or more symptoms of the following: shrinking (weight loss or sarcopenia), muscle weakness; poor energy and endurance, motor slowing, and/or reduced level of physical activity [5]. The presence of three or more of these frailty criteria in an older (>65 years) adult constitutes clinical frailty [5]. Individuals presenting with one or two symptoms are considered to be in a prefrail stage [16]. The prefrail stage (1–2 Fried et al [5] criteria) identifies a subset at high risk of progressing to frailty.

A fundamental weakness of current clinical frailty criteria [5] is that they remain specific to physical frailty and do not encompass the potential for frailty in other domains (e.g., cognitive, psychological, social, and so forth). Hence, the clinical criteria do not fully reflect the theoretical construct of frailty as a weakness in capacity across multiple systems. An additional challenge to conceptualizing prefrailty is in the relationship between frailty and other aging-related diagnostic constructs (e.g., preclinical dementia, preclinical Parkinson's disease, mild cognitive impairment [MCI], and so forth). The construct of frailty refers to a state of compromised function and capacity arising from a reduction in reserve capacity across multiple systems, creating conceptualization challenges in differentiating frailty from other aging-related syndromes involving a loss of function and capacity. For example, MCI [17–19] is a preclinical syndrome of dementia marked by subclinical cognitive impairments. The more recently described phase of preclinical dementia [20] precedes MCI and is marked by biological changes in the brain associated with later development of MCI and dementia. Neither preclinical dementia nor MCI encompasses frailty as a symptom. Similar phases of preclinical decline or deficits are also observed with various psychological and psychiatric conditions, including schizophrenia, bipolar disorders, as well as mood disturbances and various anxiety-related disorders. If frailty is considered to represent a state of vulnerability in an aging individual to adverse events as a result of subtle and progressive metabolic and physical changes, then the construct of frailty represents either: (1) a fully independent diagnostic entity; or, (2) an umbrella term encompassing all aging-related vulnerabilities, from which specific diagnostic constructs emerge (e.g., MCI). The relationship between frailty and other aging-related disorders is an important consideration that ultimately determines the clinical features of frailty and prefrailty. If frailty is considered to be an umbrella term, then the diagnostic features for specific conditions can be incorporated into frailty subtypes. If, however, frailty is considered to be independent of other aging-related disorders, then the presence of clinical features of other aging-related disorders precludes a diagnosis of frailty.

1.1. Overall approach of the My Active and Healthy Aging project

There has been a recent emergence of information and communications technology (ICT)–based solutions to support active aging and tackle frailty, cognitive decline, and social isolation of older adults. Although these ICT-based solutions have demonstrable value in reducing single risks (e.g., fall risk, and so forth), a holistic approach integrating solutions to multiple individual risk factors has not been developed to date. Furthermore, there is a need to provide tailored interventions based on an analysis of the combined multiple risks for each individual, rather than a specific intervention offered to all individuals irrespective of their level of risk. For example, balance training exercises offered to all older adults rather than providing balance training selectively to those at greatest risk of falls will result in low treatment efficacy. With frailty representing a state of compromise across multiple systems, it is necessary to tailor interventions to meet the individual's level of risk for frailty across these multiple systems (physical, cognitive, psychological, and social).

The My Active and Healthy Aging (My-AHA) project is designed to support and promote active and healthy aging by enabling early detection and minimization of multidimensional frailty risks. Early risk detection of compromise will occur across multiple domains of physical activity, cognitive activity, diet and nutrition, sleep, and psychosocial activities. The My-AHA project will map an individual's frailty risk profile across multiple domains to enable the implementation and delivery of ICT-based interventions tailored and targeted to identify risk profile for each individual. Interventions with established efficacy in improving cognitive, physical, social, and nutritional function in older adults will be deployed via a purpose-built software platform (My-AHA platform) with integrated hardware. The My-AHA platform is an ICT network composed of the following: (a) a database that records data about the user (demographic, health status, habits, and activity), (b) a decision support system that implements the rules for assessing the risk of frailty-related problems and the interventions addressed to reduce them, (c) a front end ("dashboard") designed for web and mobile applications, and (d) connectors with third-party applications that can be used to register data (e.g., physical activity monitoring through wearable sensors) or support the proposed interventions (e.g., cognitive games). The My-AHA platform is novel in that it will enable the deployment of intervention packages individually tailored to meet the frailty risk profile for each individual. This approach will ensure maximal treatment efficacy and response to treatment of prefrailty in older adults.

Currently, operational criteria for prefrailty exist only for the physical domain, whereby older adults (>65 years) displaying one or two of the five Fried et al [5] frailty criteria are considered to be in a prefrail state [16]. The question therefore remains as to whether frailty (and by extension preclinical frailty) possesses domain-specific subtypes is defined by physical weakness with secondary weaknesses in other domains or is a multidimensional nondomain-specific weakness. There are no validated operational criteria for prefrailty (or frailty) in the domains of cognition, mood (psychological), or social function. Consequently, although it is possible that an individual may display prefrailty across multiple domains, the capacity to determine prefrail status of an individual exists only for the physical domain. For the purposes of participant recruitment, participants will be screened for prefrailty status in the physical domain (Table 1). For cognitive and psychological measures, as there are existing validated thresholds for clinically significant deficits, participants will be screened to ensure that they are below the threshold for a clinically significant deficit which would exceed the level required for a prefrail state (Table 2). Assessment of level of functioning across all domains (physical, cognitive, psychological, and social) will be undertaken across the duration of the trial, and this data will be used to later develop and validate criteria for identifying prefrailty in nonphysical domains.

The primary outcome of this study is to determine the efficacy of an individually tailored multidomain ICT-delivered intervention package in prefrail older adults in improving physical, cognitive, psychological, and social function. Multiple secondary outcomes will also be examined during the course of this study: (1) that the My-AHA platform leads to a significant reduction in risk for clinical physical frailty in prefrail older adults; (2) to identify syndromic markers for prefrailty across nonphysical domains of cognition, social activity, and psychological health, (3) to develop and validate of a multidimensional model of prefrailty in older adults; and, (4) to provide evidence of the efficacy of ICT platforms in delivering home-based supportive care to older adults in the community.

2. Methods

2.1. Study Design

The My-AHA project is a multicenter, 18-month randomized controlled trial (RCT) (ClinicalTrials.gov identifier: NCT03342976) involving centers from Europe, Australia, and Asia. The RCT will conform to Consolidated Standards of Reporting Trials guidelines [21] and is designed to result in the development of objective criteria for multidimensional prefrailty (physical, cognitive, social, and psychological) as well as undertake an evidence-based examination of the efficacy of ICT-based platforms to deliver tailored interventions to prevent decline into clinical frailty states. The design of the assessment component of the study is illustrated in Fig. 1.

2.2. Selection of study participants: Inclusion and exclusion criteria

Participants will be adults aged 60 years and older meeting study inclusion criteria for physical prefrailty and not meeting one or more of the study exclusion criteria (Table 3) for clinically significant cognitive and/or mood disturbance or for concomitant diseases. A total of 600

Table 1
Operational criteria for identification of physical prefrailty in the My-AHA project

Physical domain						
Prefrail = 1 or 2 of the following criteria are met						
1. Shrinking, evidenced by weight loss (unintentional)	≥4.5 kg unintentional in prior 12 months; or at follow-up assessment ≥ 5% of body weight in prior 12 months			Self-reported weight loss (not due to dieting or fasting) in preceding 12 mo ≥ 4.5 kg. Follow-up: K = (weight in previous year– current measured weight)/(weight in previous year). If K ≥ 0.05, meets weight loss frailty criteria		
2. Weakness	Grip strength in lowest 20% at baseline adjusted for gender and BMI					
	Males	BMI	Grip strength (kg)	Females	BMI	Grip strength (kg)
		≤24	≤29		≤23	≤17
		24.1–26	≤30		23.1–26	≤17.3
		26.1–28	≤30		26.1–29	≤18
		>28	≤32		>29	≤21
3. Poor endurance and energy	Self-report of exhaustion as indicated by responses to two questions on CES-D scale			Using the CES–D Depression Scale, response of "2" (a moderate amount of the time, 3–4 days) or "3" (most of the time) to either of the following 2 items: (a) I felt that everything I did was an effort; and/or (b) I could not get going.		
4. Slowness	Time to walk 4.00 m ≤ slowest 20% adjusted for gender and standing height					
	Male	Height (cm)	Time to walk 4 m	Female	Height (cm)	Time to walk 4m
		≤173	≥6.13 sec		≤159	≥6.13 sec
		>173	≥5.25 sec		>159	≥5.25 sec
5. Low physical activity level	Energy expenditure per week below established cutoff		Short version of the IPAQ questionnaire assesses activity levels for walking, moderate-intensity and vigorous-intensity activities for work, transportation, domestic chores, gardening, and leisure-related activities.		IPAQ activity category level = low	

Abbreviations: My-AHA, My Active and Healthy Aging; IPAQ, International Physical Activity Questionnaire; CES-D, Center for Epidemiologic Studies Depression Scale; BMI, body mass index.

participants will be recruited across 10 study centers (see Table 4).

2.3. Randomization/treatment assignment

Participants are randomly allocated to one of two study arms: Study Arm 1 (standard care Control group) and Study Arm 2 (My-AHA intervention group). Randomization will occur at each study site independently. Initial randomization of participants at each site will occur using a simple randomization 1 (control):1 (intervention) ratio, with allocation of participants to each treatment arm being undertaken using on alternating allocation sequence based on order of entry into the study. Once allocation of 20 participants has occurred at each site, the study site coordinator will submit to the RCT study coordinator demographic information (gender, age, and education level) for the 20 participants recruited and allocated to each study arm. The RCT study coordinator will review the balance of participants across study arms for these demographic variables within each study site and vary allocation procedures for remaining participant assignment to study arms to ensure equivalence of study arms within each site.

2.4. Intervention program

At baseline, all participants undergo comprehensive assessment of multidomain functions (Fig. 1, Table 5 and Section 2.5). These assessments are repeated at six monthly intervals across the duration of the RCT (6, 12, and 18-month time points). Data from these four assessment points will be used to ascertain the effect of the intervention program on the functional status of each participant in each study arm. Any participant in the control study arm who meets clinical criteria for frailty following baseline assessment will be provided access to My-AHA interventions.

A suite of interventions will be available to all participants in the intervention study arm. The selection of interventions available to each participant will be individually tailored to match the domain(s) identified as being within the parameters for prefrailty. Interventions are recommended where benefit to the participant is likely and risk of harm is low. In this case, benefit is considered to be evident where there is improvement across one or more of the measures of outcome assessed at each of the four assessment points. Assignment of interventions

Table 2
Operational criteria for detection of clinically significant deficits cognitive and psychological function

Cognitive domain		
Exclude if both of the following criteria are met		
1. Evidence of lowered general cognitive function	Mini–Mental State Examination test (MMSE)	Age-adjusted MMSE ≤ 23
2. Evidence of lower than age-appropriate learning and recall of verbal information	Hopkins Verbal Learning Test (HVLT)	HVLT-total recall score ≤ 24
Psychological domain		
Exclude if any of the following criteria are met		
1. Increased levels of anxiety and/or lowered mood experienced over the preceding week	Hospital and Depression Scale (HADS)	HADS-a score ≥ 15 (severe symptoms) HADS-d score ≥ 15 (severe symptoms)

occurs based on algorithms developed to match the need for intervention across each domain and participant preference (Supplementary Table S1). The data used by the algorithms are designed so as to be ultimately incorporated into the My-AHA application, enabling the system to continuously update and modify intervention packages for individuals as new information is fed into the system. Data for the algorithms involve a combination of self-report, sensor-based, and questionnaire-based information (Supplementary Table S1), with this data being used to determine the allocation of intervention type and load across domains (Supplementary Table S2). This will result in a "prescription" of interventions tailored to individual participant needs. The intervention prescription will be a maximum of 210 minutes per week (or average of 30 minutes per day); however, participants are able to undertake

additional interventions at their own choice. Recalculation of the intervention package for each participant will occur following assessment point, with intervention prescriptions having an effective 6-month duration. Intervention packages have been developed for physical, cognitive, psychosocial, nutrition, and sleep domains. Participants will undertake different intervention packages depending on individual tailoring. The goal of this trial is not to test the efficacy of a single intervention, but rather to examine the efficacy of a multidimensional interventional approach whereby each participant is prescribed an intervention package matching their specific needs.

2.4.1. Physical interventions

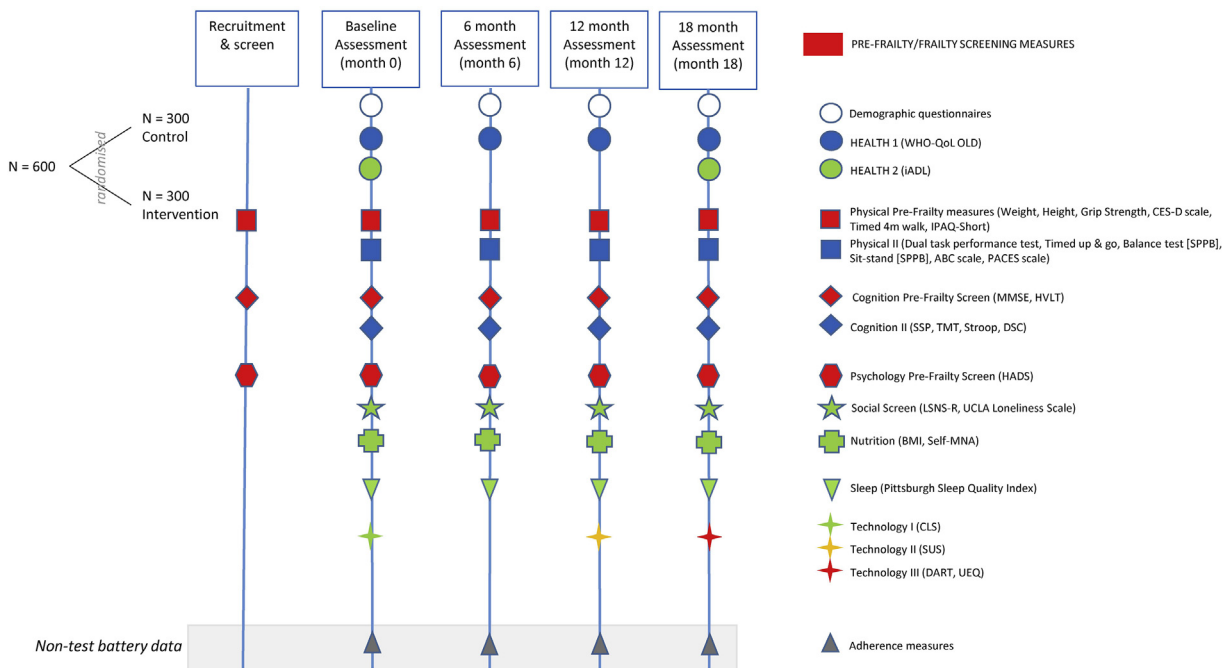Interventions have been selected to target the key physical markers of frailty: weight loss, physical weakness,

Fig. 1. Schematic of study design.

Table 3
My-AHA RCT inclusion and exclusion criteria for participant screening

Inclusion criteria
1. Age: over 60 yrs
2. Familiar with use of smartphones and/or tablet computers
3. Meet criteria for physical prefrailty (Table 1)
4. Ambulatory—able to stand and walk unassisted (Table 4)
5. Free of significant cognitive impairment (Table 2)
6. Free of clinically significant mood disturbance (Table 2)
7. Free of any acute or unstable medical conditions (Table 4)
8. Able to understand directions and participate in the protocol
9. Able to sign informed consent

Exclusion criteria	Participant excluded if meets 1 or more of below:
Mobility problems	1. Unable stand and ambulate unassisted
	2. Painful arthritis, spinal stenosis, amputation, or painful foot lesions that limits balance and mobility,
Concurrent chronic disease independently contributing to frailty	1. Suffers from a significant neurodegenerative CNS disorder (e.g., dementia, Parkinson's disease, multiple sclerosis, progressive supranuclear palsy, amyotrophic lateral sclerosis, hydrocephalus, Huntington's disease, and prion diseases)
	2. Affected by severe peripheral nervous system and/or neuromuscular disorders, e.g., CIDP, myasthenia gravis, multiple sclerosis, and polymyositis
Concomitant injury or disease known to impact independently cognitive, psychological, or physical function	1. Clinical evidence or history of stroke (within 2 yrs)
	2. Clinical evidence or history of transient ischemic attack (within 6 months)
	3. Significant head injury with loss of consciousness, skull fracture or persisting cognitive impairment (2 years)
	4. Epilepsy (a single prior seizure is considered acceptable)
	5. If meets DSM-5 criteria for the following: major depressive disorder (current), schizophrenia or other psychotic disorders (lifetime), bipolar disorder (within the past 5 years), and substance (including alcohol)-related disorders (within the past 2 years)
Presence of deficits that interfere with assessment validity	1. Have language deficits that impair testing
	2. Have significant visual impairment
	3. Have a significant hearing loss
Presence of other conditions or diseases that will compromise participants ability to undertake interventions (especially physical)	1. Have clinically significant cardiovascular disease (e.g., hospitalization for acute coronary syndrome, acute myocardial infarction or unstable, angina; symptoms consistent with angina pectoris (within the 12 months), signs or symptoms of clinical heart failure within the 12 months, evidence of uncontrolled atrial fibrillation, a cardiac pacemaker).
	2. Preexisting or current signs or symptoms of respiratory failure (e.g., chronic obstructive pulmonary disease, bronchial asthma, lung fibrosis, and other respiratory disease)
	3. Untreated hypertension
	4. Metastatic cancer or immunosuppressive therapy
	5. Concurrent acute or chronic clinically significant immunologic, hepatic (such as presence of encephalopathy or ascites), or endocrine disease (not adequately treated).
Unacceptable Test/Laboratory Values	1. Postural hypotension (fall in systolic blood pressure of greater than 30 mm Hg or fall in diastolic blood pressure of greater than 20 mm Hg on standing compared to sitting) at the time of screening. Participants who present at the time of screening with postural hypotension yet have no known history of postural hypotension, nor underlying medical condition related to hypotension, may be rescreened

Abbreviations: My-AHA, My Active and Healthy Aging; RCT, randomized controlled trial; CNS, central nervous system; CIDP, chronic inflammatory demyelinating polyneuropathy; DSM5, Diagnostic and Statistical Manual of Mental Disorders 5th edition.

reduced energy, motor slowing, and reduced physical activity [5]. With falls being the most likely consequence of increasing physical frailty [37], prevention of falls through balance training to enhance gait pattern and postural control is a key approach to be used in the My-AHA project. The multicomponent physical interventions deployed in the My-AHA project involve activities that combine strength and balance training over an extended duration ($\geq$5 months), with high-frequency repetition (performed three times per week) for 30–45 minutes per session. Such

Table 4
Participant recruitment by study center

Region	Country	Study center	Total n	Control arm	Intervention arm
Europe	Italy	University of Torino	40	20	20
	Germany	Johanniter e.V.	100	50	50
	Austria	Johanniter Osterreich	100	50	50
	Spain	IBV/Gesmed	80	40	40
	UK	St John Ambulance	40	20	20
	Belgium	Johanniter International	50	25	25
	Sweden	Johanniterjalpen	40	20	20
Australia	Australia	University of the Sunshine Coast	50	25	25
Asia	Japan	Tohoku University	50	25	25
	South Korea	University of Seoul	50	25	25
		Total	600	300	300

physical interventions have been found to result in superior outcomes compared with other exercise programs [38] and that multicomponent exercise interventions display the greatest reduction in falls rate and improvement in gait, balance, and strength performance in physically frail older adults [39,40].

For the strength and balance domains, the OTAGO home-based exercise program (OEP) [41] and the Fitness and Mobility Exercise program [42] will be applied. Following an initial training session with an exercise instructor, the OEP will be deployed as a home-based exercise program used by older adults in their own homes without supervision up to a maximum of three 30-minute sessions per week. Participants will undertake the OEP program one session per week. Fitness and Mobility Exercise program is a group-based exercise program which participants will complete a maximum of a 1 hour session per week under the supervision of a

Table 5
Assessment battery

Domain	Test name
Demographic	Standardized questionnaire assessing age, gender, education level, residential status, falls history, prior mental activity, medical history, and continence
Adherence	Cognitive games (in My-AHA platform) time spent in game, time scheduled
	FAME–calendar with diary
	OTAGO–calendar with diary
	VitalinQ–time spent/recipes used
	Technology–duration and frequency of app use
Health	World Health Organisation Quality of Life scale–OLD extension (WHO-QoL-OLD) [22]
	Lawton-Brody Instrumental Activities of Daily Living (iADL) scale [23]
Physical	Weight (kg)
	Height (cm)
	Grip strength
	Center for Epidemiologic Studies Depression Scale (CES-D)–2 items [24]
	Time to walk 4 m
	International Physical Activity Questionnaire–Short Version (IPAQ-SV)
	Dual-Task Performance
	Timed up and Go test
	Short Physical Performance Battery (SPPB)–Balance subtest, Sit-Stand subtest [25]
	Activities-specific Balance Confidence (ABC) scale [26]
	Physical Activity Enjoyment Scale (PACES) [27]
Cognitive	Mini–Mental State Examination (MMSE) [28]
	Hopkins Verbal Learning Test (HVLT) [29]
	Spatial Span (SSP) from the Wechsler Memory Scale, 3rd edition [30]
	Trail Making Test (TMT) [31]
	24 item Victoria version Stroop test [31]
	Digit Symbol coding subtest (DSC) from the Wechsler Adult Intelligence Scale [32]
Psychological	Hospital Anxiety and Depression Scale (HADS) [33]
Social	Lubben Social Network Scale, Short form (LSNS-R) [34]
	University of California, Los Angeles Loneliness Scale–Revised [35]
Sleep	Pittsburgh Sleep Quality Index (PSQI)
Nutrition	BMI (derived from height/weight data in physical battery)
	Self-Mini Nutritional Assessment (Self-MNA) [36]
Technology	Evaluation of usability scale (SUS)
	DART questionnaire
	Computer literacy scale (CLS)
	User experience questionnaire (UEQ)
	Measures of prefrailty/frailty criteria

Abbreviations: My-AHA, My Active and Healthy Aging; FAME, Fitness and Mobility Exercise program; BMI, body mass index.

physical exercise instructor (appropriately qualified and trained fitness instructors, physical therapists, or occupational therapists). Physical intervention type and frequency (dose) is determined on an individual basis by the intervention algorithm (Supplementary Tables S1 and S2) with the maximum physical intervention schedule of two OTAGO sessions and one Fitness and Mobility Exercise program session per week (total 120 minutes per week).

2.4.2. Cognitive interventions

Cognitive interventions in the My-AHA project will comprise working memory training (N-back task) and cognitive bias modification therapy using attention bias modification (ABM) tasks. As with physical interventions, the type of cognitive intervention offered to each participant will be individually tailored as determined by their individual areas of strength and weakness identified at each assessment point (see Supplementary Tables S1 and S2).

To achieve maximum adherence, self-efficacy, and engagement, the n-back task will use graded difficulty whereby task difficulty is continuously adjusted to match participant level of performance. The level of n is maintained when participants give between 75% and 89% correct responses. Two versions of the n-back task will be used: a letter-based and a visuospatial version. For both letter-based and visuospatial n-back tasks, eight combinations of presentation time and interstimulus intervals will be used. A session comprises 15 blocks of n-back training (approximately 15 minutes). At the end of the session, participants are provided with an overview of their performance, for example, correct hits and misses, as well as average level of n. The training will be delivered via the My-AHA app directly but can also be installed on the participant's home computer and operated with a keyboard or computer mouse.

Cognitive bias modification therapy trains anxious or depressed individuals to disengage from threat-related stimuli and redirecting their attention toward other "positive" stimuli [43]. There are two common variants of cognitive bias modification therapy, namely ABM and interpretative bias modification, both reported to be effective in reducing anxiety and depression pathology [44]. ABM is a modified computerized visual-probe procedure in which participants learn to direct their attention toward relatively positive stimulus, which can be a word or a picture, and away from threat-related stimuli. A session of ABM comprises 96 trials, and participants are recommended to complete three 5-minute-long sessions per week for 28 sessions in total.

2.4.3. Psychosocial interventions

Three social interventions will be implemented in the My-AHA project: group activity interventions, group support interventions, and a social media platform. Group activity interventions will increase participant engagement in social interaction by provision of targeted group-based activities including: group autobiographical recall activity (www.Activ84Health.eu) in which participants are able to visit a location from their past (using google street view imagery) and guide others through the area while describing their memories and experiences, group cooking classes, and group excursion-based activities (e.g., visiting a museum). The My-AHA platform will match participant's preferences for type of activity and will create digital activity groups for participants with common preferences. The My-AHA platform then matches appropriate group activity proposals and presents the demand for specific group activities to secondary stakeholders (e.g., community organizations, local councils, support groups, and so on) as providers of group activities. Group support interventions will provide an opportunity for participants to find targeted help and support (e.g., bereavement support, disease support such as cancer support groups). My-AHA participants can set corresponding parameters in their profile to indicate their need for support. The My-AHA platform will match support groups to individual participants, based on the parameters and preferences set by the participant. The social media platform will encompass the exchange and sharing of information as well as communication with other participants. It will provide a digital space for participants to interact with each other and share information, opinions, and recommendations.

2.4.4. Nutritional interventions

Nutritional interventions will be implemented in a nutrition application for mobile devices. The interventions to be deployed include the following: individual meal plan generation and tailored nutritional advice and education. In the My-AHA nutritional application, meal plans and recommendations will be generated and presented to the user. The meal planning system takes into account anthropometric data, lifestyle, activity level, and nutritional status of the participant as well as user preferences when creating individually tailored meal plans. The recommendations are official guidelines, determined by official nutritional institutions in each participating country. Recommendations will be compared with the recipes in the database and adjusted for participant preferences (such as known allergies, lifestyle (e.g., vegetarian), and/or preferred cuisine).

Participants will also be able to receive nutritional advice based on the food intake they log into their food diary [45]. They will be educated on what they eat and be provided advice on how to improve their nutritional intake to meet their requirements.

2.4.5. Sleep interventions

Sleep interventions will be an optional offering to participants and will comprise advice on methods to enhance sleep duration and quality. Participants will be provided with two advice options: passive body heating or light exposure. For

passive body heating, participants will be provided detailed advice on using a 30-minute-long hot bath (40–41°C) 1.5–2 hours before going to bed, with 50–100 mL of water to be consumed following the bath. The recommended schedule for passive body heating is in blocks of 5 consecutive days, followed by a single rest day. Light exposure will be recommended for participants experiencing either advanced sleep phase or delayed sleep phase. For advanced sleep phase, participants will recommended to undertake bright light (460 nm light blue, 2000–10,000 lux) or sunlight exposure of 1–2 hours duration between 17:00 and 19:00 hours each day. For delayed sleep phase, participants will be recommended to undertake bright light (460 nm light blue, 2000–10,000 lux) or sunlight exposure of 1–2 hours duration between 07:00–09:00 hours each day.

2.5. Assessment measures

At baseline, 6, 12, and 18 months, each participant will undergo a comprehensive assessment (Table 5 and Fig. 1). The assessment battery includes measures required to assess for the presence of frailty/prefrailty as well as measures sensitive to changes in cognitive, physical, and psychosocial function.

2.6. Statistical considerations

Between-group comparisons of continuous measures using analysis of covariance will be made for each of the five main outcomes in the main wave: well-being (World Health Organisation Quality of Life scale – OLD extension [WHOQOL-OLD]), physical fitness, cognitive function, psychological state, and social connectedness. Each of the final four outcomes will be based on compound scores of the relevant outcome variables, weighted by the first component of a principal component analysis of all variables in each domain. To correct for multiple comparisons, we will use a Bonferroni adjustment of alpha = 0.05/5 = 0.01, and significant confounding variables (e.g., age, gender, education, and so forth) will be corrected for. An intention-to-treat approach will be used for all between-group analyses, and we project a drop-out rate of 30% over the 18 months of the RCT. As lifestyle effects are typically weak but likely to have a significant impact on health in the wider population, we power generically to detect at least weak effects (f = 0.1). Assuming a correlation among the repeat measures of 0.5 and the sample size of n = 600 yields actual power of 93.4%, indicating that the trial in the main wave is well powered with the planned participant recruitment.

2.7. Ethics and safety aspects

The My-AHA RCT has been approved by the coordinating center ethics committee (University of Torino) and will be approved by the relevant ethics boards for each of the RCT trial sites. Participants gave written fully informed consent before enrollment in the study. Ethical principles as specified under the Helsinki Declaration will be adhered to at each RCT site. Safety issues of the interventions are carefully considered with a project safety committee meeting regularly for the assessment and management of any occurring adverse events.

2.8. Data management process

A purpose-built e-portal (My-AHA platform) has been developed for use by participants and site investigators. The My-AHA platform enables the connection with multiple third-party applications that provide physiological data through sensors (physical activity duration and intensity, sleep quality and duration, weight, heart rate, blood pressure, and glucose levels) as well as the manual input of additional data. Through the My-AHA interface, participants are able to connect with external e-systems (e.g., nutritional platforms provided by VitalinQ) as well as multiple intervention platforms. The My-AHA portal represents a common interface between each individual participant and multiple external connections, with participant data being stored securely within the platform.

2.9. Study progress

Pilot testing of the My-AHA platform and all ancillary systems was undertaken in 2017 with a small number of participants in Europe, with additional examination and modifications to the system based on usability testing undertaken in Living Labs held in Germany. On the basis of the pilot testing and living lab data, final modifications of the My-AHA platform are being completed ahead of the scheduled commencement of the RCT in early 2018 with each participant to complete the 18-month trial by late 2019.

3. Results of alpha wave

The alpha wave of the My-AHA protocol was planned as a pilot study to evaluate, in a limited sample of representative participants, the portability and usability of the My-AHA platform, including assessment protocols, questionnaires, and technical aspects of the platform. No intervention was delivered as part of the alpha wave. Sites participating in the alpha wave were Torino (Italy), Valencia (Spain), Vienna (Austria), and Kempten (Germany). The alpha wave commenced on February 1, 2017 following approval from the Ethics Committee in Torino, with the alpha wave trial concluding June 30, 2017.

A sample of 97 participants (57 female, 40 male) underwent screening procedures. In accordance with Fried et al. [5] criteria, 20 prefrail participants (12 female, 8 male; mean age 70.1 ± 7.4 years) were recruited into the 3-month alpha wave trial. Following baseline assessment, participants were individually examined by the local principal investigator on a monthly basis. The assessment protocol was in keeping with the RCT protocol described above with minor deviations.

All enrolled participants in the alpha wave reported the protocol to be well accepted. Minor technical problems relating to connections between devices and the middleware software were reported by three participants. Supplementary Fig. S1 displays the output from the My-AHA platform for physical activity data (daily steps) from one participant enrolled in the alpha wave through the use of the SmartCompanion application. Supplementary Fig. S2 displays the frequency of cognitive exercises performed by a single participant on one of the cognitive platforms tested in the alpha wave. Participant and investigator feedback regarding the graphical interface for providing activity feedback were collected and incorporated into platform revisions. As expected, no significant differences were detected between participants neuropsychological test performances and Fried criteria over the course of the 3-month alpha wave trial. The results of alpha wave trial indicate that the My-AHA platform is suitable for implementation in the full RCT study.

4. Discussion

The My-AHA project is designed to undertake a multidomain assessment and intervention of prefrail levels of physical, cognitive, social, or psychological impairment in older adults to prevent or delay the development of clinical frailty. At present, there is little understanding of the antecedent risk factors for clinical frailty; hence, a key aim of this project is to identify risk markers of prefrail levels of impairment so as to optimize targeted interventions. Frailty is a significant risk factor for the development of multiple age-related diseases [1–5] and confers a significantly increased risk for poor health outcomes, incident disability, hospitalization, and mortality [7,10–14]. Through the use of in-home ICT-based solutions, the My-AHA project will implement and trial an integrated system of assessment and intervention that will deliver individually tailored solutions for older adults at risk of developing frailty. The platform developed is designed to be technology-agnostic, enabling the integration of new devices and sensor platforms as they emerge. Furthermore, the platform has been developed across multiple languages (English, Italian, Spanish, German, Dutch, Korean, and Japanese) to enable rapid deployment across multiple countries.

At the conclusion of the RCT, we expect to have developed evidence-based criteria for the detection and diagnosis of prefrailty across multiple domains as well as have evidence-based intervention efficacy data relating to the capacity of individually tailored interventions to delay, prevent, or treat clinical frailty in older adults.

Acknowledgments

Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.trci.2018.06.004.

RESEARCH IN CONTEXT

1. Systematic review: Frailty increases risk of negative outcomes including death in older adults. The My Active and Healthy Aging (My-AHA) project is a multisite, multinational longitudinal randomized control trial to test the efficacy of delivering information and communications technology (ICT) supported in-home multidomain interventions tailored to individual risk profiles for older adults with prefrailty.

2. Interpretation: Prefrail adults aged 60 years and older will participate in an 18-month-long randomized controlled trial. Participants will be randomly allocated to a standard care control group or My-AHA intervention group. Individual frailty risk across physical, cognitive, mood, social, and nutrition domains will be monitored at six monthly intervals with individually tailored interventions being provided to each participant in the intervention group. The efficacy of the My-AHA intervention platform will be evaluated at the completion of the randomized controlled trial.

3. Future directions: This study expands on current conceptualizations of frailty as physical disease and incorporates the notion of frailty as a multidimensional disease state. The My-AHA randomized controlled trial study will assess the efficacy of providing ICT-based in-home tailored interventions to reduce the incidence of frailty in older adults at risk of developing frailty. This may lead to future implementation of new technologies to assist older adult remain in their own home as they age through reduction of the incidence of frailty in the aging community.

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