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Faculteit Revalidatiewetenschappen

master in de revalidatiewetenschappen en de kinesitherapie

Masterthesis

The effect of a multicomponent intervention program, the My-AHA study, on frailty status in pre-frail older adults

Hannelore Steyvers
Lore Vanmunster
Scriptie ingediend tot het behalen van de graad van master in de revalidatiewetenschappen en de kinesitherapie, afstudeerrichting revalidatiewetenschappen en kinesitherapie bij musculoskeletale aandoeningen

PROMOTOR :
Prof. dr. Joke SPILDOOREN

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PROMOTOR :

Prof. dr. Joke SPILDOOREN

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Research context

This paper is situated in the domain of geriatric rehabilitation.

Frailty is a multifaceted syndrome affecting older adults and is correlated with a loss of physical functioning (Clegg, Young, Iliffe, Rikkert, & Rockwood, 2013). In community-dwelling older adults, aged 65 years or more, 17% have been described as frail and 42% as pre-frail (Santos-Eggimann, Cuénoud, Spagnoli, & Junod, 2009). Since more and more people live longer, one can become more vulnerable to develop frailty. This may lead to a loss of independence, functional decline, a higher demand of care and mortality (Morley et al., 2014). Physical activity seems to be effective to counteract this decline in physical functioning (Landi et al., 2018). There is evidence that a multicomponent intervention program, including a physical, cognitive, psychosocial and nutritional intervention had positive effects on the prevalence of frailty in older adults (Apóstolo et al., 2018). However, too little is known about the effect of a multicomponent intervention program on physical functioning in pre-frail older adults. Given the high prevalence of pre-frailty and its associated adverse health outcomes, it is necessary to do more research in this population.

This research project is part of an international study, called the My Active and Healthy Aging (My-AHA) project. The aim of this international project is to prevent older adults from becoming pre-frail or frail, by increasing the level of physical activity, cognitive functioning, psychosocial status, nutritional status, sleep and overall wellbeing. Several trial sites from different countries are involved: Australia, Austria, Belgium, Germany, Italy, Spain, Sweden and The United Kingdom. Researchers of the My-AHA study developed the overall design and methods used in this paper. Our promoter, Joke Spildooren, defined the procedure of approaching the participants.

The contribution of the master thesis students to this research was to investigate the control group in Belgium. Four Master students took the recruitment and data-acquisition of participants in Belgium for their account. They recruited 32 participants, and further subjected them to screening, baseline and follow-up measurements.

In this part of the duo master thesis, we used data from the control group (n=32) in Belgium and previously obtained data of 13 participants who participated in the intervention group in Austria. Despite the fact that the multicomponent intervention included physical, cognitive, psychosocial and nutritional interventions, our thesis project focused on the physical functioning of the participants. In addition, the other two Master students focused on the cognitive functioning of these pre-frail older adults.

On the one hand, we aimed to examine the effects of a multifactorial intervention program on the frailty characteristics and physical functioning in pre-frail older adults. On the other hand, we were also interested if the intervention program is effective to turn pre-frail older adults into robust older adults or to prevent them for becoming frail.

This paper was written independently by the students and was regularly sent to the promoter for improvement. In addition, the data-processing was carried out by the students and was checked by the promoter.

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The effect of a multicomponent intervention program, the My-AHA study, on frailty status in pre-frail older adults.

Abstract

Background Frailty and pre-frailty are considered highly prevalent in the older population (aged 60+ years). Nevertheless, most research focused on the effect of exercise in frail older adults to reverse this frail state. However, the potential beneficial effects of physical interventions in the pre-frail population remain underexplored.

Objectives To determine whether a multicomponent intervention program has a positive effect on frailty status and physical functioning in pre-frail older adults. Secondly, to investigate whether the intervention program is effective to prevent pre-frail older adults from becoming frail.

Methods We compared participants (n=13) subjected to a multicomponent intervention (intervention group) by researchers of the My-AHA group in Austria to participants recruited in Belgium (n=32), who received no intervention (control group). The Fried frailty criteria, physical tests, including Timed Up and Go (TUG), Timed Chair Stand Test (TCST), Four-meter walk test (4MTW), 4MTW + dual task and three static balance measures, were used to assess the level of frailty and physical function at baseline and after six months follow-up. These outcomes were then compared between the intervention and control group.

Results Descriptive analysis showed that 63.64% of the older adults became robust in the intervention group. In both the control group and intervention group, one participant switched to frailty. Statistical analysis demonstrated no significant differences in balance, strength, IPAQ score (International Physical Activity Questionnaire) and 4MWT. However, there was a significant improvement of mobility in the intervention group, compared to the control group at six months follow-up.

Conclusion Literature is inconsistent in findings about the reversal of frailty. This could be due to different definitions of frailty or due to the different types of physical interventions. Amelioration in mobility, found in the intervention group, is consistent with literature about frail older adults.

Introduction

Frailty is a complex syndrome in which there is a loss of homeostasis due to a weakening of multiple physiologic systems. This could lead to a decreased resistance to stressors, causing an increased vulnerability (Fried et al., 2001; Lang, Michel, & Zekry, 2009). Frailty is associated with rising hospitalization, adverse events, mortality (Fried et al., 2001) and poor social functioning (Hoogendijk, Suanet, Dent, Deeg, & Aartsen, 2016).

Estimates by the World Health Organization showed that the number of people aged 60 years was estimated at 600 million in the year 2000, a figure that is expected to rise to 1.2 billion by 2025 and 2 billion by 2050 (Janssen, Shepard, Katzmarzyk, & Roubenoff, 2004). Despite this drastic increase, there are not enough caregivers available for this geriatric population. Furthermore, it is crucial to keep this older population healthy for the general well-being of the whole population but also for socio-economic reasons (World Report on Ageing & Health. Luxembourg: World Health Organization; 2015).

A great number of people over 60 years are likely to become frail. In a systematic review, published in 2012, the overall prevalence of frailty was found to be 10.7 % and increases with age and (female) gender (Collard, Boter, Schoevers, & Oude Voshaar, 2012).

Hence, frailty is becoming a key problem, which should be faced in the upcoming decades. Therefore, a standardized and valid method for screening those who are truly frail is necessary to effectively develop interventions to target care.

Fried et al. (2001) provided a potential standardized definition in community-dwelling older adults for clinical assessment for those who are frail or at risk, based on five criteria: unintentional weight loss, self-reported exhaustion, weakness (grip strength), slow walking speed, and low physical activity. If three of the five markers are present in an older individual, this person is considered frail.

Pre-frailty, a state preceding frailty, is an intermediate state between robust, healthy older adults and frail older adults. The presence of one or two markers of the frailty phenotype is necessary to identify an older adult as pre-frail (Fried et al., 2001). It is important to detect these older adults to prevent them from becoming frail. Pre-frail older adults are less vulnerable to stressors than frail older adults, however they experience more depressive symptoms, nutritional problems, score worse on self-reported health, the Mini-mental State

Examination (MMSE) and the Functional Comorbidity Index than robust older adults (Tikkanen et al., 2015).

It is possible to counteract the markers of frailty in frail older adults. In the literature study for master thesis part one, the effects of an exercise intervention on frailty were researched. These results supported the effect of a multicomponent (different types of exercise) intervention program in the improvement of frailty. Moreover, exercise in combination with interventions in other disciplines also has a positive effect (Apóstolo et al., 2018; Dedeyne, Deschodt, Verschueren, Tournoy, & Gielen, 2017). A nutritional program with sufficient protein intake (1.1g/kg/day, distributed over three meals) in combination with exercise showed a positive effect on the frailty and nutritional status (Artaza-Artabe, Sáez-López, Sánchez-Hernández, Fernández-Gutierrez, & Malafarina, 2016).

Little evidence is available for the recommendation of a multicomponent intervention program in pre-frail older adults (Frost et al., 2017). According to Seino et al, the combination of resistance exercise, nutritional education and a psychosocial program twice a week for three months caused a reduction in frailty and a better functional health in (pre-) frail older adults (Seino et al., 2017). Physical intervention plays a key role in multicomponent interventions (combined with a nutritional, psychosocial or cognitive intervention) (Dedeyne et al., 2017). Three to 12 months of group-based exercise is beneficial for physical functioning, balance and muscle strength in pre-frail older adults (Frost et al., 2017). On the other hand, home-based therapy in pre-frail older adults is often a great alternative for group-based therapy (Daniel, 2012), or could be combined with a group-based program in order to exercise more regularly (Mehra et al., 2018).

In literature, less is known about pre- frail older adults and the possibility to reverse their pre-frailty status. Previous studies have shown that nutritional interventions, exercise, social events and cognitive training each had positive effects on markers of frailty. Hence, the objective of this clinical trial was to investigate whether pre-frail older adults could also benefit from these interventions during a six-month intervention period. We hypothesize that a multicomponent intervention has a positive effect on frailty and physical characteristics.

Methods

Participants

Participants were recruited from July 2018 until September 2018 through advertisements, contact with senior groups and social media. The people who were interested in participating in this study were contacted by telephone or e-mail to make a first appointment. During the first testing moment, participants were screened for inclusion and exclusion criteria. Participants received an informed consent, which they signed before screening began. Inclusion criteria included community-dwelling older adults (aged ≥ 60 years), being pre-frail (one or two markers of the Fried frailty phenotype), lack of impaired cognitive functioning (Mini Mental State Examination, MMSE) and no depression or anxiety (Hospital anxiety and depression scale,(HADS)). Pre-frailty was defined if one or two of the five markers of the Fried frailty phenotype were present: (1) unintentional weight loss, (2) self-reported exhaustion, (3) weakness (grip strength), (4) slow walking speed, and (5) low physical activity. Unintentional weight loss can be described as a decrease in weight of ≥4.5 kg or ≥ 5% of the body weight in the last 12 months. To determine whether this was present after six months of follow-up, the margin was set to ≥ 2.25 kg or ≥ 2.5% of body weight. Grip-strength, measured by using the Jamar Dynamometer (cut-off values based on gender and Body Mass Index (BMI)). Exhaustion was assessed by two multiple-choice questions from Centre for Epidemiologic Studies Depression Scale: CES-D (Radloff, 1977)). Walking speed was measured by the four-meter walk test (4MWT, cut off based on gender and height) and level of physical activity was measured by the IPAQ. Lack of impaired cognitive functioning was assessed by the MMSE (MMSE >24), with correction for less education. To rule out severe cognitive impairments, the MMSE, a valid and reliable test for diagnostic purposes in older adults with dementia, depression and cognitive impairments, was used (Folstein, Folstein, & Mchugh, 1975). To rule out anxiety (HADS Anxiety <15) or depression (HADS Depression < 15), the HADS was incorporated for its good sensitivity and specificity in the general population (Bjelland, Dahl, Haug, & Neckelmann, 2001; Zigmond & Snaith, 1983). The participants who met the inclusion criteria and did not have any of the exclusion criteria were included in the control group. The same screening protocol was used for the intervention group, located in Austria. Exclusion criteria for the physical and/or psychological conditions are listed in table 1.

Procedure

This study is part of an international research project, called the My Active and Healthy Aging study (My-AHA project). The countries participating in this study include Australia, Austria, Belgium, Germany, Italy, Spain, Sweden and The United Kingdom. In this clinical trial, randomization was not possible between the intervention group and the control group. However, the overall design of the international My-Aha project was randomized. For this Master Thesis, subjects were divided into two groups: an intervention and a control group. The intervention group received a multicomponent intervention program of six months, including physical exercise, cognitive interventions, nutritional education and psychosocial interventions. The control group did not receive any intervention. Researchers of the My-AHA project in Austria conducted the multicomponent intervention. Master students at the UHasselt in Belgium collected the data of the control group. A screening test was performed prior to the start of the study, followed by the baseline measurement (T0), one month later. Six months after baseline testing, the follow-up (T1) measurement was conducted. This study was approved by the Medical Ethics Committee of the University of Hasselt (CME2018/034) at July 15,2018. Trial number: B9115201836735.

Despite the fact that the multicomponent intervention included physical, cognitive, psychosocial and nutritional interventions, our thesis project will focus on the physical functioning of the participants. Baseline (T0) and follow-up testing (T1; 6 months later) were performed using the five frailty markers mentioned before and four physical function tests: Timed Chair Stand Test (TCST), the TUG (Podsiadlo & Richardson, 1991), a balance test (standing with feet together, semi tandem- and tandem stance) and the 4MWT(+ dual task). These physical function tests are able to identify a deterioration of function (Yamako, Chosa, Totoribe, Fukao, & Deng, 2017). According to Savva et al. (2013), the TUG can detect whether a person becomes frail (TUG>10 s) (Savva et al., 2013). Every assessment was carried out at the place where the participants lived. The primary outcome of this study was the prevalence of pre-frailty after six months follow-up, according to the criteria of the Fried's frailty phenotype. One can be described as robust, by meeting none of these criteria, pre-frail when meeting one or two of the criteria and frail when meeting three or more of these criteria. Secondary outcomes were mobility, assessed by using the TUG, strength using the TCST (Csuka & Mccarty, 1985) and balance.

Intervention group

Thirteen participants were included in the intervention group. A multicomponent intervention, called the My-AHA platform, was applied to the experimental group in Austria. The four components of this intervention program are a physical, cognitive, psychosocial and nutritional intervention. The effect of a multifactorial approach has been proven to be positive on the prevalence of frailty (Apóstolo et al., 2018).

First, the physical component will be discussed. Activities that focus on strength, balance and endurance were implemented. A multicomponent exercise intervention, consisting of resistance, balance and gait exercises, can meliorate functional parameters (Cadore et al., 2014; Weening-Dijksterhuis, de Greef, Scherder, Slaets, & van der Schans, 2011). Participants trained at a frequency of three times a week, 30 to 45 minutes per session. The total amount of physical training was three hours each week. The programs applied in this study were the Otago home-based Exercise program (OEP), the Fitness and Mobility Exercise program (FAME) and an endurance training program. OEP (Gardner, Buchner, Robertson, & Campbell, 2001), a home-based, individually tailored program focusing on strength, balance and the ability to walk for the ultimate goal of fall reduction, was performed once a week for 30 to 45 minutes without supervision (Beato, Dawson, Svien, & Wharton, 2018). In advance an instructor explained all the exercises and handed over a booklet with a short description of the exercises. Ankle cuffs were used to provide resistance during the exercises. FAME (Eng, 2010), a group-based muscle strength, balance and endurance training program, proven to provide a significant decline in fall rate, was carried out with supervision of a physical instructor, once a week for 30 to 45 minutes (Iliffe et al., 2014). One instructor was provided per five participants to ensure that adequate supervision was possible. Endurance training was targeted by an activity of choice, executed once a week. The intensity of the training started at moderate intensity (month 1-2: 50% $HR_{max,}$ 30min/session) and gradually increased during the study (month 6: 60% $HR_{max,}$ 40 min/session). The goal was to achieve a minimum of 65% of the HR max for 150 min per week.

The cognitive intervention contained working memory training (N-back task) and cognitive bias modification therapy (CBMT). Working memory training for several weeks with the N-back task seems to be important to improve the fluid intelligence, responsible for pattern recognition, reasoning and problem solving abilities, in adults (Au et al., 2015). Intensity is adapted to meet for individual needs and to achieve maximum adherence. N-back task challenged the working memory. Two versions were used, namely a letter-based and a visuo-spatial (a 3 by 3 blue square) version. Participants were asked to remember which letter or which square was displayed n-letters previously. Each participant could use this tool on the My-AHA app. The larger the number of n, the more difficult the task would be. Level of difficulty was progressed individually to ensure the working memory was being challenged (von Bastian & Oberauer, 2014). Immediate feedback was given to the participants. Cognitive bias modification therapy was used to train participants by letting them unconsciously give attention to a positive option over a negative option. For example, a happy and a sad face appeared on the screen. The participants had to select the button beneath the face according to the number of presented dots. When doing this frequently, it will become a habit to choose positive stimuli and let go of threat-related stimuli which leads to reduced vulnerability to negative stimuli (MacLeod, Rutherford, Campbell, Ebsworthy, & Holker, 2002).

Three different psychosocial interventions were incorporated: a group support intervention, group activity interventions and social media platforms. Good quality of life can be partially obtained by maintaining a strong social network (Rogers & Mitzner, 2017). Participants received suggestions for support groups on their My-AHA platform. Furthermore, groups were created with shared interests to undertake activities together. That way, participants could interact with each other while engaging in activities and were able to seek support with one another. Furthermore, the social platform encouraged to communicate and provide recommendations to each other. Participants could enter the platform whenever they wanted.

The last intervention focused on stimulating healthy nutritional habits of the participants. Prevention of malnutrition will reduce the risk to become frail (Artaza-Artabe et al., 2016). An application, VitalinQ, was used to plan meals ahead of time, taking personal preferences into account. Based on their food diary, they also got advice and education from the VitalinQ nutritional database of regarding their nutritional habits.

Control group

The 32 participants in the control group continued their daily routine without any form of intervention. When a participant in the control group was considered frail at one of the measurement moments (baseline or six months), one was able to get access to the intervention platform to meet ethical obligations.

Statistical analysis

The statistical analyses were carried out by using JMP Pro 14.1 (SAS). Baseline characteristics (age, gender, height, weight, BMI and cognitive function) were evaluated. The Welch test was used for age while a pooled t-test was employed for height, weight and BMI. Means of cognitive function were checked by a Wilcoxon test. The Fisher's exact test was used for gender and balance. For the categorical data (balance, frailty criteria), descriptive statistics were applied. For the continuous data (TCST, TUG, 4MWT, 4MWT+dual task, IPAQ and hand grip strength) , a mixed model analysis with repeated measures was implemented. An alpha level of 0.05 was significant for all tests.

Results

A total of 45 participants were included in this trial. In Austria, the intervention group consisted of 13 participants, whereas 32 participants were part of the control group in Belgium. No significant difference in demographics (age, height, weight, BMI, cognitive functioning) were observed between the intervention and the control group except for gender which differed significantly (p=0.02). The number of female participants in the control group was 84.38%, whereas the male participants represented 15.62% of the control group. In the intervention group, 46.15% of the participants were female and 53.85% were male. Table 2 represents the baseline characteristics of the participants.

Some drop-outs were reported (see flowchart in figure 1.) and statistics were not applied to the drop-outs. At six-months follow-up, the intervention group consisted of 11 participants and the control group of 26 participants. During this six-month trial, two participants deceased in the control group. The remaining subjects who dropped-out had difficulties in persevering a long-term commitment (six months) for this study.

Frailty criteria

Only pre-frail older adults were included in this study. At baseline, the majority of the participants in the intervention group (63.64%) and in the control group (76.92%) had one criterion of the Fried frailty criteria. A total of 36.36% in the intervention group and 23.08% in the control group scored positively on two of the five frailty criteria (table 3).

At six months follow-up, a total of seven participants in the intervention group became robust (meeting none of the frailty criteria), accounting for 63.64%, whereas six participants in the control group became robust, accounting for 23.08%. Nineteen controls remained pre-frail, accounting for 73.07%. In the intervention group, 27.27%, was still pre-frail. A shift towards frailty was made for one (3.85%) participant in the control group, scoring positive on three criteria and one (9.1%) person in the intervention group (table 3).

The most common criterion for meeting the pre-frailty criteria in the control group was hand grip strength (table 4). Twenty-two participants met this criterion at baseline testing, indicating that they had a hand grip strength less than the cut-off criterion. However, in the intervention group, participants were pre-frail mostly because of unintentional weight loss, accounting for eight participants. After six months follow-up, there was an even distribution of the participants over the criteria in the intervention group. In the control group at the follow-up measurement, 16 participants met the threshold for poor hand grip strength. Nine people in the control group scored less than the cut-off score for the characteristic of exhaustion at T1 (table 4). Although, two participants met this criterion during baseline measurement (T0).

Balance

In the intervention group 27.27% made progression regarding balance, for the remaining 72.73%, no change was observed between baseline and follow-up measurements. Most of the control group (76.92%) showed no progression nor decline. Hence, 11.54% demonstrated a retrogression in balance, whereas only 11. 54% showed an improvement in balance (table 5). No significant difference was found in balance when comparing the control and intervention group and the times of measurements (p=0.39).

Mobility

Analysis demonstrated a significant interaction effect of group by time (p=<.0001*). In the intervention group, there was a significant decrease in the time required to complete the TUG (p= <.0001) after follow-up (T1). This was not seen in the control group (p=0.68) after six months follow-up (T1) (table 6). The Timed Up and Go Test showed a significant main effect of group (p=<.0001*), where both groups differed significant at baseline (T0). The mean score for the intervention group was 13.75s and for the control group 9.90s. A significant main effect of time (p=0.03) was present. The intervention group improved significant after the intervention. (p=<.0001*)

Strength

The control group showed a significant improvement (p=0.0101*) on the TCST, compared to baseline (T0). A decrease in the time, required to complete the TCST, was observed in the control group. The intervention group demonstrated no significant differences over time (p=0.12). The mixed model with repeated measures analysis showed no interaction effect of group by time (p=0.88). However, there was a main effect of time (p<0.01). Analysis showed a significant increase at T1 for the control group (p=0.0101). No main effect of group (p=0.30) (table 6).

Hand-grip strength was measured, using the Jamar Dynamometer. Data-analysis showed no significant interaction effect of group by time (p=0.81). But, a main effect of time (p=0.0064) where the control group improved significant and a main effect of group (p=<.0001) at baseline and follow-up was present. Both groups differed significantly at baseline (p=<.0001) and follow-up (p=<.0001), where the mean grip strength of the intervention group was 31.23 kg and the control group scored 17.25 kg at baseline. At follow-up, these mean scores were respectively 32.75 kg for the intervention group and 19.05 kg for the control group respectively. The intervention group did not improve (p=0.12), whereas the control group made significant improvements (p<0.01) (table 6).

International physical activity questionnaire (IPAQ)

There was no interaction effect of group by time (p=0.85). A main effect of time (p=0.76) for the IPAQ-score was not present. However, a main effect of group (p=<.0001*) was apparent. There were significant differences in baseline score between the intervention group and control group (0.0009*). The intervention group initially scored an average of 8397.93 kcal per week and the control group achieved an average of 2433.98 kcal per week. This difference was maintained at six months follow-up (0.0004*). Where the average in the intervention group was 8982.13 kcal per week, the control group achieved 2567.22 kcal per week. Overall, neither the intervention group nor the control group did significantly change after six months follow-up (table 6).

4-meter walk test and 4-meter walk test with dual task

An interaction effect of group by time was not found for the 4MWT (p=0.45), as well as in the 4MWT with dual task (p=0.85). Results from the mixed model with repeated measures analysis showed no significant main effect of time for the 4MWT (p=0.90) and the 4MWT with dual task (p=0.94), nor a significant main effect of group in the 4MWT (p=0.75) and the 4WMT with dual task (p=0.68) (table 6).

After six months of follow-up, both intervention group (p=0.87) and control group (p=0.92) did not significantly improve in time to perform the 4-meter walk test. Neither did the control group (p=0.92) or the intervention group (p=0.87) improve in the 4MWT with dual task (table 6).

Discussion

This study contributes to our hypothesis that pre-frailty could be reduced or be slowed down by a multicomponent intervention program. Participants in the intervention group, who cooperated in this trial, improved on mobility, measured by the TUG. For muscle strength, measured by the TCST and Jamar Dynamometer, a significant improvement of strength was observed in the control group. Moreover, a between group difference was found for hand grip strength in favour of the control group, which contradicts the hypothesis of this study. In addition, the degree of physical activity was not found to be statistically significant different for the intervention group, after the follow-up. However, at baseline, participants in the intervention group already had high levels of activity, compared to the control group. Furthermore, this study provides no evidence that a decline in balance could be prevented. No significant difference could be found. For gait speed, no differences were found after the six-month follow-up measurement.

According to descriptive analysis, a part of the participants in the intervention group improved in the degree of frailty. The incidence of pre-frail older adults after the intervention was lower than at baseline. The control group was more likely to remain pre-frail or to become frail. Several studies have shown that an exercise program appears to be effective in combating frailty, whether or not in a multifactorial setting with physical, cognitive, psychosocial and nutritional interventions. According to Nagaia et al. (2018), a six-month during resistance training program, two times per week in frail older adults, combined with feedback and monitoring and information about nutrition does not exert significant effects when compared to resistance training only. However, pre-post analysis showed significant decreases in frailty scores in the intervention group with feedback (Nagaia et al., 2018). This finding is also stated in a multifactorial intervention program in frail older adults, which comprised of resistance training, nutritional education and psychosocial assistance, which lasted three months and was carried out two times per week for 100 minutes per session. Resistance training was performed for 60 minutes per session, ten minutes of rest and the remaining 30 minutes they received either a nutritional or a psychosocial intervention, every two weeks. (Seino et al., 2017). In the My-AHA project, only participants who were pre-frail were included in the study. Resistance, balance and

endurance training were incorporated in the intervention program. No specific balance or resistance training program was applied. However, some studies do not contribute to this statement (Trombetti et al., 2018). Trombetti et al. (2018), did not associate a decrease in frailty status after a multicomponent intervention program, with two year follow-up, including aerobics, resistance training and flexibility exercises, compared to health education and stretching. However, frailty was not one of the inclusion criteria, causing a relatively small sample size (19.7%), compared to non-frail older adults.
The different studies handled different methods to state frailty. Some studies use stricter criteria to determine frailty. If the threshold is fairly low to meet the criteria, a significant difference can be determined more rapidly. One could assume that pre-frailty in community-dwelling older adults could be prevented by a multifactorial intervention program, consisting of physical activity, nutritional and psychosocial interventions. In addition, a golden standard for assessing frailty would be required.

Weight loss could be due to the intervention program or could be unintentional. It is difficult to determine in which the cause lies. Moreover, body weight varies depending the time of the day. This could lead to a bias, since the participants were not tested on the same time of the day. The participants who met the criterion for unintentional weight loss at baseline and at follow-up, were scored positively for this criterion at follow-up. Participants who did not meet the criteria at baseline, but did lose weight at follow-up, were not scored positive for the criterion of weight loss, since they received a nutritional intervention to maintain a healthy body weight.

No differences were found in the 4MWT or in the 4MWT with dual task in both groups. This is contradictory to the findings of Sugimoto et al. (2014) However, in the latter study a strength training program within the multifactorial program was applied. In healthy older adults, it is shown that a resistance training program improves leg strength hereby causing an improvement in gait speed. Leg power training was done by using a leg press for three sets of ten repetitions at 30%-40% 1RM (Uematsu et al., 2018). Furthermore, the walking activity in the OEP was replaced by an activity of choice (bicycling, home trainer, treadmill, Nordic Walking, walking). This is a possible explanation why no significant improvement was found after the intervention program, assuming that not every participant chose the same endurance activity.

The IPAQ-scores remained stable in both groups. At baseline, the scores of the intervention group were almost three times higher than in the control group. Although, the intervention group participated in an exercise intervention program, one should expect that the scores would differ significantly after the intervention. A possible explanation is that the participants in the intervention group at baseline already had a high level of physical activity, compared to the control group.

Nevertheless, this multifactorial intervention contributed to a significant improvement of mobility in the intervention group, using the TUG. Whereas in the control group, this phenomenon was not present. The control group remained stable. In studies with frail older adults, this finding is consistent with our findings. In older adults, suffering from major mobility disability, a moderate intensity exercise program is beneficial to regain mobility. The intervention involved walking of 150 min/week, strength, flexibility and balance training, 3 – 4 times a week and lasted 2.5 years (Pahor et al., 2014). Sugimoto et al. (2014), suggested that mobility significantly improved in an exercise program in pre-frail older women, compared to non-frail older women. This 1-year preventative exercise program compromised one intervention program and was carried out once a week. This included a warm-up, strength exercises by its own weight, balance and rhythmic exercises (Sugimoto, Demura, Nagasawa, & Shimomura, 2014). As depicted by Podsiadlo et al. (1991), the TUG is a reliable and valid tool for assessing mobility in frail older adults. In addition, it is sensitive to detect clinically relevant change (van Iersel, Munneke, Esselink, Benraad, & Olde Rikkert, 2008). It is a complex test, consisting of various functional tasks of the ADL, including rising from a chair, walking, rotating and sitting down on a chair (Nagaia et al., 2018). This result indicates that to maintain or to improve the mobility of these pre-frail older adults an exercise intervention program consisting of strength, balance and aerobic exercise could be beneficial.

No significant improvements were made in the intervention group for the balance test compared to the control group, however there is no deterioration detectable. According to

Cadore et al. (2014), balance melioration and a reduction in falls can best be achieved by a multicomponent exercise intervention program including strength, endurance and balance training. Balance training should include many stimuli to challenge the patient, for example standing on one leg (Cadore, Rodríguez-Mañas, Sinclair, & Izquierdo, 2013). After a four week program targeting strength and balance, a progression was seen in balance confidence, performance and gait in community dwelling older adults (Miller, Magel, & Hayes, 2010). This study included only three static tests to measure balance. At baseline most participants scored maximum on the test which causes a ceiling effect in future measurements. This is a possible explanation why no significant improvement could be found. A study with an intervention program of 10 weeks with a Wii-training (both strength and balance training) two times a week did also found no difference in static balance in community-dwelling older adults compared to a control group (Jorgensen et al., 2013). This could be due to the possibility that Wii-games are not physically challenging enough. Literature isn't conclusive about the effect of exercise for balance, but most literature is focused on community dwelling older adults or frail older adults.

Strength was assessed by using the TCST and the Jamar Dynamometer. Timed chair stand test is a reliable test with good to high test-retest reliability to assess strength in community-dwelling older adults. Additionally, clinical important change between measurements is difficult to determine (Bohanno, 2011). Although only the control group made significant improvements in strength, compared to baseline, the intervention group had a tendency towards improvement. However, this was not statistically significant, contrary to our hypothesis. However, Cadore at al. (2014) stated that a multicomponent (resistance, balance and gait retraining interventions) exercise intervention program is effective to improve mean leg strength.

Hand-grip strength was measured, using the Jamar Dynamometer. Only the control group improved in hand-grip strength and showed a significant difference compared to the intervention group. The Jamar Dynamometer is a reliable and valid instrument to assess strength (Schaubert & Bohannon, 2005). These findings contradict the existing literature. Neumann et al. stated that in older adults more difficulties were present in handling the tool due to the size and weight (Neumann, Kwisda, Krettek, & Gaulke, 2017). This could be a reason why 22 participants in the control group met the criterion for hand grip strength at baseline. Six of these participants in the control group returned to a robust, healthy state at follow-up. A possible explanation is that a learning effect was present.

In a narrative review, one concluded that a multifactorial exercise program is recommended for pre-frail and frail older adults, for improving strength, gait speed, balance and physical performance. The interventions consisted of a resistance training program, balance exercises and flexibility tasks. This was done 2-3 times a week, approximately 10-90 minutes per session for 2.5 months. (Jadczak, Makwana, Luscombe-Marsh, Visvanathan, & Schultz, 2016). According to Haider et al. (2019) there is limited evidence that a multifactorial intervention program is effective the increase muscle mass or strength. Cadore et al. (2013), stated that to improve muscle strength, a resistance training program should be part of a multifactorial intervention in order to gain more strength or muscle mass. This could lead to the contradiction in findings. The My-AHA study did not apply a specific resistance training program.

Strengths

This study is part of a larger international study. A selection of participants and times of measurements was made. However, it is still possible to look at the bigger picture and combine all the data from many different countries to see if an effect could be demonstrated with a larger sample size and follow-up.

This is one of the first studies combining a physical, nutritional, psychosocial and cognitive intervention program in pre-frail older adults.

Limitations

At baseline, the intervention group were significant more active than the control group. This is why there is probably no improvement in activity level after the intervention.

Randomisation of the participants was not possible in the control group. Hence, researchers were not blinded to group allocation. Moreover, the participants were not tested at the same time of the day, this could possibly have led that some participants were more or less fatigued at the time of testing, compared with baseline testing.

Furthermore, the sample size was very small in the intervention group and an uneven distribution of male and female participants was present. Some dropouts were reported, these dropouts were not included in the data-analysis. For hand grip strength a different instrument should be used, since in the control group most participants met this criterion and it is stated that measurement errors could occur due to the size and weight of the Jamar Dynamometer.

Risk for bias

Participants were recruited through advertisements and contact with senior groups. Only older adults who were interested to participate were included. Perhaps, especially active older adults were interested. This could lead to a selection bias because this is not always a good representation of the whole population.

Furthermore, in data-analysis too little confounding variables were taken into account. For example gender and the intensity of activities established by the participants in their leisure time.

Moreover, the researchers in the control group were not blinded which could lead to a detection bias.

Further implication for clinical application and further scientific research

Frailty criteria: grip strength and unintentional weight loss, are most frequently seen when an older adult is pre-frail. Therapy should focus on more specific needs for the individual older adult. A multifactorial intervention has a positive effect on mobility in pre-frail older adults. However, other outcomes were not found to be significant after this intervention. Further research should focus on pre-frail older adults and use bigger sample sizes to possibly detect a difference. The My-AHA study could show after termination (at 12 months) other results than those obtained in this study.

Conclusion

It is possible to return to a robust state when enrolling in a multicomponent intervention program. There is no improvement in most physical measurements, mainly due to the significant differences at baseline between both groups for the level of physical activity, mobility, strength and gender. However, a melioration in mobility could be accomplished. The program focused on different aspects of functioning which were not investigated in this study. For example, cognitive function or social interaction. For the physical component, a specific exercise program could be more effective to improve strength, balance and walking speed. Most research focuses on the biological aspect of functioning. Notwithstanding, it is also important to integrate the different facets of the biopsychosocial model. Further results of the My-AHA study could provide more clarification on this topic and other aspects of functioning.

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Appendices

Tables

Table 1

Conditions for exclusion

Physical conditions	**Psychological conditions**
Painful arthritis, spinal stenosis, amputation or painful foot lesion that affect balance and mobility.	Severe depression
Neurodegenerative pathology (central or peripheral nerve system)	Schizophrenia
Neuromuscular disease	Bipolar dysfunction in the past five years
Stroke in the past two years	Other psychotic disorders
Ischemic attack in the past two years	Substation related disorders in the past two years
Notable head injury with loss of consciousness, skull fracture or persistent cognitive disturbances	
Epilepsy	
Significant visual disturbance	
Significant hearing disturbance	
Severe heart disease	
Symptoms of respiratory failure	
Untreated high blood pressure	
Cancer	
Endocrine disease	
Orthostatic hypotension	

Table 2

Baseline characteristics for the control and intervention groups

	Control group (n=32)	Intervention Group (n=13)	P value
Age (years)	78.19 (±5.29)	73.77 (±9.39)	0.1310
Sex (%female)	84.38%	46.15%	0.0216*
Anthropometrics			
Height (m)	1.62(±0.08)	1.66 (±0.11)	0.2724
Weight (kg)	72.94 (± 13.71)	77.69 (±14.95)	0.3089
BMI (kg/m^2)	27.62 (±4.58)	28.21 (±4.26)	0.6936
MMSE	27.8333 (±2.80)	28.15 (±1.77)	0.2815

BMI: Body Mass Index; MMSE: Mini Mental State Examination

Table 3

Frailty criteria at baseline and at 6 months follow-up

Frailty criteria	T0 Intervention group (n=11)	T0 Control group (=26)	T0 Total	T1 Intervention group (n=11)	T1 Control group (n=26)	T1 Total
Robust (%)	0	0	0	7 (63.64)	6 (23.08)	13 (35.14)
1 criterion Pre-frail (%)	7 (63.64)	20 (76.92)	27 (72.97)	3 (27.27)	12 (46.15)	15 (40.54)
2 criteria Pre-frail (%)	4 (36.36)	6 (23.08)	10 (27.03)	0	7 (26.92)	7 (18.92)
3 criteria Frail (%)	0	0	0	1 (9.09)	1 (3.85)	2 (5.41)
4 criteria Frail (%)	0	0	0	0	0	0
Total (%)	11 (29.73)	26 (70.27)	37 (100)	11 (29.73)	26 (70.27)	37 (100)

Table 4

Distribution of frailty criteria

		Unintentional weight loss (n)	Handgrip strength (n)	Exhaustion (n)	Gait speed (n)	Physical activity (n)
IG	T0	8	2	4	1	0
	T1	1	2	1	1	1
CG	T0	2	22	2	4	2
	T1	1	16	9	3	0

IG: Intervention group; CG: control group

Table 5

Balance scores at baseline and at 6 months follow-up

	T0 Intervention group (n=11)	T0 Control group (n=26)	T0 Total (n=37)	T1 Intervention group (n=11)	T1 Control group (n=26)	T1 Total (n=37)
Score 3 (%)	8 (72.73)	22 (84.62)	30 (80.08)	10 (90.09)	23 (88.46)	33 (89.19)
Score 2 (%)	2 (18.18)	4 (15.38)	6 (16.22)	1 (9.09)	2 (7.69)	3 (8.11)
Score 1 (%)	1 (9.09)	0	1 (2.70)	0	1 (3.85)	1 (2.7)
Score 0 (%)	0	0	0	0	0	0
Total (%)	11 (29.73)	26 (70.27)	37 (100)	11 (29.73)	26 (70.27)	37 (100)

Table 6

Characteristics of physical functioning at baseline and 6 months follow-up

Characteristics	T0 Intervention group (n=11)	SD	T0 Control group (n=26)	SD	Between group p-value	T1 Intervention group (n=11)	SD	T1 Control group (n=26)	SD	Between group p-value	T0→T1 Intervention group	T0 → T1 Control group
Grip strength (kg)	31.23	(2.39)	17.25	(1.55)	<.0001*	32.75	(2.39)	19.05	(1.55)	<.0001*	0.12	0.0068*
TUG (s)	13.75	(0.77)	9.90	(0.50)	0.0001*	9.54	(0.77)	9.72	(0.50)	0.84	0.0001*	0.68
4MWT (s)	4.16	(0.27)	4.33	(0.17)	0.59	4.22	(0.27)	4.24	(0.17)	0.95	0.71	0.43
4MWT+DT (s)	6.23	(0.88)	6.68	(0.57)	0.67	6.42	(0.88)	6.60	(0.58)	0.87	0.87	0.92
IPAQ (kcal)	8397.93	(1437.10)	2433.98	(934.75)	0.0009*	8982.12	(1437.10)	2567.22	(954.14)	0.0004*	0.76	0.92
TCST (s)	13.74	(1.00)	14.96	(0.65)	0.31	12.45	(1.00)	13.52	(0.65)	0.37	0.12	0.0101*

TUG: Timed Up and GO; 4MWT: 4 Meter Walk Test; 4MWT+ DT: 4 Meter Walk Test with Dual Task; IPAQ: International Physical Activity Questionnaire; TCST: Timed Chair Stand Test

Figure

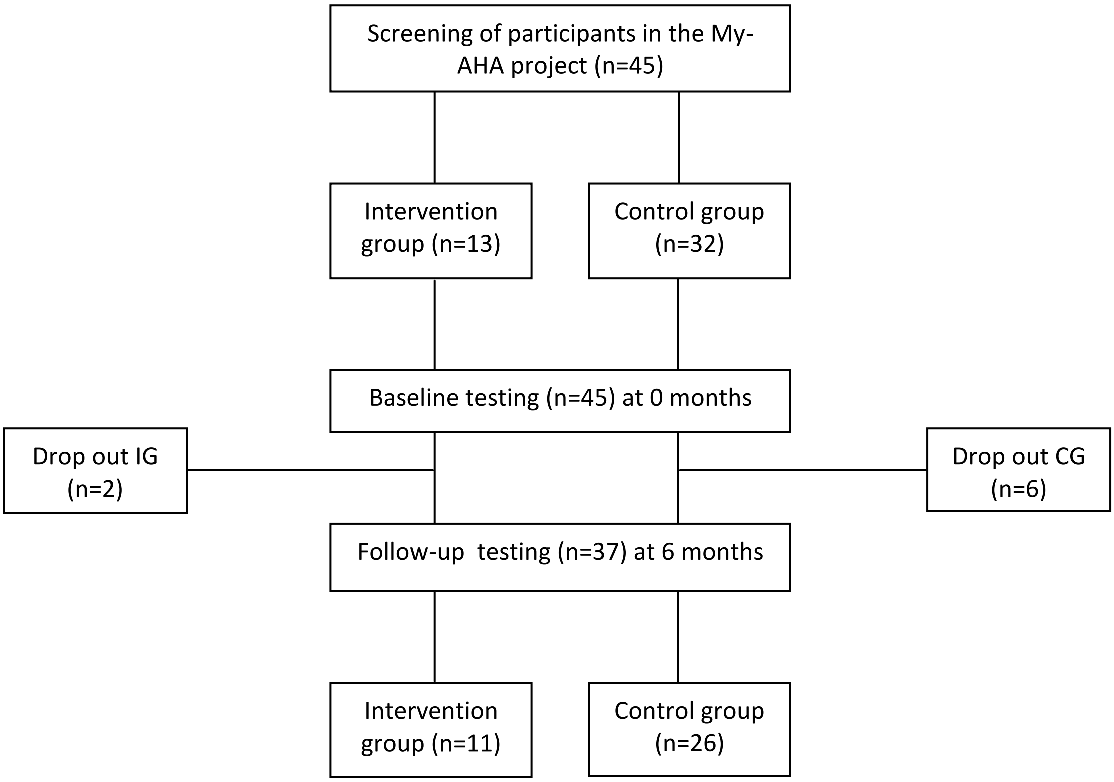

Figure 1. Flowchart

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KNOWLEDGE IN ACTION

INVENTARISATIEFORMULIER WETENSCHAPPELIJKE STAGE DEEL 2

DATUM	INHOUD OVERLEG	HANDTEKENINGEN
20/7	overleg afname + uitleg screening	Promotor: Copromotor/Begeleider: Student(e): Student(e):
14/9	Via mail: uitleg baseline testing	Promotor: Copromotor/Begeleider: Student(e): Student(e):
9/10	Evaluatie rekrutering, bespreking al gegeven data, bespreking onderzoeksvraag	Promotor: Copromotor/Begeleider: Student(e): Student(e):
15/02	Bespreking data controle groep & interventiegroep + verbetering methode	Promotor: Copromotor/Begeleider: Student(e): Student(e):
12/04	Uitleg data-analyse continuee data	Promotor: Copromotor/Begeleider: Student(e): Student(e):
26/04	Toepassing statistiek op categorische data	Promotor: Copromotor/Begeleider: Student(e): Student(e):
16/05	Bespreking resultaten sectie	Promotor: Copromotor/Begeleider: Student(e): Student(e):
24/5	ondertekenen formulier verdediging masterproef	Promotor: Copromotor/Begeleider: Student(e): Student(e):
		Promotor: Copromotor/Begeleider: Student(e): Student(e):
		Promotor: Copromotor/Begeleider: Student(e): Student(e):

In te vullen door de promotor(en) en eventuele copromotor aan het einde van MP2:

Naam Student(e): Stegwers Hannelore **Datum:** 24/5/2019

Titel Masterproef: The effect of a multifactorial intervention program, the My-AHA study, on frailty status in community-dwelling pre-frail older adults

1) Geef aan in hoeverre de student(e) onderstaande competenties zelfstandig uitvoerde:
   - NVT: De student(e) leverde hierin geen bijdrage, aangezien hij/zij in een reeds lopende studie meewerkte.
   - 1: De student(e) was niet zelfstandig en sterk afhankelijk van medestudent(e) of promotor en teamleden bij de uitwerking en uitvoering.
   - 2: De student(e) had veel hulp en ondersteuning nodig bij de uitwerking en uitvoering.
   - 3: De student(e) was redelijk zelfstandig bij de uitwerking en uitvoering
   - 4: De student(e) had weinig tot geringe hulp nodig bij de uitwerking en uitvoering.
   - 5: De student(e) werkte zeer zelfstandig en had slechts zeer sporadisch hulp en bijsturing nodig van de promotor of zijn team bij de uitwerking en uitvoering.

Competenties	NVT	1	2	3	4	5
Opstelling onderzoeksvraag	●	O	O	O	O	O
Methodologische uitwerking	●	O	O	O	O	O
Data acquisitie	O	O	O	O	●	O
Data management	O	O	O	O	●	O
Dataverwerking/Statistiek	O	O	O	●	O	O
Rapportage	O	O	O	●	O	O

2) Niet-bindend advies: Student(e) krijgt toelating/~~geen toelating~~ (schrappen wat niet past) om bovenvermelde Wetenschappelijke stage/masterproef deel 2 te verdedigen in bovenvermelde periode. Deze eventuele toelating houdt geen garantie in dat de student geslaagd is voor dit opleidingsonderdeel.

3) Deze wetenschappelijke stage/masterproef deel 2 mag ~~wel/niet~~ wel (schrappen wat niet past) openbaar verdedigd worden.

4) Deze wetenschappelijke stage/masterproef deel 2 mag ~~wel~~/niet (schrappen wat niet past) opgenomen worden in de bibliotheek en docserver van de UHasselt.
→ dit pas wel na publicatie My-AHA studie

Datum en handtekening Student(e)	Datum en handtekening promotor(en)	Datum en handtekening Co-promotor(en)

In te vullen door de promotor(en) en eventuele copromotor aan het einde van MP2:

Naam Student(e): Vanmunster Lore **Datum:** 24/5/2019

Titel Masterproef: The effect of a multifactorial intervention program, the My-AHA Study, on frailty status in community-dwelling pre-frail older adults

1) Geef aan in hoeverre de student(e) onderstaande competenties zelfstandig uitvoerde:
    - NVT: De student(e) leverde hierin geen bijdrage, aangezien hij/zij in een reeds lopende studie meewerkte.
    - 1: De student(e) was niet zelfstandig en sterk afhankelijk van medestudent(e) of promotor en teamleden bij de uitwerking en uitvoering.
    - 2: De student(e) had veel hulp en ondersteuning nodig bij de uitwerking en uitvoering.
    - 3: De student(e) was redelijk zelfstandig bij de uitwerking en uitvoering
    - 4: De student(e) had weinig tot geringe hulp nodig bij de uitwerking en uitvoering.
    - 5: De student(e) werkte zeer zelfstandig en had slechts zeer sporadisch hulp en bijsturing nodig van de promotor of zijn team bij de uitwerking en uitvoering.

Competenties	**NVT**	**1**	**2**	**3**	**4**	**5**
Opstelling onderzoeksvraag	●	O	O	O	O	O
Methodologische uitwerking	●	O	O	O	O	O
Data acquisitie	O	O	O	O	●	O
Data management	O	O	O	O	●	O
Dataverwerking/Statistiek	O	O	O	●	O	O
Rapportage	O	O	O	●	O	O

2) Niet-bindend advies: Student(e) krijgt toelating/~~geen toelating~~ (schrappen wat niet past) om bovenvermelde Wetenschappelijke stage/masterproef deel 2 te verdedigen in bovenvermelde periode. Deze eventuele toelating houdt geen garantie in dat de student geslaagd is voor dit opleidingsonderdeel.

3) Deze wetenschappelijke stage/masterproef deel 2 mag wel/~~niet~~ (schrappen wat niet past) openbaar verdedigd worden.

4) Deze wetenschappelijke stage/masterproef deel 2 mag ~~wel~~/niet (schrappen wat niet past) opgenomen worden in de bibliotheek en docserver van de UHasselt.

→ dit pas wel na publicatie My-AHA studie

Datum en handtekening Student(e)

Datum en handtekening promotor(en)

Datum en handtekening Co-promotor(en)