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RESEARCH PAPER

The My Active and Healthy Aging ICT platform prevents quality of life decline in older adults: a randomised controlled study

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Abstract

Introduction: Prevention of frailty is paramount in older adults. We evaluated the efficacy of a tailored multidomain intervention, monitored with the My Active and Healthy Aging platform, in reducing conversion from a prefrail status to overt frailty and preventing decline in quality of life.
Methods: We performed a multicentre, multicultural, randomised control study. The effects of multidomain interventions on frailty parameters, quality of life, physical, cognitive, psychosocial function, nutrition and sleep were evaluated in a group of 101 prefrail older subjects and compared with 100 prefrail controls, receiving general health advice.
Results: At the 12-month assessment, controls showed a decline in quality of life that was absent in the active group. In addition, active participants showed an increase in mood and nutrition function. No effect on remaining parameter was observed.
Discussion: Our study supports the use of personalised multidomain intervention, monitored with an information and communication technology platform, in preventing quality of life decline in older adults.

Keywords: Frailty, Prefrail subjects, RCT, ICT platform, Quality of life, Older people

Key Points

- Prevention of frailty in older adults could significantly improve health outcomes and quality of life.
- In a group of prefrail older subjects, we evaluated the effects of a personalised multidomain intervention, supported with an information and communication technology (ICT) platform, in preventing conversion to frailty.
- We found that participants in the active group, in comparison with controls, showed no decline in quality of life and improved in mood and nutrition function.
- Our study supports the usefulness of ICT platforms in the prevention of age-related quality of life decline.

Introduction

The term frailty refers to a state of reduced physiological function and is currently diagnosed on the basis of symptoms of physical weakness [1]. The dominant research diagnostic criteria are the Fried criteria, assessing five physical markers of frailty (shrinking, weakness, poor endurance and energy, slowness and low physical activity level) [2]. The presence of three or more of these markers is required for the diagnosis of frailty, with one to two markers indicating a prefrail state at elevated risk of progression to clinical frailty [3]. Frailty affects an estimated 7–12% of adults 65 years and older [4], with the prevalence increasing with age such that 45% of those aged over 85 years are considered frail [5].

Frailty results in increased risk for poor health outcomes, including incident disability, hospitalisation and mortality [6–9]. Chronic diseases in older adults can further exacerbate the level of frailty. Little is known regarding treatment efficacy for reversing or preventing progression to/of the frailty state. Furthermore, few randomised controlled trials (RCT) have been conducted, with majority of clinical trials only examining physical interventions [10–12].

Concurrent with increased research interest in frailty, there has been an increase in research investigating quality of life (QoL) in older adults [13]. Several scales evaluating QoL have been validated worldwide, and the evaluation of QoL in older adults is becoming an increasingly important outcome measure for planning health and social services [14, 15]. A robust, inverse association between frailty/prefrailty and QoL in older adults has been demonstrated [7, 16]. Interventions targeted at reducing frailty may have the additional benefit of improving corresponding QoL.

The My Active and Healthy Aging (My-AHA) Consortium, established in 2016, developed an information and communication technology (ICT) platform to support and promote active and healthy ageing, by enabling early detection of multidimensional frailty risks and promoting personalised interventions. Early risk detection occurs across multiple domains, including physical, cognitive and psychosocial activities, nutrition and sleep. In addition, the platform delivers interventions with established efficacy in improving cognitive, physical, social and nutritional function.

The purpose of this study was to determine in prefrail older adults the efficacy of an individually tailored multidomain intervention, monitored with the My-AHA platform, in reducing conversion to overt frailty and preventing decline in QoL.

Methods

Study design

The My-AHA project is a multicentre, multicultural 12-month RCT (ClinicalTrials.gov identifier: NCT03342976) involving centres from Europe, Australia and Asia. A detailed description of the study protocol has been previously published [17].

Participants

To be eligible for participating in the study, individuals were required to be over 60 years old, familiar with use of smartphones and tablets or computers, meet Fried criteria for prefrail status (Supplementary Table S1), able to stand and walk unassisted, free of significant cognitive impairment or mood disturbances and free of any acute or unstable medical conditions. Inclusion and exclusion criteria are detailed in supplementary data (Supplementary Table S1). Participants were community-residing older adults who responded to local media.

Randomisation and blinding

At screening, participants at each study centre were sequentially allocated to one of two study arms: Study Arm 1 (standard care control group) and Study Arm 2 (My-AHA intervention group). The first 20 participants at each study centre were allocated to study arm using an alternating sequence of 1 (control):1 (intervention) ratio by order of entry into the study. Once 20 participants had been allocated at each site, the RCT Study Coordinator reviewed the demographic information for each study arm at each study site to ensure equivalence of samples. Participants were fully aware of their group allocation rendering full blinding of the study centre research teams unfeasible.

Procedures

At baseline, all participants underwent comprehensive assessment of multidomain functions, including extensive physical, cognitive, psychosocial, nutrition and sleep examination (Supplementary Table S2). These assessments were repeated at 6-month intervals across the duration of the RCT (6- and 12-month time points—Supplementary Figure S1), and data from these three assessment points were used to ascertain the effect of the intervention programme on the functional status of each participant. Each study centre adhered

to a common study protocol manual to ensure consistency across study sites. Language appropriate versions of the tests were used at each centre (English, Italian, Austrian-German, Spanish and Japanese). Where validated alternate language versions were not available, forward–backward translation methods were used. Assignment of interventions was based on algorithms developed to match the need for intervention across each domain. Intervention packages were developed for physical, cognitive, psychosocial, nutrition and sleep domains [17].

Physical interventions

Interventions were selected to target the key physical markers of frailty: weight loss, physical weakness, reduced energy, motor slowing and reduced physical activity. The multicomponent physical interventions involved activities that combine strength and balance training over an extended duration. For the strength and balance domains, the Otago Home-based Exercise programme (OEP) [18] and the Fitness and Mobility Exercise programme (FAME) [19] were applied. Physical intervention type and frequency was determined on an individual basis by the intervention algorithm with the maximum physical intervention schedule of two OEP sessions and one FAME.

Cognitive interventions

Cognitive interventions comprised working memory training (N-back task) and cognitive bias modification therapy using attention bias modification tasks [20, 21]. To achieve maximum adherence, self-efficacy and engagement, the N-back task used graded difficulty whereby task difficulty was continuously adjusted to match participant level of performance. Cognitive bias modification therapy trains anxious or depressed individuals to disengage from threat-related stimuli and redirecting their attention toward other 'positive' stimuli.

Psychosocial interventions

Three social interventions were implemented in the My-AHA project: group activity interventions, group support interventions and a social media platform. Group activity interventions were planned in order to increase participant engagement in social interaction by provision of targeted group-based activities. Group support interventions provided an opportunity for participants to find targeted help and support.

Nutritional interventions

Nutritional interventions included individual meal plan generation and tailored nutritional advice and education. The meal planning system was based on anthropometric data, lifestyle, activity level and nutritional status of the participant as well as user preferences. The recommendations were official guidelines, determined by official nutritional institutions in each participating country. Participants received nutritional advice based on the food intake they logged into their food diary.

Sleep interventions

Sleep interventions comprised advice on methods to enhance sleep duration and quality. Participants were provided with two advice options: passive body heating or light exposure.

Platform delivery

After randomisation, subjects selected for the intervention group were enabled to use and interact with the My-AHA platform by using their own smartphone. My-AHA system is an ecosystem of platforms that integrates both commercials and developed *ad hoc* platforms in an ICT network composed of the following: (a) a middleware able to store data about the user and to connect to third-party applications, (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 designed for web and mobile applications and (d) connectors with third-party applications that can be used to register data.

Statistical analyses

Statistical analyses were performed using IBM Statistical Package for Social Science v26 (SPSS, Inc., an IBM Company, Chicago, IL, USA). Multiple hypotheses relating to intervention effects on evaluation of improvement in physical functions, cognitive function, social activity, nutrition, sleep quality, QoL and mood have been tested. Hypotheses were tested by repeated measures of multivariate analysis of variance (MANOVA)/analysis of variance (ANOVA), examining group (intervention versus control) and phase (T0, T1 and T2) main effects, with evidence of group × phase interaction effects indicating differences between groups over the course of the RCT. Covariates of age and/or education were added into the ANOVA models (analysis of covariance or ANCOVA) where independent correlations ($r > 0.30$) between any of the dependent variables and age/education were established (Supplementary Table S3). To correct for multiple comparisons, interrelated measures within each domain were analysed using MANOVA/multivariate analysis of covariance to correct for family-wise error prior to univariate ANOVA/ANCOVA analyses of individual variables [22, 23].

Results

Between 2 September 2017 and 30 September 2018, 636 individuals were screened (Supplementary Table S1) and 249 participants meeting inclusion criteria (Supplementary Table S1) were randomly assigned to the intervention group ($n = 123$) and to the control group ($n = 126$), receiving only regular health advice. A total of 201 (80.7%) participants completed the 12-month assessment. Baseline characteristics of the subjects involved in the study are shown in Table 1,

Table 1. Demographic characteristics of individuals in the intervention and control groups

Variable	Intervention	Control	*t*-test *P*	χ^2 *P*
n	101	100		
Age at baseline	70.37 (6.15)	73.40 (6.57)	0.001	
Total education (years)	13.44 (3.62)	13.13 (3.83)	0.554	
Sex (M:F)	30 (29.7%):71 (70.3%)	23 (23.0%):77 (77.0%)		0.281
Centre				<0.001
AUS	17	16		
AUT	24	10		
BEL	0	23		
GER	5	0		
ITA	18	16		
JPN	6	7		
ESP	31	28		
Relationship status				0.003
Single	10	13		
Married/*de facto*	59	48		
Separated/divorced	16	5		
Widowed	16	34		
Dominant hand				0.153
Right	101	98		
Left	0	2		
IPAQ activity level at baseline				0.435
Low	10	16		
Moderate	60	55		
High	31	29		

Table 2. Demographic comparison of active compared with withdrawn control and intervention participants

Variable	Active control	Withdrawn control	Active intervention	Withdrawn intervention	ANOVA *P*	χ^2 *P*
n at T0 (baseline)	126	NA	123	NA		
n at T1 (6 months)	112	14	114	9		0.301
n at T2 (12 months)	100	26	101	22		0.583
Age (years)–6 months	73.24 (6.58)	73.00 (6.97)	70.40 (6.22)	70.86 (8.10)	0.995	
Age (years)–12 months	73.40 (6.57)	73.93 (7.17)	70.37 (6.15)	71.11 (9.86)	0.673	
Total education (years)–6 months	13.20 (3.81)	13.18 (4.04)	13.30 (3.71)	13.00 (3.04)	0.870	
Total education (years)–12 months	13.13 (3.81)	13.48 (3.88)	13.44 (3.62)	12.55 (3.84)	0.303	

and multiple comparisons showed no significant difference between two groups.

From baseline to T2, 48 participants (22 in the intervention group and 26 in the control group) dropped out (Table 2). The drop out rate was 9.2% at 6 months and 19.3% at 12 months. Comparison between drop outs in the intervention group and drop outs in the control group showed no significant difference. The main reasons for drop out were the occurrence of family problems, long-distance travel and lack of interest in the research.

Analysis of the proportion of participants meeting prefrailty–frailty diagnostic criteria at each phase of the RCT is presented in Supplementary Table S5. Despite visual inspection of the data suggesting a higher proportion of the control group transitioned from prefrailty to frailty diagnosis across the course of the study, these differences did not reach statistical significance (Supplementary Table S5).

Analysis of the primary outcome variables indicated that there were some select domains of improvement that could be attributed to an intervention effect. A repeated measures ANOVA identified a significant phase effect (P = 0.003, η^2_p = 0.056, power = 0.873) and a significant group by phase effect (P = 0.025, η^2_p = 0.037, power = 0.682) (Supplementary Table S4). Examination of the interaction effect indicates that the control group displayed a significant decrease in QoL at the 12-month phase, with no change in QoL evident in the intervention group (Figure 1).

A repeated measures ANOVA of the Hospital Anxiety and Depression Scale (HADS)–Depression scores identified a significant group by phase effect (P = 0.048, η^2_p = 0.015, power = 0.590) (Supplementary Table S4). Examination of the interaction effect indicates that the control group displayed a significant decreased in level of depressed mood at the 6-month phase, which was maintained at the 12-month

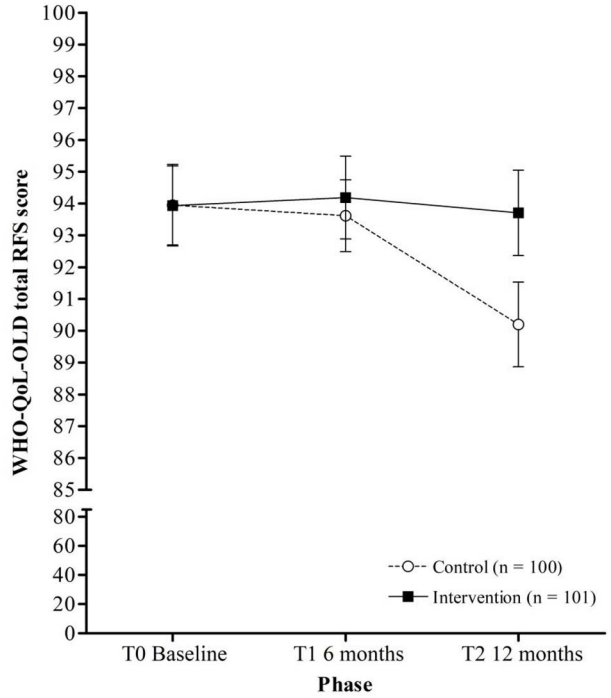

Figure 1. Group differences in World Health Organisation Quality of Life-Old module (WHOQOL-OLD) total Raw Facet Score (RFS) across RCT phases (mean ± SEM).

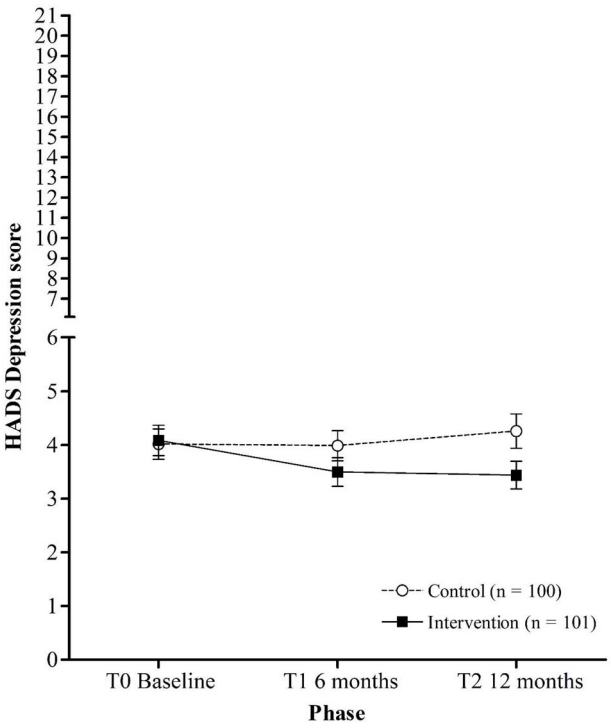

Figure 2. Group differences in HADS–Depression score across RCT phases (mean ± SEM).

phase, with the control group's level of depression mood increasing across 6- and 12-month phases of the RCT (Figure 2).

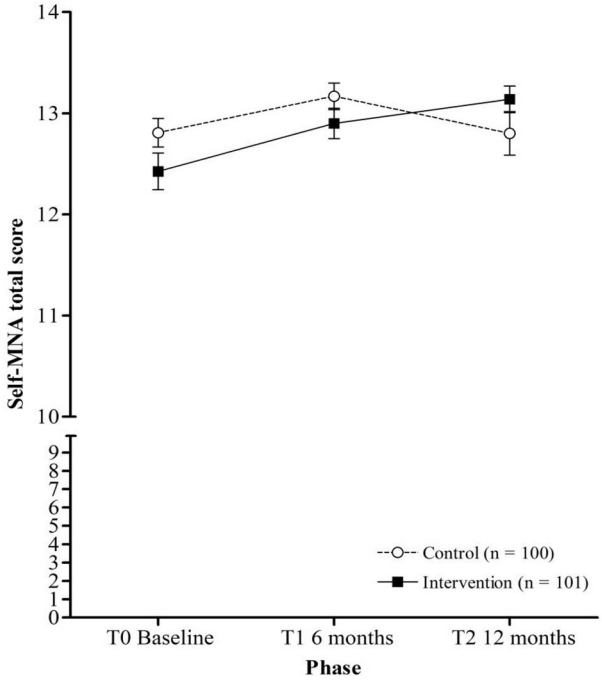

Figure 3. Group differences in self-MNA nutrition score across RCT phases (mean ± SEM).

The nutrition intervention was planned only for the 2nd period (from 6- to 12-month period) of the study. A repeated measures ANOVA of the self Mini Nutritional Assessment (self-MNA) score identified a significant phase effect (P = 0.004, η^2_p = 0.027, power = 0.849) and a significant group by phase effect (P = 0.047, η^2_p = 0.015, power = 0.591) (Supplementary Table S4). Examination of the interaction effect indicates that compared with the control group the intervention group displayed a significant increase in nutrition score at the 12-month phase relative to the 6-month phase (Figure 3).

No significant interaction effects were observed across any measures of physical function, cognitive function, social function or sleep. Significant main effects of phase were detected across multiple physical domain measures: International Physical Activity Questionnaire (IPAQ MetMin) score (P = 0.008, η^2_p = 0.024, power = 0.802), Timed Up and Go test time (P < 0.001, η^2_p = 0.048, power = 0.988), Short Physical Performance Battery (SPPB) fastest gait speed (P < 0.001, η^2_p = 0.050, power = 0.988), SPPB dual task gait speed (P = 0.049, η^2_p = 0.015, power = 0.586), SPPB total balance score (P = 0.003, η^2_p = 0.029, power = 0.876) and Activities-specific Balance Confidence Scale (ABC) total score (P < 0.001, η^2_p = 0.046, power = 0.980). The pattern of performances across these measures indicated a consistent improvement in performance displayed by both groups across the three phases of the RCT. Similarly, a significant phase effect was found on the Trail Making Test-A (P = 0.001, η^2_p = 0.034, power = 0.925), with a consistent improvement in simple visuomotor information processing speed observed across the three phases of the RCT in

both groups. Significant main effects of group were only detected on two measures: Stroop C incongruent time (P = 0.012, η^2_p = 0.032, power = 0.716) and Stroop C incongruent errors (P = 0.015, η^2_p = 0.030, power = 0.685). On both measures, the intervention group performed better than the control group across all three phases of the RCT (Supplementary Tables S1 and S2). No serious intervention-related adverse events were reported, and no individual died or was hospitalised.

Discussion

The purpose of our study was to evaluate the effects of an ICT supported personalised intervention in order to prevent conversion to overt frailty in prefrail older subjects. Our data indicate that the interventions deployed did not significantly improve measures of physical, cognitive, social or sleep function. Furthermore, there was no significant reduction in incidence of frailty over the 12-month trial duration. However, the intervention packages were found to result in a significant protection against a decline in QoL, which was observed in the control group, and to significantly reduce level of depressed mood and increase nutritional status.

The My-AHA RCT study targeted subjects in the prefrail stage, recruited from the general population and not from clinical settings, and without clinically significant cognitive or physical impairment. Therefore, lack of significant effects on physical prefrailty/frailty status is not unsurprising. The 12-month trial duration may not have been of sufficient length to detect relatively small changes in physical capacity required to transition from prefrail to nonfrail status. However, the significant difference observed between intervention and control individuals on measure of QoL is of intriguing relevance. QoL is a composite measure of multiple domains of a person's subjective experience of capability; the control group displayed a significant decline over the 12-month trial not observed in the intervention group suggests that a subjective experience of loss of capability is being noticed by older adults, which clinical measures lack sufficient sensitivity to detect.

Among older people, good QoL is an important public health goal [24, 25]. Our study showed that a personalised, multimodal intervention in prefrail subjects, increasing mood and nutrition function, significantly reduces age-related decrease in QoL. Several studies have shown that both depression and nutrition influence QoL in older adults [22–28]. Understanding additional factors related to QoL in older prefrail people can be used to accommodate patient needs and to reduce the burden of disease on older people and the health system. Furthermore, QoL measures should be routinely employed in clinical studies aimed at promoting healthy ageing.

Some limitations of our study require comment. The number of individuals recruited in this study is relatively low. We recruited a significantly higher percentage of female versus male individuals and there are significant differences in frailty parameters related to gender. Prefrail subjects were recruited in several European and non-European centres, with large intercentre cultural variability. However, such heterogenous, multicultural background may also be considered a strength of the study, showing effects of the personalised, multidomain interventions in individuals recruited in culturally different nations and with different lifestyles. Finally, the nature of the interventions deployed rendering standard blinding procedures unfeasible. Consequently, participants in the control group may have decided to engage in their own intervention programme that may reduce the magnitude of treatment effects. Further analyses of continuous sensor-based activity data collected (activity tracking watches) is currently being examined as a potential secondary source of information on the effect of the intervention on physical activity levels.

In conclusion, our study provides evidence that multidomain interventions, targeting physical, cognitive and psychosocial frailties, with the support of an ICT platform, may prevents decline in QoL of prefrail individuals. Additional studies are warranted in order to better investigate the neurobiological mechanisms underlying this effect.

Supplementary Data: Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

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Declaration of Conflicts of Interest: None.

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