PhysioDom-HDIM WP5 Evaluation

Deliverable D5.1

Part II Effectiveness study

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SUMMARY	Effectiveness study - Document to be integrated in Deliverable - D5.1
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Abstract

Introduction: The steadily increasing absolute and relative number of older persons in Western countries puts pressure on public health and care services leading to a substantial social and economic impact on the society, and therefore asks for innovative solutions.

Objectives: To study the effectiveness of the PhysioDom Home Dietary Intake Monitoring (HDIM) intervention in stabilizing or improving health related quality of life (HR-QoL) and to prevent or treat malnutrition in elderly home dwelling clients, through a change in life-style of the end users by monitoring and coaching dietary habits and physical exercise. Secondary objectives were to stabilize or improve appetite, weight, BMI, fat mass and step counts, and the tertiary objective was to stabilize or reduce blood pressure in patients with hypertension.

Methods: 243 community dwelling elderly people receiving home care within care organizations in three locations across Europe (Spain, The Netherlands and the United Kingdom) were monitored and coached for six months and multilevel interventions depending on the severity of the problem were taken when necessary.

Results: The dietary and nutritional coaching were effective in keeping nearly all the different outcome measures of the HR-QoL dimensions, nutritional status, appetite, weight, proportion of fat mass in female subjects and blood pressure stable over time in each of the pilot sites, while steps remained stable in CST only. Furthermore, PhysioDom-HDIM was effective in increasing the QoL dimension scores in those with the poorest scores, the nutritional status in persons at risk of malnutrition, to increase appetite in those with poor appetite and to reduce the APS in subjects with hypertension at the level of the pooled data. Subjects with a poor appetite would have a higher chance of increasing the nutritional status with two points and prefrail subjects, defined according to our criteria, would have the most chance of increasing the MCS with three points. In CST, the number of hospital admissions and visits to nurses dropped significantly during the intervention as compared with the same period one year ahead.

Conclusion: Overall, the outcome measures monitored during PhysioDom remained stable during the intervention study. However, the results indicate that nutritional and physical activity monitoring and coaching through telehealth applications can help to improve HR-QoL, nutritional status, physical activity and weight and hypertension in the most vulnerable groups.

1. Introduction and rationale

1.1 The ageing population in Europe

The advances of modern technologies, medicine and healthcare have enabled mankind to live longer. However, in the EU there is a gap between life expectancy and healthy life years. In addition, there is steady and rapid increase of the absolute and relative number of older persons in Western countries.

Spending more years in ill health and disability not only affects the quality of life but also puts pressure on public health and care services leading to substantial social and economic impact on the society. Therefore, concerted multilevel efforts will undoubtedly be needed to help the population age healthier: from the responsibility of self-care of the individuals, to coordinated care and health services at the community level and to reformed policies on health-care, workforce and pension arrangements at the national level (1).

1.2 Lifestyle behaviours and healthy ageing

From the individual's standpoint, the first step in the prevention of chronic diseases and disabilities in old age is to adopt appropriate lifestyle behaviours including good nutrition and physical activity throughout life (2-5).

1.2.1 The problem of undernutrition among older adults

Diet is a key contributor to healthy ageing, while undernutrition and nutrient deficiencies play a large role in age-related functional decline (6). Undernutrition is a common disorder in older people as a result of reduced nutrient intake and/or impaired metabolism (7). Undernutrition in the elderly is associated with increased morbidity, mortality, prolonged hospitalization or rehospitalisation, and increased health care costs (8-11).

Regular screening for malnutrition and frailty are effective strategies to prevent certain diseases and reduce mortality among older people, particularly with underlying medical conditions (12, 13).

Interventions to prevent or revert undernutrition like screening, a dietitian's consultation, nutritional supplements and protein-energy enriched meals can be effective and cost-effective (14-17). Surveys show that undernutrition is common among community-dwelling older adults: eleven to 35 percent are undernourished, with the highest prevalence observed among the elderly receiving home care (18). To improve health and to minimize societal costs associated with undernutrition among the elderly, undernutrition should be prevented as much as possible.

Both underweight and loss of appetite are highly associated with undernutrition, therefore regular weighing may enable the detection of weight loss in time and prevent undernutrition.

1.2.2 Physical activity

Limitations of functionality and mobility due to age-related decrease in muscle strength, balance and physical endurance are closely related to weakness, risk of falls, malnutrition as well as an increase in morbidity and mortality. Physical activity intervention have been shown to reduce sedentary behaviour and frailty (19-21) and is associated with reductions in low-density lipoprotein and cholesterol, systolic blood pressure, weight, symptoms of depression, risk of cardiovascular all cause-mortality and an improvement in health-related Quality of life (HR-QoL)(22, 23).

Aerobic exercise has long been an important recommendation for preventing (5, 24) and treating many of the chronic and typically age-associated diseases, including noninsulin-dependent diabetes mellitus (NIDDM) (Type 2 Diabetes), hypertension, heart disease and osteoporosis. Older persons can benefit a lot from regularly performed exercise, and for obese older people it is a much better strategy of weight management than weight loss as the latter promotes sarcopenia and bone loss (25). Moreover, research indicates that strength training is necessary both to stop or reverse sarcopenia—the age-associated loss of body protein—and to increase bone density. Increasing muscle strength and muscle mass in older persons is a realistic strategy for maintaining this group's functional status and independence. For aerobic exercise the recommendation is 30 minutes on a daily basis—for example walking, swimming, aqua gym and stationary cycling. Strength training is recommended 2 to 3 days a week, with a day of rest between workouts.

1.1 The potential of Ehealth

The European Commission has identified active and healthy ageing as a major societal challenge and aims to develop innovative responses to this challenge.

Therefore, governments and care organizations are increasingly turning towards the use of Ehealth and home telemonitoring to improve health or support health care. Telemonitoring is defined as 'the use of information technology to monitor patients at a distance (26).

Home telemonitoring (HT) represents a promising approach for enabling patients with chronic conditions to be followed up by clinicians more frequently and over longer periods of time, away from hospital settings (27-29). HT is a particular form of telehealth that encompasses the use of remote access information and communication technologies (e.g. telemetry devices, intelligent sensors, hand-held or wearable technologies) for the timely transmission of symptoms, physiological, and disease-related data from the patients' home to a telemonitoring center supporting clinical decisions (26, 28, 29). The underlying goal of HT is to provide doctors and nurses with accurate and timely information necessary to remotely detect any abnormal health parameters and complications associated with the disease, earlier than during a scheduled follow-up or an emergency visit. This allows timely interventions before exacerbations and complications occur, necessitating admission to the hospital and use of more resources.

Systematic reviews have shown that Ehealth interventions can contribute to improving health in patients with chronic diseases like CVD (30-32), diabetes (33, 34) COPD (35), or (frail) elderly in general (36, 37). It is also known that (frail) elderly in general can benefit from Ehealth applications (38).

A review of qualitative studies showed that older adults express both concerns and benefits regarding the use of Ehealth (39). High costs, privacy implications, forgetting or losing technology were the most frequently mentioned concerns. On the other hand, increased safety, perceived usefulness and increased independence were most frequently mentioned as benefits. In line with this, a Dutch national survey showed that a majority of older adults (71%) is willing to use Ehealth if this permits them to age at home. Ehealth has positively effects on the patients' empowerment and satisfaction (38).

A review of telemonitoring interventions targeted at older adults showed that a majority of them was able to handle the technology employed in the interventions themselves

(37). Thus, from an elderly point of view, Ehealth and telemonitoring are worthwhile possibilities to consider in the care for older people.

1.3 Ehealth for the prevention of undernutrition

Ehealth might contribute to maintaining or improving nutritional status in elderly by screening undernutrition so that timely intervention is possible. However, there is no scientific base for this yet.

There have been several studies involving telemonitoring applications for the elderly (36, 37). These applications mainly focused on monitoring of vital signs in older adults with chronic diseases like cardiovascular disease and diabetes. Studies showed positive results, especially for behavioural outcomes such as adherence to medication and self-efficacy (37). To our knowledge there has only been one study in the Netherlands that focused on a telemonitoring instrument to improve nutritional status among community dwelling elderly (40). This pilot study focused on elderly patients who were already malnourished and received oral nutritional supplements. A telemonitoring system was used to measure weight and adherence to the prescription of oral nutritional supplements. However, due to a limited sample size (N=26) and a high drop-out rate no effect size could be established. Clearly, more research is needed to show that telemonitoring is able to contribute to the prevention of undernutrition in the elderly.

1.4 PhysioDom Home Dietary Intake Monitoring

PhysioDom Home Dietary Intake Monitoring (HDIM) is a European project which implemented a telemonitoring system for community dwelling elderly people, embedded within care organizations in three locations across Europe (Spain, The Netherlands and the United Kingdom). The nutritional and physical activity states were monitored and coached and, depending on the severity of the problem, multilevel interventions were taken when necessary.

2. Principal objectives of the PhysioDom - HDIM effect study

The application of this complex telemedicine intervention will contribute to patient empowerment and better self management of daily dietary intake and physical exercise thereby improving the quality of life, lead to healthier ageing and reduce health care costs.

2.1. Main Objectives

The main objectives of the HDIM intervention were therefore to study the effectiveness of the PhysioDom HDIM coaching in **stabilizing or improving health related quality of life (HR-QoL) and to prevent or treat malnutrition** in elderly home dwelling clients, through a change in life-style of the end users by improving dietary habits and physical exercise.

2.2 Secondary and tertiary objectives

The secondary objectives of the HDIM intervention were to study the effects of PhysioDom HDIM on nutritional parameters (appetite, weight, BMI, fat mass), and on physical activity (steps walked). We hypothesized that **the nutritional parameters, and physical activity remained stable or improved in elderly home dwelling clients.**

The tertiary objective was to study the effect on blood pressure in patients with hypertension. We hypothesized that **the blood pressure remained stable or improved in elderly home dwelling clients with hypertension.**

3. Study design

A pre-test post-test design was employed in which each participant was its own control. The effect study lasted 9 months and was divided in two periods (Figure 2):

- a control phase of 3 months (period between T0 and T1)
- an intervention period of 6 months (from period T1 to T3)

Figure 2: Time schedule for the PhysioDom HDIM intervention study

The control phase allowed for within person comparison of the participants' results between the phase without and with PhysioDom intervention. Measurements were performed at the beginning of the control (T0) and intervention period (T1), in the middle of the intervention period (T2) and at the end of the intervention (T3).

4. Study populations

4.1 Study sites

Three sites in Spain (CST), the Netherlands (WU) and the United Kingdom (CYB), respectively, agreed to participate in the project.

4.1.1 Spain

Subjects were recruited from four of the seven primary health care centers of the Consorci Sanitari de Terrassa (CST): Terrassa Nord, Sant Llàtzer, Matadepera, Anton de Borja having a reference population of around 14,000 subjects. CST provides integrated healthcare services to its patients in all kinds of acute and chronic diseases.

4.1.2 The Netherlands

The source population for the intervention and control group in the Netherlands consisted of community dwelling older adults, receiving home care from two care organizations Zorggroep Noordwest-Veluwe (ZNWV) and Opella. These care providers offer a broad range of care in institutions and among community dwelling older adults in the region North West Veluwe and South Veluwe in the Netherlands.

4.1.2 United Kingdom

The source population for the Large Scale Pilot consisted of community dwelling older adults. Many have been referred by Age UK South Lakes, Age UK Carlisle and Eden and Age UK Northumberland. The Age UK South Lakes covers the South of Cumbria in North West, and have over 10,000 clients who access their services.

4.2 In- and exclusion criteria

In order to be eligible for participation in the study, individuals had to meet the following inclusion criteria:

- Individuals aged 65 years or older
- Individuals receiving one or, preferably, a combination of the following types of care: - domestic care
  - personal care
  - nursing care
- Individuals in a pre-frailty state
- Individuals being malnourished
- Dehydrated individuals
- Overweight individuals
- Individuals with a minor cognitive impairment (MMSE)
- Individuals with chronic pathologies (these pathologies may be due to diabetes and/or obesity)
  - Cardiac insufficiency - level I-II
  - Renal insufficiency (excluded those receiving dialysis)
  - Hypertension (first phases)
  - After chemotherapy (> 1 month)
  - COPD (first phases)

The exclusion criteria were formulated as follows**:**

- Individuals who did not sign the informed consent
- Less than 65 years
- Individuals that did not have a television at home
- Severe cognitive impairment (MMSE < 20), including those with diagnosis of Alzheimer disease

- Expected length of receiving home care > one year
- Individuals with a visual impairment (not able to watch the television screen)
- Individuals with a physical impairment who are incapable to use the telemonitoring devices
- Subjects receiving chemotherapy
- Dependent Individuals (unable to walk and bedridden)
- Individuals living in a nursing home

4.3 Sample size

A sample size of 142 subjects per pilot site was required to detect a difference of 4 points in health-related quality of life (HR-QoL) between the beginning and the end of the intervention study, assuming an alpha of 0.05, a power of 80%, a two-sided test, and an expected dropout rate of 30%.

5. PhysioDom intervention

5.1 PhysioDom HDIM monitoring

In PhysioDom, the nutritional and physical activity state of the participants were monitored at home and coached for six months at different levels depending on the individual needs, by the surveillance of several indicators (weight, fat mass, BMI, blood pressure, steps), through screening instruments (MNA-SF to measure nutritional status, SNAQ to measure appetite) and by setting alert levels for each parameter (see Table 1 in §6.6 for minimal measurements). For example, a threshold for weight could be set as a deviation of five percent from baseline weight of a client, as such a deviation is regarded to be medically relevant (33).

The monitoring was done by multidisciplinary team, but each patient had a reference professional. The telemonitoring system was complementary to usual care and was embedded within the care procedures of each of the care organizations. It was the responsibility of the district nurse to assure the management and follow-up of the monitoring signals, to employ the telemonitoring system properly (trained and supported by the research team) and to provide care when alerts appeared in one of the telemonitored parameters.

The PhysioDom coaching structure in each of the three pilot sites consisted of four levels of care:

- *Level 1: Monitoring of the Dietary and Physical Activity data*
- *Level 2: Local healthcare and social welfare services - homecare services*
- *Level 3: Dietary and physical exercise coaching services providing measures ranging from simple dietary counselling (via the Messaging service) to arranging hospital care.*
- *Level 4: Family physicians and specialists*

Level 1: **Monitoring**

Weight, fat mass (%), nutritional status, appetite and physical activity were monitored by several instruments. Measurements were performed at home by the client. The frequency of monitoring was individually determined by the district nurse according to the client's needs. The participants had a schedule of dates for monitoring and some parameters were measured every day. Measurements were recorded - on the PhysioDom channel of the TV – and they were reminded when it was time for a certain measurement. Results of self-measurements were displayed on the television screen of the elderly and were automatically sent to the PhysioDom server.

Level 2: District nurse/social worker

Self-measurement results were handled in the first line by the district nurse/social worker. To simplify this, the district nurse defined individual thresholds for alerting signals when values are above or below normal levels. Upon receipt of an alerts, the district nurse decided if follow-up was needed and if so, to assign the care giver to be concerned with follow-up (level 3&4). This could be the district nurse herself, but this could also be another care giver from the home care organization or other medical specialists.

Level 3 and 4: other care professionals.

When follow-up could not be given by the district nurse, she referred to other health care professionals (e.g. a dietitian, physiotherapist or GP).

Thus to resume, the difference with the traditional treatment of care is the timing of usual treatment or care referral, as it was aimed that deteriorations will be detected earlier through the telemonitoring system. As the telemonitoring system is complementary to usual care, the participants will remain able to contact (para)medicals directly, without care referral of the district nurse (indicated by the arrows from level one - the participant - to level three and four).

5.2 PhysioDom HDIM dietary coaching

5.2.1 Spain

A nurse interviewed the patient completing questionnaires. In relation to their chronic diseases and their weight, patients were given an individualized diet agreed with the nutritionist (for under nutrition, overweight, normal weight, Parkinson's, renal insufficiency or diabetes). After delivering the diet plan, the patient received messages for motivational reinforcement through the platform and achieving goals.

5.2.2 The Netherlands

Dietary quality was assessed by the DHD-FFQ, which stands for Dutch Healthy Diet index Food Frequency Questionnaire (41). The Dutch dietary guidelines form the basis of this assessment. The result of the DHD-FFQ is the DHD index: a score ranging from 0-80, with a higher score meaning better compliance to the dietary guidelines. The score consists of eight subscores ranging from zero to ten for vegetables, fruit, fish, alcohol, saturated fat, trans-fat, salt and dietary fibre. Based on the DHD-FFQ score and subscores, participants received personalized advice on how to improve diet concerning each of the food groups or nutrients.

5.2.3 UK

Initial coaching involved a diet plan delivered via the PhysioDom system with general healthy eating guidelines according to the nutritional status of the individual - under nutrition, overweight, normal weight, or diabetes. Individual online coaching was offered by a registered dietitian with the development of agreed dietary goals. The subject provided a list of the food intake during one week, providing information about all meals. The dietitian prepared an appropriate diet plan and also agreed with each person the objectives to pursue.

5.3 Physical activity coaching

All participants were screened for contra-indications for doing physical exercise and a medical examination was performed if required. All participants were informed on the benefits of regular physical activity and they were encouraged to challenge themselves to set goals.

5.3.1 Spain

In Spain, an individual physical activity program was set up depending on the participants' health status and motivation. Participants were informed on healthy city routes and could participate to physical activity actions organised by the community.

5.3.2 Netherlands

Every fourth week of each month, a "physical activity" week was organized. In this particular week the participants were encouraged to wear the pedometer and to set daily a new goal for the next day. During this week, participants received motivational TV messages with the aim to stimulate physical activity.

5.3.3 UK

An individual physical activity program was set up depending on the participants' health status and motivation.

5.4 Technology

Figure 3 gives an overview of the technology of the telemonitoring system. Below, a description of the main elements is given.

Measurement devices. In the homes of the participants the following devices were installed: a weighing scale, a pedometer, and when indicated by the district nurse, a blood pressure measurement device. Questionnaires concerning diet, appetite and nutritional status were filled out on a PC or tablet. If necessary, the participants were assisted with the entrance of the questionnaire data.

TV Box. In the homes of the participants a TV Box was installed. Results from the measurement devices were send to the TV box (via Bluetooth, internet or via a remote control).

TV – HHR-Home. Participants received a TV channel on their television: Home Health Record Home (HHR-Home). Participants could navigate throughout this TV channel with a remote control. The main functions of HHR Home are:

- By viewing the results of self-measurements participants could become aware of their weight, dietary intake, nutritional status, and other measured parameters.
- Participants received feedback on their dietary intake and physical activity levels with advices how to improve compliance to national guidelines for diet and physical activity.
- Care professionals used HHR-Home as a way of communication to the participants. They could send messages to participants as part of regular care, e.g. tips to adhere to a healthy diet, special diet information, etc. Care professionals were notified when a participant had opened the message.

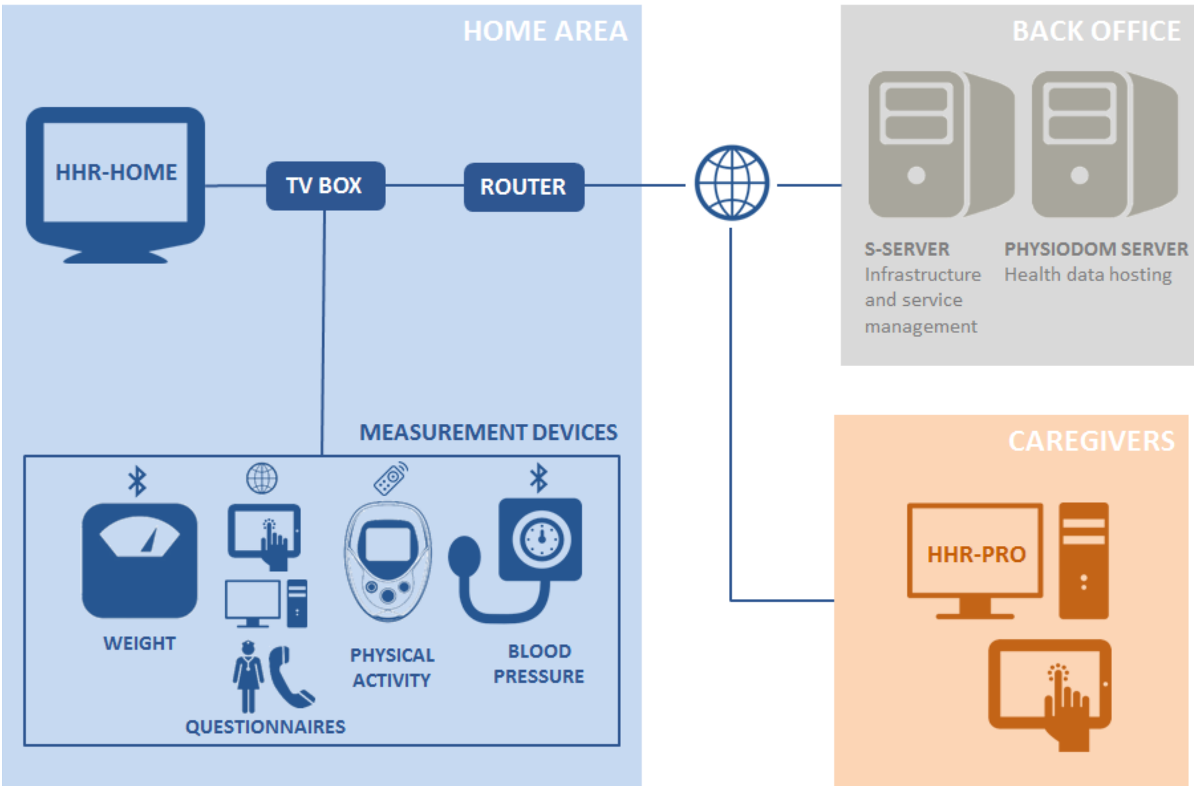


Figure 3: Overview of the telemonitoring system

Back office. Two servers, the S-server and the PhysioDom server, functioned as back office and were used to securely store data from the telemonitoring system.

HHR-Pro. Authorized caregivers involved in the care of participants accessed the telemonitoring system via software called HHR-Pro, available on PC or tablet. The main functions of HHR-Pro were:

- Authorized caregivers were able to view the participant's care plan and results from the telemonitoring system.
- The district nurse defined thresholds for each parameter that was monitored. She did this individually for each client. Defining thresholds was based on the scientific literature. Thresholds for scores from questionnaires for appetite and nutritional status followed the classifications that belong to that questionnaire (see §6.1 and §6.2, respectively). When parameters exceeded the defined threshold value, the district nurse received an automated alert.

6. Methods

6.1 Primary study parameters

The **primary study parameters** health related quality of life (HR-QoL) and nutritional status were chosen to demonstrate effects of nutritional telemonitoring on nutritional status (clinical outcome) and quality of life (more sustainable outcome).
Measurements of quality of life and nutritional status were conducted as follows:

Health Related Quality of life – HR-QoL was measured by the SF36, one of the most widely used measures to study **HR-QoL**. It includes eight dimensions of quality of life: 1) limitations in physical activities because of health problems (Physical function, PF); 2) limitations in social activities because of physical or emotional problems (Social Functioning, SF); 3) limitations in usual role activities because of physical health problems (Role-Physical, RP); 4) bodily pain (BP); 5) general mental health (MH); 6) limitations in usual role activities because of emotional problems (Role-Emotional, RE); 7) vitality (VT); and 8) general health (GH) perceptions. The SF36 provides scores for each of the eight dimensions, and provides physical component summary (PCS) and mental component summary (MCS) scores (42).
The scores were calculated using the RAND-SF36. Higher scores represent better health.

As the WU pilot used a more recent version of the SF36 questionnaire, the categories of the questions in the box below were recoded. The main difference was that for question 4a-d and 5a-c, the Dutch questionnaire contained 5 modalities (1=most of the time, 2=a good bit of the time, 3=some of the time, 4= a little bit of the time, 5=none of the time), while for the other two pilots there were only two modalities (1=yes/2=no).

Box 1: Recoded questions of the Dutch SF36 scores

Q4a-d Q5a-c	Recode scores 1-3 into 1 (yes) and 4&5 into 2 (no)
Q9a-i	Score 3 does not exist Recode: 3 into 4; 4 into 5; 5 into 6

Neither in the manual of the RAND-36 questionnaire nor in the literature, an indication what should be considered poor scores and which change in the HR-QoL domain scores are relevant. Following the proposal of Slagter et al (43), to define poor scores, we determined the 25th percentile cut-off scores for the pooled data and separately for both genders for each of the summary domain scores. We evaluated the number of subjects that improved 5 points below and above this cut-off point.

Nutritional status was assessed by the Mini Nutritional Assessment (MNA). The MNA is an assessment tool that identifies persons aged 65 and higher who are malnourished or at risk of malnutrition (44). The full MNA consists of 18-items and classifies a person as malnourished (0-16), at risk for malnutrition (17-23.5), or having a good nutritional status (24-30).

Patients at risk for malnutrition have not yet started to lose weight and do not show low plasma albumin levels, but have lower protein-calorie intakes than recommended. For them, a multidisciplinary geriatric intervention is needed, which takes into account all aspects that might interfere with proper alimentation and, when necessary, proposes therapeutic interventions for diet or supplementation. If the MNA score is less than 17, the patient has protein-calorie malnutrition. It is important at this stage to quantify the severity of the malnutrition (by measuring biochemical parameters like plasma albumin or prealbumin levels, establishing a three day record of food intake, and measuring anthropometric features like weight, BMI, arm circumference and skin folds). Nutritional intervention is clearly needed and should be based on achievable objectives established after a detailed comprehensive geriatric assessment. The MNA has been shown to be useful for nutritional intervention follow-up as well. The MNA can help clinicians design an intervention by noting where the patient loses points when performing the MNA. Moreover, when a nutritional intervention is successful, the MNA score increases.

There exists also a MNA short form (MNA-SF), which focuses on appetite, weight loss and mobility. MNA-SF is normally used for screening but was used in this study for telemonitoring purposes in the middle of the study as it is able to show the modifications in the nutritional status and can help to induce behavioural changes. The MNA-SF score scales from of 0 to 14. A score <8 indicates malnutrition, a score of 8–11 indicates to be at risk of malnutrition, and a score of 12-14 indicates a normal nutritional status.

6.2 Secondary study parameters

The **secondary study parameters** below were selected as they give an enhanced insight into the various effects associated with using the telemonitoring system. These parameters are both indicators for enhanced surveillance and tailored coaching as well as study end points.

Appetite was measured by the Simplified Nutritional Appetite Questionnaire (SNAQ), which has been proven to be reliable and valid in identifying elderly people at risk of unintentional weight loss (45). The SNAQ consists of four questions addressing several aspects of appetite. The outcome is a score ranging from 4 to 20, with a higher score indicating more appetite. Furthermore, a score of <15 indicates a significant risk of at least five percent weight loss within six months (45).

Weight, BMI and fat mass (%) were measured using weighing scales from the brand A&D, type UC-411PBT-C. Participants were instructed when and how to weigh themselves. In the final analyses BMI was always recalculated using the weight (in kg) at that particular time point divided by the height (cm^2) at baseline. BMI categories were

created according to Consensus Statement of the European Society for Clinical Nutrition and Metabolism: underweight <20 (<70y) or <22 (≥70y); normal weight: 20-24.9 (<70y) or 22-24.9 (≥70y); overweight: 25.0-29.9; obese: ≥30.
There was a relatively high day-to-day fluctuation for the fat proportion and APS/APD data. Therefore, an average of three to five measures was taken (depending on the availability) for time points T1 and T3.

Physical activity was monitored by a pedometer from A&D, type UW-101B.
Data on steps were counted for each month and divided by the number of days available. A minimum of five measures were necessary to validate a month.
For the analyses, only subjects having entered their steps for at least four consecutive months were considered. Categories to define the physical activity levels were adapted to elderly (46): inactive: <1000; low activity: 1000-2999; somewhat active: 3000-4999; active: 5000-7999; highly active: ≥8000.

6.3 Tertiary study parameters

Blood pressure was monitored in a selection of participants having hypertension or renal failure.
Blood pressure measurement devices (type UA-767PBT-CI) were Bluetooth connected to the TV Box.

6.4 Demographic variables and subject characteristics

Upon entering in the study, a baseline questionnaire was administered to all the participants. The variables age, gender, educational level, marital status, disease history, number of chronic diseases, dental and swallowing problems were collected as they may be confounding factors in the analyses of the effect of the intervention (the dietary and physical activity monitoring and coaching) on quality of life and nutritional status.
The number of visits at home of the nurses, social workers, dietitians, nutritionists and GPs were collected in order to use it as a proxy for the intensity of the dietary intervention (See §6.5).
Data on educational level were recorded according to the ISPED classification (Annex I).

Data on diagnoses were treated in two different ways: 1) to calculate the number of chronic diseases; and 2) to be able to use as covariate in the adjusted analyses (see Annex II).

Ad 1) To calculate the number of comorbidities, the chronic diseases were counted individually.

Ad 2) For adjustment purposes, the single morbidities were clustered in the following 12 subgroups: Pulmonary; Cancer; CVD; Head; Gastrointestinal & Liver; Kidney and Bladder; Neurological diseases; Blood disorders; Musculoskeletal diseases; Dermatological diseases; Mental disorders and Hormonal disorders. If the participant had at least one morbidity within the subgroup, this subgroup was coded as being present. The formation of the subgroups are based on morbidities which affect the same organs or systems, or they share the same biological mechanism.

impairment) and comparing them to those of a control period of six months, one year earlier.

6.5 Hospital admissions and visits at home

The frequency and number of hospital admissions were recorded for the intervention and control period and for a six month period one year ahead of the study. The data on hospital admissions were analysed in two ways: 1) by introducing it as confounding variable in the models (as the number of days three months before each measurement points); 2) by comparing the number of stays and the number of days for the principal diagnoses (cardiac incapacity I-II, renal insufficiency, hypertension, cancer (not under chemotherapy), COPD) between the six month intervention and a six month period one year earlier (Spain only). The number of visits of the nurse, GP, social worker, dietitian at home or with professionals of the healthcare centre or were summed up and analysed in relation to SF 36 dimension scores, weight .

6.6 Measurement of the impact of the dietary coaching

The impact of the dietary coaching was measured in the first place by comparing the intakes of questions j, k, l and m of the full MNA between the beginning and the end of the intervention (see Box 2).

Box 2: Questions of full-MNA used to measure the impact of the dietary coaching

MNA question		Possible answers	Possible Score
J	How many full meals does the patient eat daily?	0 =1 meal , 1 = 2 meals, 2 = 3 meals	0, 1, 2
K	Selected consumption markers for protein intake	*- At least one serving of dairy products (milk, cheese, yoghurt) per day* *yes* □ *no* □ *- Two or more servings of legumes or eggs per week* *yes* □ *no* □ *- Meat, fish or poultry every day* *yes* □ *no* □ 0.0 if 0 or 1 yes ; 0.5 = if 2 yes; 1.0 = if 3 yes	0, 0.5, 1
L	Consumes two or more servings of fruit or vegetables per day?	0 = no; 1 = yes	0,1
M	How much fluid (water, juice, coffee, tea, milk...) is consumed per day?	0.0 = less than 3 cups; 0.5 = 3 to 5 cups; 1.0 = more than 5 cups	0, 0.5, 1

Secondly, a proxy for the intensity of the dietary coaching was created by summing up the number of interventions of dietitians, social workers, nurses and nutritionists at home. Three categories were defined (0, 1 or 2 interventions and ≥3 interventions) and analysed in relation to the change in weight, nutritional status (MNA score), the quality of life (scores on the 8 dimensions of the SF36) and the number of chronic diseases between the beginning and the end of the intervention study.

6.7 Prefrailty

As many professionals involved in the study lacked the expertise and/or the instruments in classifying subjects as (pre)frail, we developed an ad hoc method to determine the subjects' pre-frailty status based on available data. The criteria are listed in Box 3. As only four criteria were applied, instead of the usual five defined by Fried et al. (2004)(47), our method is more conservative and should be interpreted with caution. Therefore, we prudently qualified a subject only as "at least prefrail" (furthermore simply called "prefrail") if one of the criteria was met, and we omitted the qualification frail.

Box 3: Criteria to fit in order to be defined as prefrail (at least one positive answer)

Criterium	Positive if
1. Fatigue, from the SF36	
Q29 - "Did you feel worn out"	· all of the time (score=1) · most of the time (score=2)
Q31 - "Did you feel tired" -	· all of the time (score=1) · most of the time (score=2)
Q27 - "Did you have a lot of energy?"	· a little of the time (score=5), · none of the time (score=6)
2. Resistance (ability to climb a single flight of stairs), from the SF36	
Q7 - "Does your health limit you to climb one flight of stairs"	· limited a lot (score=1)
3. Ambulation (ability to walk one block), from the SF36	
Q11 – "Does your health limit you walk one block"	· limited a lot (score=1)
4. Weight loss (>2 kg in 1 month, > 3 kg in 3 months or > 5% of bodyweight in 6 months)	
At T1 by comparing weight loss between T1 (start intervention) and T0 (inclusion)	> 3 kg in 3 months
At T3 by comparing weight loss between T3 (end intervention) and T1.	> 5% of bodyweight in 6 months

6.8 Time schedule

Measurements necessary for the effect study were performed according to the time schedule described in Table 1. For the SNAQ, SF-12 and MNA-SF, the number and type of in-between assessments varied depending on the participants' needs. Repeated evaluations were done in case of warnings on weight, appetite or pedometer (increasingly staying in bed, or increase in sedentary behaviour). These results were not used in the analyses of the results.

Table 1: Time schedule for the measurements required for the effect study

Measurement *Month*	T0[1] -3	T1[2] 0	T2 3	T3 6
• Baseline characteristics	x			
• SF36	x	x		x
• Full MNA	x	x		x
• MNA-SF		* x *		
• SNAQ	x	x * x * x		
• Weight	x	Every week from T1 till T3*		
• BMI	x	Every week from T1 till T3		
• Fat mass (%)	x	Every week from T1 till T3		
• Steps		Continuously from T1 till T3[4]		
• APS, APD, cardiac frequency[3]	x	Every week from T1 till T3		

[1]Beginning of the control period of the effect study
[2]Beginning of the intervention period of the effect study
[3]Only in patients with cardiac insufficiency, hypertension or renal failure
[4]Beneficiaries measured steps continuously and filled out data as steps per day or per week
*Frequency of monitoring was adjusted between T1 and T3 on the basis of personal needs of the participants, evaluated by the nurse. If MNA-SF score revealed (risk for) undernutrition a full MNA was performed to see if intervention was necessary

6.9 Dropouts

Participants could discontinue the trial at any moment without obligation to state the reason for discontinuation. Withdrawn subjects were not replaced.

Reasons for discontinuation of the study were collected (medical reason, person's own decision, technical problem, death) and their characteristics as well as nutritional status were compared to those of the group that stayed till the end of the study.

6.10 Data collection and compilation of the database

The data for all variables were collected via the back office of the system, called Redmine, except for the SF36 data. Three *.csv* datafiles called "Beneficiaries", "Currentstatus" and "DataRecordItems" were recuperated from Redmine via the website of Viveris (http://forum.PhysioDom.viveris.fr/redmine/login).

The SF36 data were collected on paper and entered in an Excel file by the pilots. This file contained predefined cells, allowing only a certain number of entries. A single database was compiled with the pooled data of the three pilots and the three time points. The date on which MNA was measured was taken as reference date. All other measures were recuperated as close as possible to this date, but no later than 40 days beyond. Contrary to T0, starting from baseline the subjects entered the data themselves, which enhanced the number of errors. To correct these errors, we used methods which are described in the section "quality controls". In order to reduce the number of errors for the data at month six, professionals were asked to assist the subjects in recording their last data on HHR-home.

6.11 Quality controls

6.11.1 Outliers

Distributions were produced for each variable and outliers checked for each measurement point (Table 2).

Table 2: Thresholds for the outcome measures

Variable	Minimum	Maximum
Age	65	100
Height	1.40	2.10
Weight	40	130
APS	80	250
BMI	15	40
APD	60	130
Pulse	40	180
SF36	0	100
MNA	0	30
SNAQ	4	20
Steps	0	20000
MMSE	20	30

6.11.2 Data at inclusion

At inclusion, data were entered with the help of professionals in the pilot sites. As there was only one measure for each variable, only a standard quality control was performed using the thresholds above.

6.11.3 Data from the intervention study

The following type of errors were checked:

- Entry errors
- Couples who swapped their HHR-Home accounts
- Couples who swapped their weighing scale accounts

To fix errors, the accounts were divided into two groups: 1) homes with a single account and 2) homes with two accounts.

1) In homes with a single account, only "entry errors" could occur. To fix these errors, for each subject the medians for the variables weight and BMI were calculated, by taking the values 40 days before and 40 days after the date of MNA. If an outlier was detected, and this concerned the first value, this value was discarded and the next closest value to the MNA date was taken.

Outliers for weight were ± 5 kg from the median and for BMI ± 2 units from the median.

2) In homes with two beneficiaries, in addition to the errors described above, both swapping of the box and weighing scale accounts occurred.

To identify patients who had swapped their data, each measure (e.g. weight) was compared with the data at inclusion. If between these two values there was a difference (using the thresholds mentioned above) we checked if this difference was true or false, by checking the rest of the data. If the difference was true we assigned the correct value(s) to the correct patient. Of course, caution was taken not to delete data from subjects who steadily changed weight. Once these corrections had been completed, the method to detect outliers was applied.

6.12 Statistical Analysis

6.12.1 Baseline characteristics

Baseline characteristics of the participants were presented quantitatively as means ± standard deviations (SD) for continuous data and as percentages for categorical data by centre and for the three centres combined. Continuous data were analyzed using Kruskall-Wallis. Categorical variables were analysed using χ^2 tests or Fisher's exact tests. *P* values less than 0.05 were considered significant, and all the tests were two-sided.

6.12.2 Primary study parameters

The primary outcome measures evaluated in this study were the eight dimension scores, as well as the physical and mental component summary scores of the SF-36, and the full MNA score. The ability to detect a treatment effect in the study outcomes was evaluated by analyzing the difference between the mean score at the end of the intervention (T3) and the mean outcome at baseline (T1). For this purpose, Wilcoxon's signed rank tests were used to compare the changes in full MNA and SF36 outcomes. Differences in time for prevalence data (low nutritional status, obesity and low activity) were tested with a McNemar test.

Finally we used logistic regression analyses to describe which baseline variables were independently associated with an improvement in the PCS and MCS summary score dimensions and an improvement of the nutritional status. The following potential confounders were significantly different between pilots and therefore included in the pooled models: sex, age (continuous), marital status (5 categories), weight, health conditions (classified into 0, 1 and 2 or more health conditions (Annex II) and steps (continuous). In addition, the number of nights stayed in hospital, chewing and swallowing problems (both 5 categories) were added as a confounder because they may affect the outcome measures.

6.12.3 Secondary and tertiary study parameters

Wilcoxon's signed rank tests were conducted to compare changes in continuous outcomes of appetite (SNAQ), weight, fat mass (%), BMI and physical activity, stratified by pilot and for the pooled data.

The ability to detect a treatment effect in the secondary study parameters was evaluated by analyzing the difference between the mean score at the end of the intervention (T3) and the mean outcome at baseline (T1). The data were analysed with SAS, version 9.4.

7 RESULTS

During follow-up, 140 subjects (CST=57; WU=21; CYB=62) dropped out.

After exclusion of seven subjects because of missing data on MNA and/or SF36 (CST=4; CYB=2; WU=1) data from 243 (CST=96, CYB=102, WU= 45) were used for statistical analyses. The number of subjects for the WU was lower because the Dutch ethics committee did not allow to start recruitment before the results of the pre-pilot study were known. This resulted in a delay of three months compared to the other pilot sites. WU recruited in total 107 participants in the intervention group. Complete data from 45 participants were available at the moment of analysing the results for this report.

As there were no significant differences between the deltas of the SF36 dimension, MNA and appetite scores, and weights of the periods T0-T1 (the beginning of the control period and baseline) and T1-T3 (baseline and month 6), the results of the control period were not taken into account.

7.1 Baseline Characteristics

Table 3 shows the baseline characteristics of the 243 subjects (CST: n=96; CYB: n=102; WU: n=45) included in the present analyses, of which 51.0% was female.

On average subjects were 72.9 (SD 5.8) years old and had 1.5 chronic diseases, 45.7% were overweight (BMI 25-30 kg/m2), 35.8% were obese (BMI≥30 kg/m2), and 35.4% were prefrail at baseline.

The pilots were significantly different for most of the baseline characteristics: age (WU subjects were older), gender (more female subjects in the WU), marital status, the level of education (none of the CYB subjects only had primary education), mobility, the number of comorbidities (less people had no comorbidity in CST) and prefrailty state (more prefrail people for WU). Pilots were not different for country of birth, BMI and in terms of problems with chewing and swallowing foods. Table 4 shows the distribution of subjects by age, gender and pilot site.

Table 3: Baseline characteristics of the participants in the three pilot sites & pooled data

	CST (n=96)		CYB (n= 102)		WU (n=45)		Total (n=243)		$P^{\dagger}$
	n	%	n	%	n=	%	n	%	
Age (years), mean (SD)	71.9 (4.9)		72.1 (5.7)		76.7 (6.3)		72.9 (5.8)		<0.0001
Length (cm), mean (SD)	162 (8)		167 (9)		165 (8)		165 (9)		0.0002
Gender, %									
Male	54	56.3	50	49	15	33.3	119	49.0	0.04
Female	42	43.8	52	51	30	66.7	124	51.0	
Country of birth, (%)									
Spain/UK/Netherlands[1]	94	98	102	100	45	100	241	99.18	
Other country	2	2	0		0		2	0.82	0.34
Marital status, (%)									
Married	86	90.5	64	68.8	20	44.4	170	73.0	
Divorced/widow(er)/partner died	6	6.3	22	23.7	22	48.9	50	21.5	
Single (never married)	2	2.1	5	5.4	3	6.7	10	4.3	
Living with partner	1	1.1	2	2.2	0		3	1.3	
missing	1		9		0		10		<0.0001
Education, n (%)									
Primary education or less	62	64.6	0		10	22.2	72	29.6	
Secondary education	19	19.8	62	60.8	29	64.4	110	45.3	
Tertiary education	15	15.6	40	39.2	6	13.3	61	25.1	<0.0001
Mobility, %									
Bed or chair bound	0		1	1.0	1	2.2	2	0.8	
Able to get out of bed/ chair but does not go out	0		0	0	4	8.9	4	1.7	
Goes out	96	100	101	99.0	40	88.9	237	97.5	0.0003
Comorbidities, %									
No chronic disease	3	3.1	36	35.3	10	22.2	49	20.2	
One chronic disease	33	34.4	34	33.3	20	44.4	87	35.8	
Two or more chronic diseases	60	62.5	32	31.4	15	33.3	107	44.0	<0.0001
Frailty state, % (M0)									
Robust	71	74.0	81	79.4	5	11.1	157	64.6	
Pre-frail	25	26.0	21	20.6	40	88.9	86	35.4	<0.0001
BMI, kg/m^{2}§									
Underweight	4	4.2	4	3.9	2	4.4	10	4.1	
Normal weight	9	9.4	20	19.6	6	13.3	35	14.4	
Overweight	45	46.9	51	50.0	15	33.3	111	45.7	
Obese	38	39.6	27	26.5	22	48.9	87	35.8	0.08
Problems to chew, %									
Never	88	91.7	96	94.1	38	84.4	222	91.4	
Rarely	4	4.2	1	1.0	2	4.4	7	2.9	
Sometimes	4	4.2	4	3.9	1	2.2	9	3.7	
Often			1	1.0	3	6.7	4	1.7	
Very often					1	2.2	1	0.4	0.06
Problems to swallow, %									
Never	90	93.8	96	94.1	39	86.7	225	92.6	
Rarely	3	3.1	3	2.9	3	6.7	9	3.7	
Sometimes	3	3.1	2	2.0	1	2.2	6	2.5	
Often	0		0		2	4.4	2	0.8	
Very often	0		1	1.0	0		1	0.4	0.26

†Differences across pilots

§underweight: <20 for <70y or <22 for ≥70y; normal weight: 20-24.9 for <70y or 22-24.9 for ≥70y; overweight: 25.0-29.9; obese: ≥30

Table 4: Distribution of subjects across age groups, gender and pilot

	<75 years			≥ 75 years			Both ages
pilot	Female	Male	subTotal	Female	Male	subTotal	Total
CST	34	39	73	8	15	23	96
CYB	40	37	77	12	13	25	102
WU	11	6	17	19	9	28	45
Total	85 (35%)	82 (34%)	167 (69%)	39 (16%)	37 (15%)	76 (31%)	243(100%)

7.2 Primary Outcome measures

7.2.1 SF36 dimension scores

The eight SF36 dimension scores and the two summary scores MCS and PCS remained all stable during the PhysioDom intervention (Table 5a), except the Vitality score for CST which increased significantly (p=0.007), Role-Physical and Mental Health scores which decreased significantly (p=0.03 and p=0.01, respectively) in CYB and Role-Physical for the pooled data.

Results were similar within each of the gender, age and BMI categories and nutritional status strata, except for the Role-Physical and Mental Health dimensions which decreased significantly (p=0.01 for both) in the 65-74 year olds upon intervention, the Role-Physical score which decreased in the male population (p=0.02), the Physical Function score which decreased in the underweight subjects (p=0.047) and the Mental Function score which decreased (p=0.006) in the normal weight group (Tables 5b and 5c). However, as can be seen from Figures 3a and 3b, there were large inter-individual differences for the changes in the two summary scores and particularly those having poor scores improved significantly more for all the dimension scores than the rest of the population (Table 5d). Furthermore, there were differences in almost all dimensions across age groups, gender, nutritional status and BMI categories (Tables 5b and 5c).

Table 5a: Changes in the SF36 dimensions scores during PhysioDom, by pilot site and pooled data

	CST			CYB			WU			Pooled data		
	Baseline	6 Months	*P* §	Baseline	6 Months	*P* §	Baseline	6 Months	*P* §	Baseline	6 Months	*P* §
	Mean (SD)			Mean (SD)			Mean (SD)			Mean(SD)		
MCS	54.9 (8.0)	54.7 (8.4)	0.74	55.6 (8.0)	55.1 (7.3)	0.23	48.9 (11.5)	50.5 (12.0)	0.7	54.1 (9.1)	54.1 (17.1)	0.44
PCS	46.4 (9.0)	47.3 (9.3)	0.2	47.9 (9.1)	47.0 (9.9)	0.22	33.9 (9.5)	34.8 (11.8)	0.4	44.7 (10.5)	44.9 (15.4)	0.73
PF	79.3 (21.9)	81.7 (19.8)	0.09	80.5 (22.1)	80.0 (22.5)	0.69	45.7 (29.6)	48.7 (29.2)	0.24	73.6 (27.0)	74.9 (26.0)	0.32
RP	88.3 (28.3)	85.4 (31.3)	0.23	86.5 (31.2)	78.9 (37.2)	0.03	26.1 (40.6)	22.8 (37.6)	0.61	76.0 (39.9)	71.1 (42.0)	0.03
BP	66.2 (25.5)	68.5 (26.4)	0.52	75.0 (23.6)	74.0 (23.2)	0.71	57.6 (29.3)	60.5 (26.6)	0.2	68.3 (26.2)	69.3 (25.5)	0.62
GH	65.8 (19.4)	67.0 (19.0)	0.31	72.2 (17.3)	70.49 (18.9)	0.26	46.6 (13.3)	54.1 (17.9)	0.09	65.0 (19.8)	66.1 (19.6)	0.52
VT	67.2 (22.4)	72.3 (19.5)	0.007	66.3 (17.3)	65.5 (18.6)	0.5	51.1 (21.1)	54.0 (21.8)	0.17	63.8 (21.0)	66.0 (20.6)	0.09
SF	89.7 (19.9)	90.2 (15.6)	0.76	93.8 (16.0)	92.3 (15.7)	0.33	59.7 (24.7)	61.4 (29.1)	0.69	85.9 (23.1)	85.8 (22.1)	0.59
RE	93.4 (21.4)	89.9 (27.0)	0.09	90.5 (26.3)	91.8 (25.0)	0.66	51.1 (21.1)	58.5 (45.0)	0.19	84.4 (33.1)	84.9 (32.8)	0.61
MH	79.1 (17.9)	78.6 (18.8)	0.62	83.4 (15.0)	80.5 (15.4)	0.01	74.9 (18.5)	76.6 (18.2)	0.91	80.1 (17.1)	79.0 (17.3)	0.09

Table 5b: Changes in the SF36 dimensions scores during PhysioDom stratified by age and gender - pooled data

	Age										Gender						
	65-74 (n=161)			75-84 (n=74)			≥85 (n=8)				Male (n=119)			Female (n=124)			
	Baseline	6 Months	*P* §	Baseline	6 Months	*P* §	Baseline	6 Months	*P* §	*P* ¶	Baseline	6 Months	*P* §	Baseline	6 Months	*P* §	*P*¶
	Mean (SD)			Mean (SD)			Mean (SD)				Mean (SD)			Mean (SD)			
MCS	54.1 (9.5)	53.5 (9.4)	0.06	53.6 (8.4)	54.8 (8.0)	0.23	56.5 (7.3)	57.6 (4.8)	1	0.0014	55.5 (7.5)	55.3 (7.9)	0.71	52.7 (10.2)	52.8 (9.6)	0.55	0.0006
PCS	46.8 (8.7)	47.01 (9.99)	0.69	40.4 (12.3)	40.7 (12.2)	0.72	41.7 (12.5)	39.5 (10.0)	0.46	0.44	47.3 (8.5)	47.1 (9.8)	0.58	42.2 (11.6)	42.7 (11.8)	0.36	0.04
PF	80.0 (20.9)	80.6 (22.1)	0.39	60.9 (33.2)	63.4 (30.0)	0.33	60.6 (31.1)	65.6 (24.6)	0.46	<0.001	79.8 (22.8)	81.1 (22.8)	0.14	67.6 (29.4)	68.9 (27.5)	0.56	0.0005
RP	83.1 (34.1)	77.6 (38.6)	0.01	60.8 (46.6)	59.1 (44.9)	0.63	75.0 (46.3)	50.0 (53.5)	0.5	0.001	87.8 (29.1)	79.2 (36.9)	0.02	64.7 (45.3)	63.3 (45.1)	0.55	<0.0001
BP	69.4 (24.9)	70.7 (26.1)	0.5	65.6 (28.6)	67.2 (24.8)	0.54	72.4 (30.7)	62.5 (19.4)	0.31	0.63	74.6 (24.5)	74.9 (23.4)	0.89	62.3 (26.5)	64.0 (26.4)	0.34	0.0002
GH	67.8 (18.9)	68.0 (18.9)	0.87	58.7 (20.9)	61.5 (21.1)	0.4	65.1 (15.3)	69.9 (12.0)	0.6	0.0048	67.2 (20.3)	67.5 (19.4)	0.64	62.8 (19.1)	64.8 (19.8)	0.23	0.0502
VT	65.8 (20.9)	67.9 (20.7)	0.07	60.3 (20.7)	62.6 (20.3)	0.13	56.3 (22.2)	61.9 (16.2)	0.46	0.1	68.0 (20.1)	70.9 (20.3)	0.007	59.9 (21.2)	61.4(19.8)	0.38	0.003
SF	88.1 (22.1)	88.0 (20.2)	0.84	80.9 (24.9)	80.9 (25.7)	0.92	85.9 (19.4)	85.9 (19.4)	1	0.008	90.7 (19.0)	89.6 (19.7)	0.66	81.3 (25.6)	82.1 (23.7)	0.96	0.0012
RE	88.8 (28.9)	87.2 (30.5)	0.39	74.32 (40.0)	80.2 (37.0)	0.1	87.5 (24.8)	83.3 (35.6)	0.5	0.01	90.5 (26.4)	87.4 (31.0)	0.09	78.5 (37.6)	82.5 (34.4)	0.19	0.004
MH	80.0 (18.0)	77.5 (19.0)	0.01	79.7 (15.4)	81.4 (13.5)	0.53	86.5 (14.6)	87.5 (4.5)	0.5	0.36	83.7 (15.1)	83.1 (15.4)	0.39	76.8 (18.3)	75.1 (18.3)	0.09	0.0015

MCS=Mental Component Summary; PCS=Physical Component Summary; PF=Physical Function; RP=Role-Physical; BP=Bodily Pain; GH=General Health; VT=Vitality; SF=Social functioning; RE=Role-Emotional; MH=Mental Health

§Difference between baseline and 6 months

¶Differences across groups for baseline values

Table 5c: Changes in the SF36 dimensions scores during PhysioDom stratified by Nutritional Status and BMI category - pooled data

	Nutritional status							BMI category												
	At risk of undernutrition (n=18)			Normal nutritional status (n=225)				Underweight (n=10)			Normal weight (n=35)			Overweight (n=111)			Obese (n=87)			
	Baseline	6 Months	*P*§	Baseline	6 Months	*P*§	*P*¶	Baseline	6 Months	*P*§	Baseline	6 Months	*P*§	Baseline	6 Months	*P*§	Baseline	6 Months	*P*§	*P*¶
	Mean (SD)			Mean (SD)				Mean (SD)			Mean (SD)			Mean (SD)			Mean (SD)			
MCS	43.4 (14.2)	47.5 (14.3)	0.17	54.9 (8.0)	54.6 (8.1)	0.25	0.0016	56.5 (5.3)	55.2 (8.7)	0.81	55.0 (9.1)	54.1 (9.0)	0.09	55.0 (8.0)	54.5 (8.1)	0.37	52.2 (10.5)	53.2 (9.8)	0.40	0.01
PCS	36.2 (12.5)	35.2 (13.3)	0.59	45.4 (10.0)	45.6 (10.6)	0.60	0.0005	46.6 (13.3)	46.8 (13.1)	0.55	46.3 (10.4)	45.7 (11.8)	0.74	45.8 (10.0)	46 (10.4)	0.80	42.4 (10.5)	42.8 (11.3)	0.87	0.35
PF	43.3 (32.4)	45.5 (32.1)	0.61	76.0 (25.1)	77.2 (24.0)	0.37	<0.0001	77.0 (38.6)	74 (37.2)	0.047	78.1 (28.0)	75.9 (29.0)	0.83	77.7 (23.2)	79.2 (22.2)	0.71	66.0 (28.5)	69.0 (27.0)	0.09	0.0006
RP	47.2 (49.9)	33.3 (44.5)	0.23	78.3 (38.2)	74.1 (40.3)	0.06	0.0052	80.0 (42.2)	65 (47.4)	0.16	83.6 (35.3)	67.1 (43.2)	0.05	79.7 (37.8)	76.5 (39.2)	0.19	67.8 (43.1)	66.4 (44.1)	0.68	0.08
BP	43.7 (33.0)	51.3 (27)	0.25	70.3 (24.6)	70.8 (24.9)	0.89	0.0011	76.8 (26.8)	84.9 (22.4)	0.66	67.3 (27.4)	71.2 (27)	0.18	71.2 (24.3)	69.9 (24.5)	0.38	64.1 (27.7)	66.1 (26.0)	0.36	0.19
GH	51.8 (19.6)	53.7 (20.1)	0.93	66.0 (19.5)	67 (19.3)	0.50	0.0053	71.0 (23.3)	73.2 (26.5)	0.43	72.3 (17.7)	73 (17.6)	0.81	65.9 (20.9)	66.8 (17.9)	0.76	60.1 (17.5)	61.5 (20.7)	0.57	0.0024
VT	44.7 (21.9)	51.9 (24.1)	0.23	65.4 (20.2)	67 (19.9)	0.15	0.0002	72 (20.2)	72 (19.6)	0.77	63.1 (21.7)	67.7 (17.8)	0.29	65.3 (20.4)	67.3 (19.9)	0.23	61.4 (21.5)	63 (22.4)	0.49	0.31
SF	43.1 (29.5)	54.1 (38.8)	0.11	89.3 (18.7)	88.2 (18)	0.25	<0.0001	85 (31.1)	90 (27.5)	0.16	87.9 (24.2)	84.2 (26)	0.08	89.5 (20.0)	86.7 (20.9)	0.07	80.5 (24.6)	84.6 (21.5)	0.12	0.01
RE	44.4 (54.7)	57.4 (44)	0.22	87.6 (29.8)	87.1 (30.8)	0.32	<0.0001	90 (31.62)	83.3 (32.4)	0.16	86.7 (31.5)	87.6 (32.4)	0.70	90.4 (26.4)	88.3 (28.3)	0.21	75.1 (39.4)	79.7 (37.8)	0.34	0.005
MH	67.8 (24.4)	69.1 (23.4)	0.76	81.1 (16.0)	79.8 (16.6)	0.06	0.001	86.8 (11.8)	81.2 (20.9)	0.71	84.7 (16.3)	78.3 (18.9)	0.006	81.0 (15.3)	80.6 (15.0)	0.33	76.5 (19.4)	77.0 (19.0)	0.83	0.07

Table 5d: Changes in the summary SF36 dimensions scores stratified according to the baseline score[1] during PhysioDom

		Poor score				Normal score			
			Baseline	6 Months	*P*§		Baseline	6 Months	*P*§
SF36 dimension	cut-off score	n	Mean (SD)			n	Mean (SD)		
MCS	40	57	30.0 (6.7)	32.8 (9.8)	0.02	186	50.2 (4.9)	49.4 (7.6)	0.11
PCS	50	66	40.5 (8.2)	46.5 (11.6)	<0.001	177	58.2 (3.7)	56.4 (6.3)	<0.001
PF	55	47	26.1 (15.8)	36.4 (25.3)	0.001	196	85.0 (13.2)	83.6 (17.1)	0.49
RP	50	53	3.3 (8.5)	21.2 (35.8)	0.004	190	96.3 (10.9)	85.0 (31.8)	<0.001
BP	50	52	28.9(13.1)	46.6 (21.8)	<0.001	191	79.1 (16.9)	75.6 (22.8)	0.046
GH	50	56	36.1 (8.5)	52.5 (18.0)	<0.001	187	73.6 (12.7)	70.2 (18.2)	0.009
VT	50	61	36.0 (10.7)	47.4 (19.8)	0.0004	182	73.2 (14.2)	72.3 (16.7)	0.75
SF	70	53	47.2 (17.8)	65.1 (28.9)	0.0001	190	96.6 (7.6)	91.5 (15.6)	0.0001
RE	70	51	25.5 (28.7)	48.4 (46.3)	0.0007	192	100 (0)	91.8 (94.6)	<0.001
MH	70	61	55.6 (12.9)	63.8 (19.8)	0.003	182	88.3 (8.0)	84.1 (12.9)	<0.001

MCS=Mental Component Summary; PCS=Physical Component Summary; PF=Physical Function; RP=Role-Physical; BP=Bodily Pain; GH=General Health; VT=Vitality; SF=Social functioning; RE=Role-Emotional; MH=Mental Health

[1]cut-off: 25th percentile

§Difference between baseline and 6 months

¶Differences across groups for baseline values

Figure 3a: Scatter plots of the changes in the Physical Component Summary (PCS) Score between baseline and 6 months against the score at baseline, by pilot site & pooled data

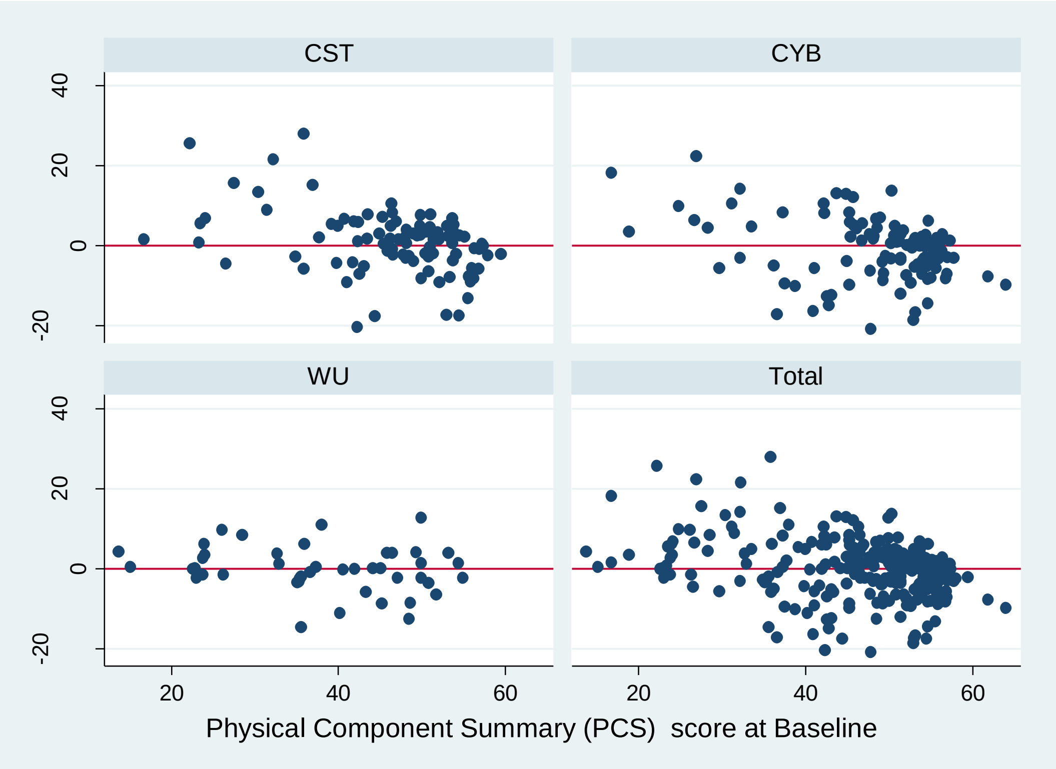
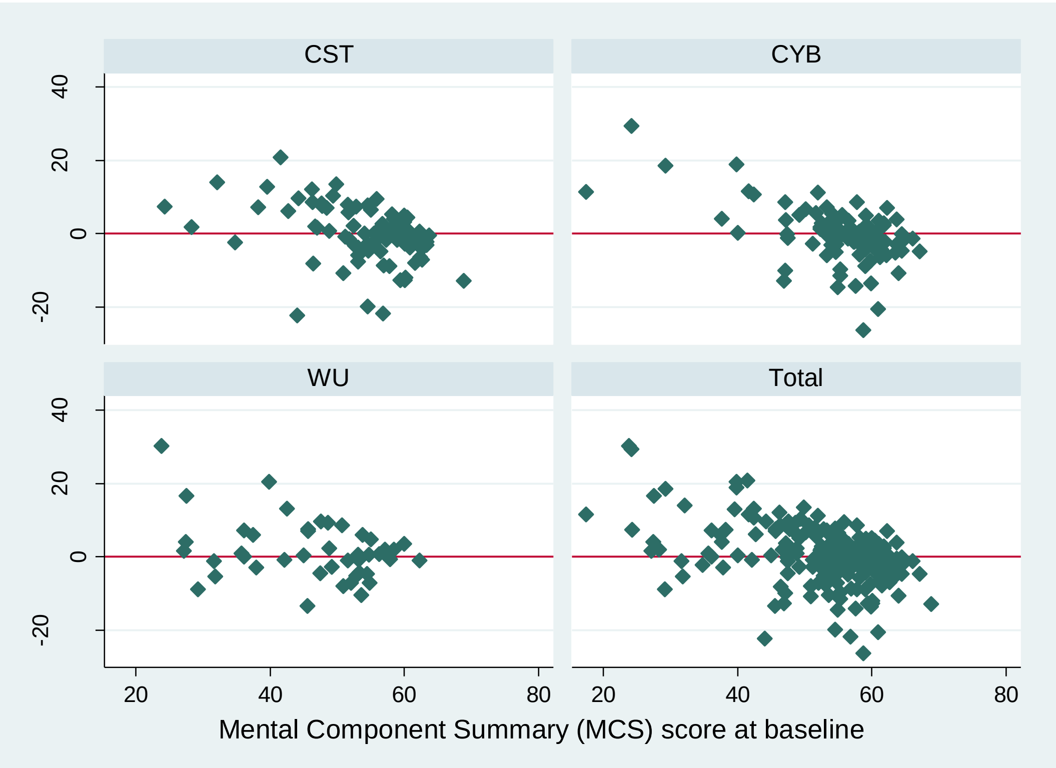


Figure 3b: Scatter plots of the changes in the Mental Component Summary (MCS) score between baseline and 6 months against the score at baseline, by pilot site & pooled data.

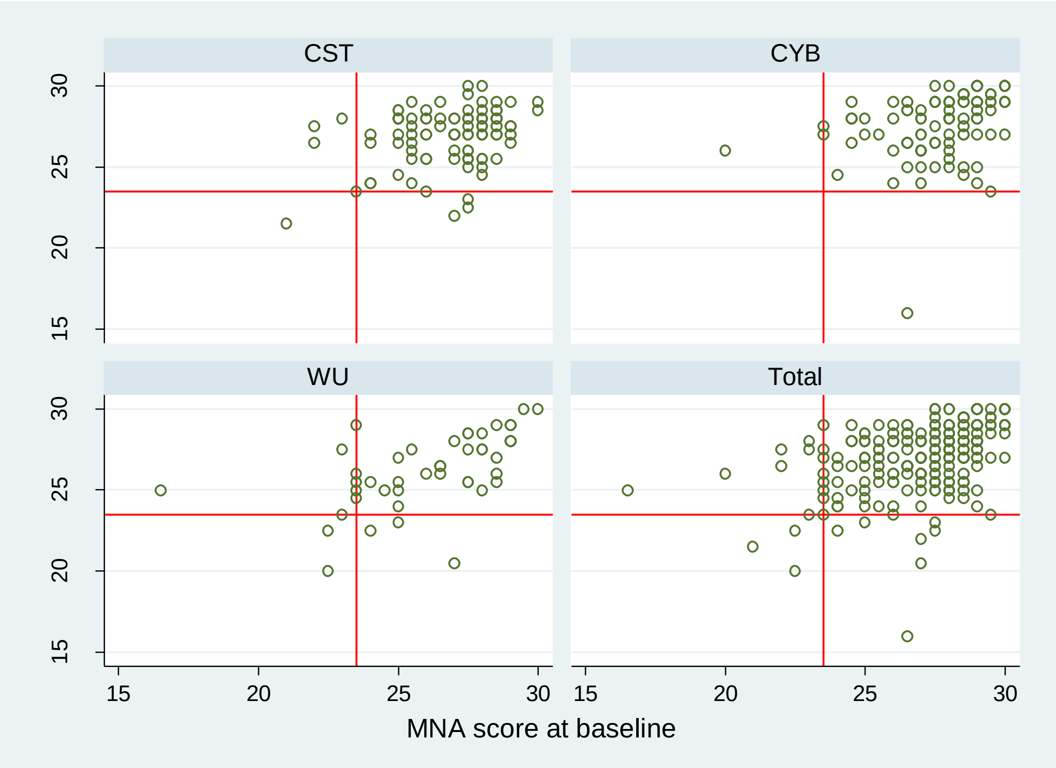


7.2.2 Nutritional Status

Figure 4 shows the individual changes in MNA status between baseline and month six of the intervention. The red lines indicate the cut-off score (23.5) below which a subject is considered at risk for undernutrition.

The prevalence of being at risk of malnutrition or malnourished remained stable (Table 6) and the overall MNA scores did not change upon the PhysioDom intervention (Table 7a). However, MNA scores of those at risk of undernutrition (n=18) increased significantly (p<0.001) from baseline till the end of the study. Upon more detailed analysis on the persons at risk, we revealed that eight out of nine subjects below 75 years returned to a normal nutritional status while this was the case for only five out of nine subjects in those above 75 years (Table 7b). On the other hand, 8 (3.6%) of the normally nourished subjects turned into an at risk for undernutrition state and one (0.4%) became undernourished at the end of the intervention, independently from age and gender (Table 7c). Only one of them was hospitalized for 5 days.

Figure 4: Scatter plots of the MNA scores[1] at baseline and after 6 Months of the PhysioDom intervention study, stratified by pilot and pooled data



[1]The red lines indicate the cut-off score (23.5) below which a subject is considered at risk for undernutrition

Table 6: Changes in the prevalence of impaired nutritional status[1] during PhysioDom intervention

		Baseline	6 Months	Change	
	Pilot	n (%)	n (%)	%	$P^{\S}$
Impaired Nutritional Status	CST	5 (5.2)	6 (6.3)	1.1	0.7
	CYB	3 (2.9)	2 (2.0)	-0.9	0.65
	WU	10 (22.2)	6 (13.3)	-8.9	0.2
	Total	18 (7.4)	14 (5.8)	-1.6	0.39

[1] Defined as being at risk of undernutrition or having a poor nutritional status
§Difference between baseline and 6 months

Table 7a: Changes in the MNA scores during PhysioDom intervention stratified by pilot and nutritional status, and pooled data

		Baseline	6 Months	
	Pilot	Mean (SD)	Mean (SD)	$P^{\S}$
MNA, score	CST (n=96)	26.8 (1.7)	26.9 (1.7)	0.59
	CYB (n=102)	27.7 (1.8)	27.6 (2.1)	0.98
	WU (n=45)	26.1 (2.6)	26.2 (2.3)	0.94
	Total (n=243)	27.0 (2.0)	27.1 (2.0)	0.76
At risk of undernutrition	CST (n=5)	22.3 (1.0)	25.4 (2.8)	
	CYB (n=3)	22.3 (2.0)	26.8 (0.7)	
	WU (n=10)	22.5 (2.1)	24.8 (2.5)	
	Total (n=18)	22.4 (1.7)	25.3 (2.4)	<0.001
Normal nutritional status	CST (n=91)	27.0 (1.4)	26.9 (1.6)	
	CYB (n=99)	27.8 (1.5)	27.6 (2.1)	
	WU (n=35)	27.2 (1.7)	26.6 (2.1)	
	Total (n=225)	27.4 (1.5)	27.2 (1.9)	0.3

MNA=Mini Nutritional Assessment
§Difference between baseline and 6 months

Table 7b: Sex and age distribution of the subjects who were at risk of undernutrition at baseline and normally nourished at the end of the intervention

	<75 year				≥75 year			
	Female		Male		Female		Male	
	Baseline Under nutrition	Month 6 Normal Nutritional state	Baseline Under nutrition	Month 6 Normal Nutritional state	Baseline Under nutrition	Month 6 Normal Nutritional state	Baseline Under nutrition	Month 6 Normal Nutritional state
CST	0	0	3	2	1	0	1	1
CYB	0	0	1	1	1	1	1	1
WU	4	4	1	1	4	1	1	1
Total	4	4	5	4	6	2	3	3

§Difference between baseline and 6 months

Table 7c: Sex and age distribution of the subjects who were normally nourished at baseline and at risk of undernutrition or undernourished at the end of the intervention

	<75 year		≥75 year	
	Female	Male	Female	Male
CST	2	2	0	0
CYB	0	1	1	0
WU	1	1	1	0
Total	3	4	2	0

7.3 Secondary Outcome measures

7.3.1 Weight and BMI

Figure 5 shows weight change between baseline and month 6 plotted against baseline weight. Weight remained stable between baseline and 6 months, both for the pooled data (Table 8) as well as across gender and BMI groups (Table 9). Prevalence of obesity remained stable as well, although the reduction was close to significance (*p*=0.06) in CST (Table 10).

Table 8: Changes in weight, fat mass (%) and BMI during Physiodom

		Female				Male				Pooled data			
			Baseline	6 Months	$P^§$		Baseline	6 Months	$P^§$		Baseline	6 Months	$P^§$
	Pilot	n	Mean (SD)			n	Mean (SD)			n	Mean (SD)		
Weight, kg	CST	42	70.1 (12.1)	69.7 (12.1)	0.27	54	81.3 (12.0)	80.6 (11.9)	0.21	96	76.4 (13.2)	75.9 (13.1)	0.08
	CYB	52	72.5 (13.3)	72.1 (13.0)	0.27	50	84.2 (12.2)	83.4 (11.8)	0.57	102	78.2 (14.0)	77.6 (13.6)	0.24
	WU	30	76.0 (12.5)	76.1 (12.1)	0.94	15	87.2 (13.3)	87.7(13.4)	0.1	44	79.7 (13.7)	79.8(13.6)	0.39
	Total	124	72.5 (12.8)	72.2 (12.6)	0.15	119	83.2 (12.3)	82.7 (12.2)	0.47	243	77.7 (13.6)	77.3 (13.4)	0.12
BMI (kg/m$^{2)}$, continuous	CST	42	29.3 (5.4)	29.2 (5.4)	0.27	54	28.9 (3.8)	28.7 (3.7)	0.21	96	29.1 (4.5)	28.89 (4.5)	0.09
	CYB	52	27.9 (4.7)	27.7 (4.5)	0.29	50	27.8 (4)	27.5 (3.6)	0.53	102	27.8 (4.3)	27.60 (4.1)	0.22
	WU	30	29.2 (4.5)	29.1 (4.3)	0.92	15	28.9 (3.5)	29.2 (3.7)	0.1	45	29.1 (4.1)	29.16 (4.0)	0.40
	Total	124	28.7 (4.9)	28.5 (4.8)	0.15	119	28.5 (3.9)	28.3 (3.7)	0.46	243	28.6 (4.4)	28.4 (4.3)	0.11
Fat mass (%)	CST	21	40.1 (5.1)	41 (5.6)	0.11	33	32.9 (6.1)	35.2 (7.2)	0.006	54	35.7 (6.7)	37.5 (7.2)	0.002
	CYB	24	40.1 (6.2)	39.5 (6.8)	0.9	37	31 (5.3)	33.3 (6.7)	0.02	61	34.6 (7.2)	35.7 (7.4)	0.08
	WU	4	43.3 (5)	44.9 (4)	0.12	2	33 (0.9)	35.3 (2)	0.5	6	39.9 (6.6)	41.7 (6)	0.03
	Total	49	40.4 (5.6)	40.6 (6.2)	0.14	72	32 (5.7)	34.2 (6.9)	0.0003	121	35.4 (7.0)	36.8 (7.3)	0.0001

§Difference between baseline and 6 months

Table 9: Changes in weight stratified by gender and BMI during Physiodom

BMI category[1]	Pilot	Female			Male		
			Baseline	Month 6		Baseline	Month 6
		n	Mean (SD)		n	Mean (SD)	
Underweight	CST	2	57.8 (2.9)	57.7 (0.21)	2	57.1 (0.1)	57.9 (1.2)
	CYB	3	55.3 (3.7)	56.9 (4.1)	0		
	WU	1	53.7	54.4	1	62.0	63.8
	Total	6	55.9 (3.1)	56.7 (2.8)	3	58.7 (2.8)	59.8 (3.5)
Normal weight	CST	5	57.2 (1.6)	57.7 (1.6)	4	71.6 (7.9)	72.0 (7.5)
	CYB	8	59.4 (5.4)	58.7 (5.1)	12	73.0 (6.1)	72.7 (6.9)
	WU	5	63.8 (7.0)	65.1 (7.5)	1	65.8	67.3
	Total	18	60.0 (5.6)	60.2 (5.9)	17	72.3 (6.33)	72.2 (6.7)
Overweight	CST	18	64.7 (4.3)	64.3 (5.5)	27	77.3 (6.9)	77.0 (7.4)
	CYB	26	70.1 (8.3)	69.5 (7.4)	26	82.7 (6.7)	82.9 (6.6)
	WU	10	75.3 (8.5)	74.8 (8.9)	4	82.1 (9.5)	81.5 (8.9)
	Total	54	69.3 (8.1)	68.8 (7.9)	57	80.1 (7.3)	80.0 (7.6)
Obese	CST	17	81.1 (11.1)	80.5 (11.1)	21	90.5 (10.9)	89.1 (11.6)
	CYB	15	87.2 (10.3)	86.6 (10.6)	12	98.8 (12.1)	95.3 (14.0)
	WU	13	83.6 (11.4)	83.1 (10.9)	9	94.6 (8.2)	95.4 (8.6)
	Total	45	83.8 (11.0)	83.3 (10.9)	42	93.7 (11.1)	92.2 (11.9)

[1]underweight: <20 for <70y or <22 for ≥70y; normal weight: 20-24.9 for <70y or 22-24.9 for ≥70y; overweight: 25.0-29.9; obese: ≥30 kg/m^2

Table 10: Changes in the prevalence of obesity[1] during PhysioDom

		Baseline	6 Months	Change	
	Pilot	n (%)	n (%)	%	p[§]
Obesity	CST	38 (39.6)	33 (34.4)	-5.2	0.06
	CYB	27 (26.5)	25 (24.5)	2.0	0.41
	WU	22 (48.9)	22 (48.9)	0	1
	Total	87 (35.8)	80 (32.9)	-2.9	0.07

[1]BMI obese: ≥30 kg/m^2

[§]Difference between baseline and 6 months

7.3.2 Fat mass

Due to missing values, data from 122 subjects (50%) were excluded. The proportion of fat mass in the remaining group (n=121) increased significantly in the male population (p=0.0003) during the period under study (Table 8).

7.3.3 Appetite

On average, the score on appetite did not change upon the PhysioDom intervention (Table 11). However, those having poor appetite at baseline improved their score on the SNAQ questionnaire upon the 6 months follow-up.

Table 11: Changes in appetite during PhysioDom

			Baseline	6 Months	$P^{§}$
	pilot	n	Mean (SD)		
Appetite, score	CST	96	17.0 (1.5)	16.9 (1.5)	0.66
	CYB	102	16.2 (1.8)	16.2 (1.8)	0.93
	WU	45	15.5 (1.8)	15.7 (1.7)	0.19
	Total	243	16.4 (1.7)	16.4 (1.6)	0.95
Poor appetite	CST	5	13.6 (0.5)	15.8 (1.3)	
	CYB	17	13.4 (0.9)	13.9 (1.3)	
	WU	7	12.3 (1.6)	13.3 (1.8)	
	Total	29	13.1 (1.1)	14.1 (1.6)	<0.001
Normal appetite	CST	91	17.1 (1.3)	16.9 (1.4)	
	CYB	85	16.9 (1.3)	16.7 (1.5)	
	WU	38	16.1 (1.0)	16.2 (1.2)	
	Total	214	16.9 (1.3)	16.7 (1.4)	0.19

§Difference between baseline and 6 months

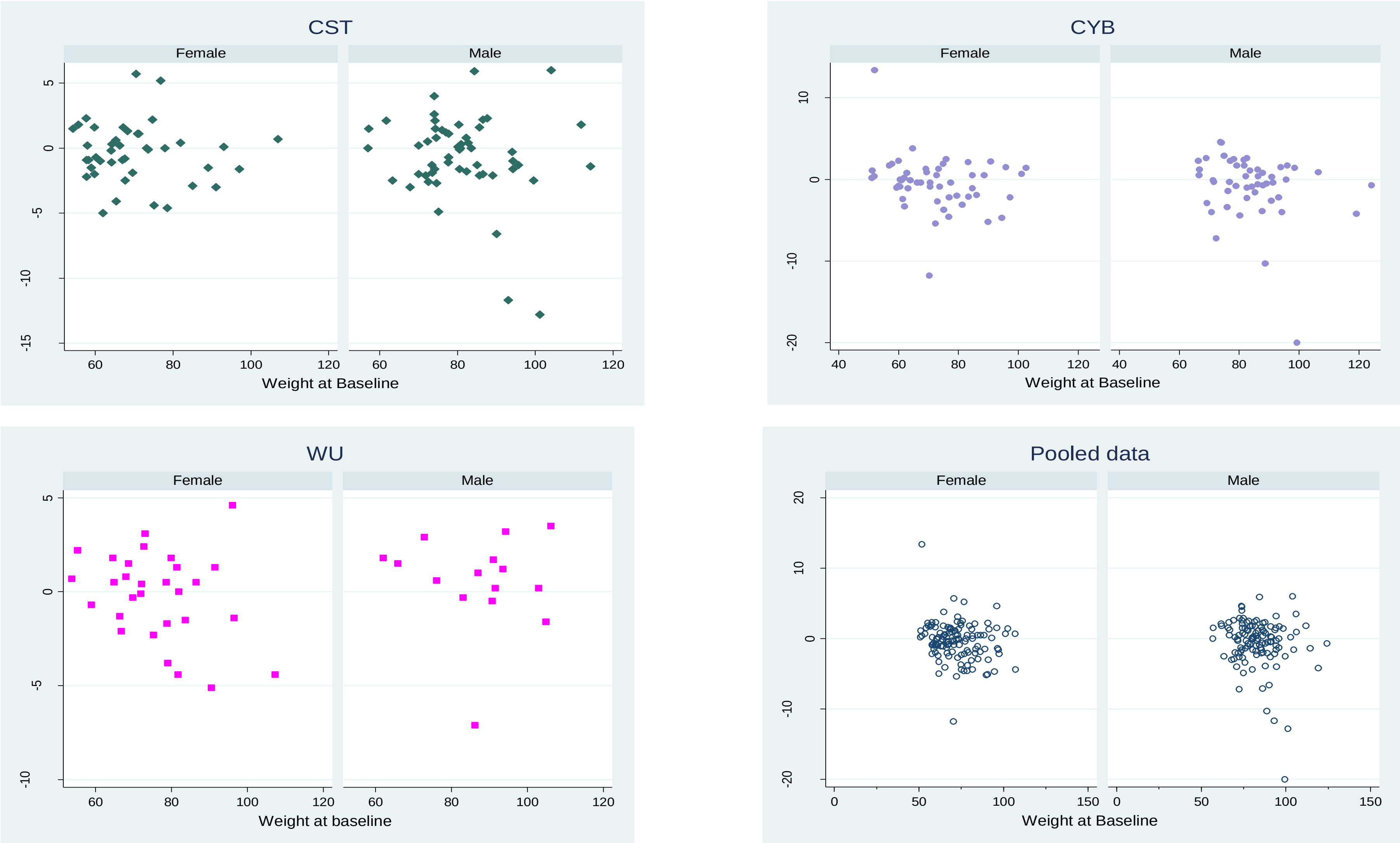


Figure 5a-d: Scatter plots of the weight change between month 6 and baseline against weight at baseline stratified by gender and pilot

7.4 Steps

For the comparison on steps counts between the beginning (month 1 or 2) and the end of the study (month 5 or 6), data were included for 195 subjects, as for 48 subjects (CST: n=33; WU: n=15) data were recorded less than 4 months (97% recorded steps for at least 5 months). Steps counts diminished significantly in the CYB (*P*=0.004) and WU (*P*<0.001) pilots, and remained stable in CST (Table 12). In particular, the somewhat active and highly active groups significantly (*P*=0.03 and *P*<0.001, respectively) diminished their step counts. For CYB, both the male population and those aged over 75 years reduced their steps, for WU both genders and age groups diminished their steps. There were also significant differences across age (*P*<0.001) and gender (*P*=0.01) strata (Tables 13a and 13b). The prevalence of low activity did not change over the period under study (Table 14).

Table 12: Step counts for month 1 and month 6[1], stratified by pilot and level of activity

		Month 1		Month 6		*P*
	Pilot	Mean	SD	Mean	SD	
Steps, continuous	CST (n=63)	7961	3459	8322	3562	0.14
	CYB (n=102)	6663	3258	6183	3493	0.004
	WU (n=30)	3772	2660	2764	2365	< 0.001
	Total (n=195)	6637	3500	6348	3809	0.01
Steps, categories[2]						
Inactive	CST (n=0)					
	CYB (n=3)	507	418	464	527	
	WU (n=5)	504	412	307	396	
	Total (n=8)	505	383	366	419	0.46
Low activity	CST (n=4)	2444	490	4751	1763	
	CYB (n=12)	2296	542	2626	1775	
	WU (n=8)	1869	650	1397	909	
	Total (n=24)	2178	594	2571	1863	0.86
Somewhat active	CST (n=9)	3948	725	4512	1385	
	CYB (n=20)	4097	527	3636	1637	
	WU (n=10)	4166	417	2739	1471	
	Total (n=39)	4080	545	3608	1628	0.03
Active	CST (n=22)	6637	932	7443	2073	
	CYB (n=33)	6614	777	6534	2331	
	WU (n=5)	7189	679	5672	1089	
	Total (n=60)	6670	832	6796	2204	0.9
Highly active	CST (n=28)	11079	2289	10747	3381	
	CYB (n=34)	10305	1897	9102	3012	
	WU (n=2)	9039	633	7232	2074	
	Total (n=64)	10604	2088	9763	3254	0.006

[1]If data for month one or six were missing steps were taken either for month 2 and 6 or 1 and 5 if the first or the last were missing respectively

[2]Categories for the number of steps were defined as follows: inactive: <1000; low activity: 1000-2999; somewhat active: 3000-4999; active: 5000-7999; highly active: ≥8000

Table 13a: Step counts for month 1 and month 6[1], stratified by pilot and age

	Pilot	n (65-74)	Baseline Mean (SD) (65-74)	6 Months Mean (SD) (65-74)	$P^{§}$	n (≥75)	Baseline Mean (SD) (≥75)	6 Months Mean (SD) (≥75)	$P^{§}$	P
Steps, continuous	CST	53	8150 (3602)	8506 (3752)	0.21	10	6958 (2477)	7348 (2196)	0.49	
	CYB	77	7270 (3106)	7067 (3312)	0.22	25	4794 (3049)	3463 (2531)	<0.0001	
	WU	11	5077 (2767)	3913 (2152)	0.002	19	3016 (2345)	2099 (2273)	<0.0001	
	Total	141	7430 (3354)	7362 (3605)	0.48	54	4569 (3014)	3702 (2988)	<0.0001	<0.0001

Table 13b: Step counts for month 1 and month 6[1], stratified by pilot and gender

	Pilot	n (Male)	Baseline Mean (SD) (Male)	6 Months Mean (SD) (Male)	$P^{§}$	n (Female)	Baseline Mean (SD) (Female)	6 Months Mean (SD) (Female)	$P^{§}$	P¶
Steps, continuous	CST	34	8593 (3383)	9323 (3441)	0.13	29	7219 (3457)	7149 (3392)	0.56	
	CYB	50	7001 (3396)	6173 (3476)	0.002	52	6339 (3118)	6194 (3544)	0.35	
	WU	12	4676 (2824)	3559 (2766)	0.001	18	3167 (2437)	2234 (1961)	<0.001	
	Total	96	7275 (3516)	6962 (3875)	0.04	99	6020 (3388)	5754 (3667)	0.14	0.01

[1]If data for month one or six were missing, steps were taken either for month 2 and 6 or 1 and 5 if the first or the last were missing respectively

Table 14: Prevalence of low physical activity[1]

	Pilot	Baseline n (%)	6 Months n (%)	Change %	Change $P^{§}$
Low physical activity	CST	4 (4.2)	4 (4.2)	0	1
	CYB	15 (11.7)	19 (18.6)	6.9	0.24
	WU	13 (26.7)	16 (35.6)	8.9	0.08
	Total	32 (12.3)	39 (13.3)	1.0	0.12

[1]low physical activity was defined as step count <3000 in month one or two if no steps were registered for month one

The boxplots in Figure 6a-c show step counts for subjects who had registered steps for each of the six months. The median step counts were stable with time in the three pilot sites.

Figure 6a: Boxplots of the number of steps made during the intervention study by the CST pilot subjects (n=40)

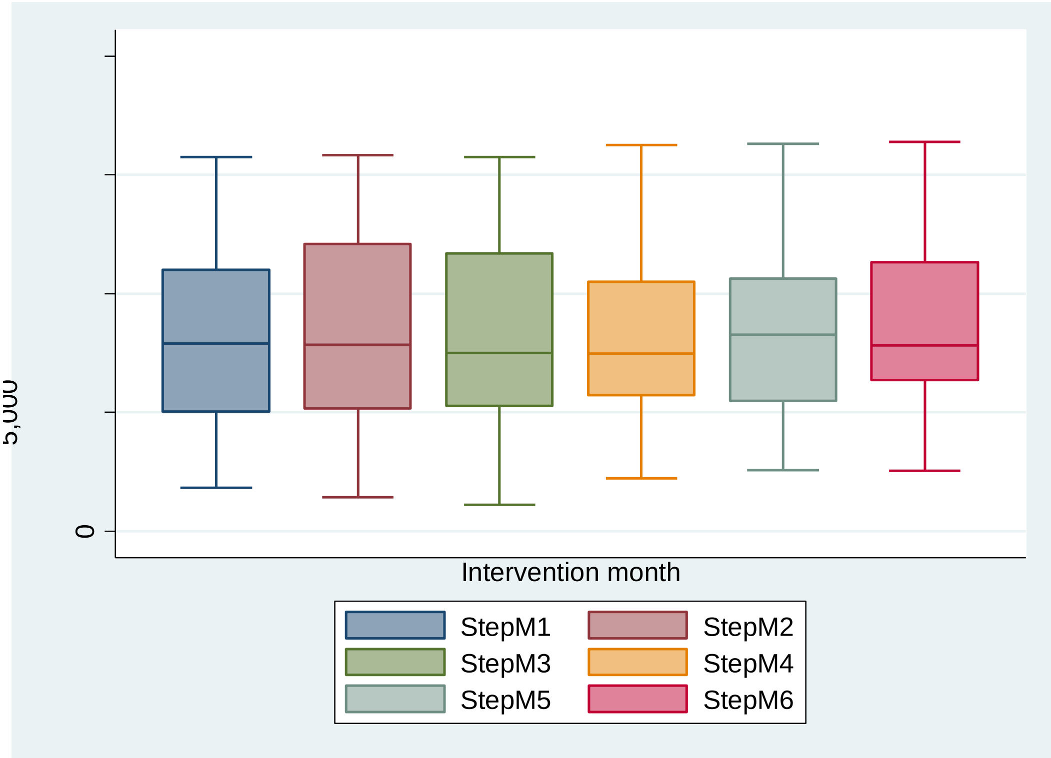


Figure 6b: Boxplots of the number of steps made during the intervention study by the CYB pilot subjects (n=94)

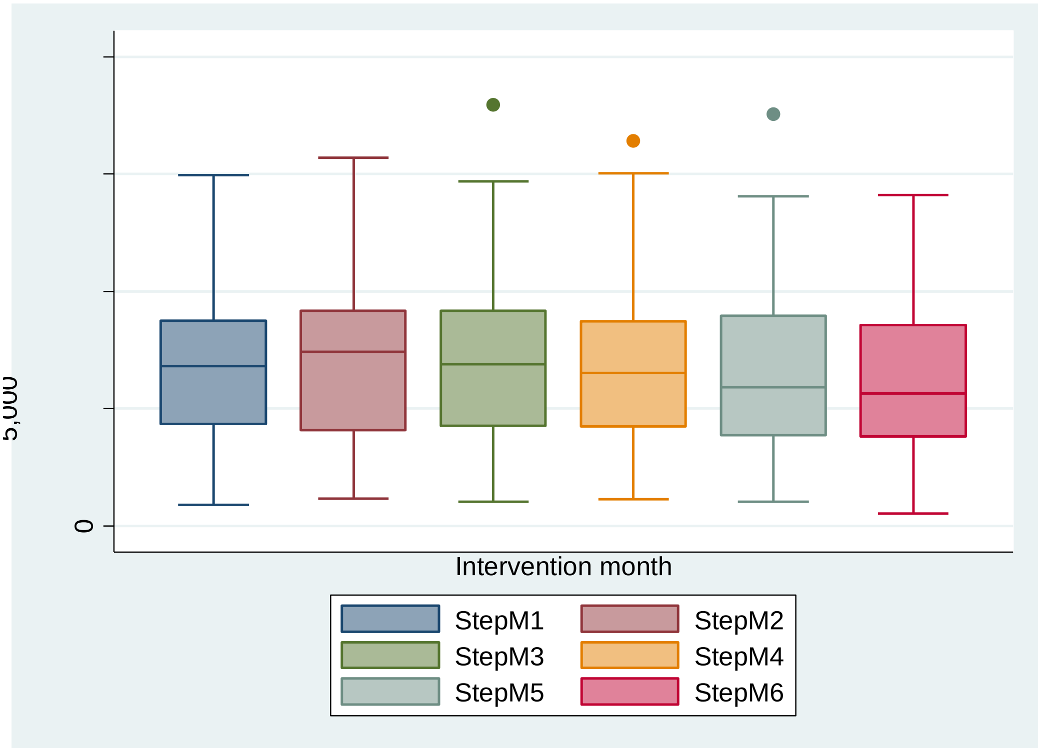
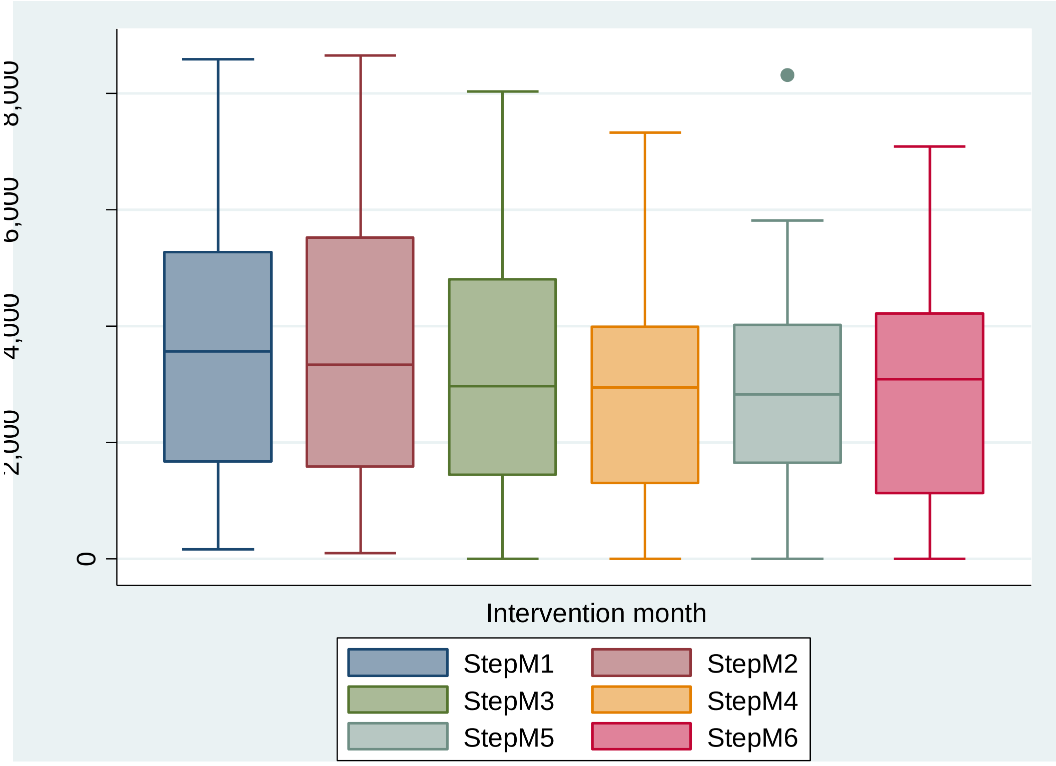


Figure 6c: Boxplots of the number of steps made during the intervention study by the WU pilot subjects (n=19)



7.5 Blood pressure

Both APS and APD remained stable in the 100 subjects whose blood pressure was monitored during the study period. For the WU subjects, the APS data were for both time points out of the normal range (APS<140 mm Hg, APD<90 mm Hg) as defined by the American heart association (Table 15). The 25 subjects having APS values above the normal range, improved their values significantly (P=0.003) by the end of the study. However, for nine others having initial values below 140 mm Hg, the end values were significantly worse than the baseline values (P=0.004), and ended out of the normal range.

Table 15: Effect of PhysioDom-HDIM on in blood pressure parameters, stratified by pilot and pooled data

			Baseline (M0)		6 Months		Change
Hypertension status	Parameter	Pilot	Mean (SD)	$P^{§}$	Mean (SD)	$P^{§}$	$P^{¶}$
All	ASP	CST (n=62)	133.4 (13.3)	0.0006	132.4 (12.2)	0.0021	
		CYB (n=33)	126.3 (13.2)		124.9 (12.3)		
		WU (n=5)	158.2 (17.9)		153.4 (23.2)		
		Total (n=100)	132.3 (15.0)		131 (14.2)		0.56
	ADP	CST (n=62)	75.5 (8)		73.8 (8.5)		
		CYB (n=33)	72.9 (7.9)	0.2	72.3 (9.1)	0.16	
		WU (n=5)	81 (15.2)		80.4 (15.6)		
		Total (n=100)	74.9 (8.5)		73.7 (9.1)		0.08
ASP ≥ 140 mmHg at baseline	ASP	Total (n=25)	152.6 (10.0)		142.6 (16.6)		0.003
	APD	Total (n=25)	80.5 (9.6)		76.1 (10.2)		0.01
ASP < 140 mmHg at baseline	ASP	Total (n=9)	130.7 (2.2)		143.1 (0.9)		0.004
& ≥ 140 mmHg at T3	APD	Total (n=9)	71.0 (3.4)		74.6 (3.5)		0.2

ASP=Arterial Systolic blood Pressure, ADP=Arterial Diastolic blood Pressure
§Differences between pilots
¶Difference between baseline and 6 Months

7.6 Models

Of the baseline characteristics presented in Table 16, poor appetite was significantly (*P*=0.02) associated with an improvement in nutritional status of 2 points, the presence of prefrailty and a normal appetite were independently (*P*=0.047 and *P*=0.003, respectively) associated with a higher chance of an improved MCS dimension score of 3 points. None of the characteristics were significantly associated with an increase in PCS of 3 points.

Table 16: Models to determine independent associations between baseline characteristics[1] and the outcome measures nutritional status, MCS and PCS after 6 months of PhysioDom intervention

	MNA improvement >2 points OR (95% CI)	PCS improvement >3 points OR (95% CI)	MCS improvement >3 points OR (95% CI)
Age	1.03 (0.95-1.12)	0.98 (0.92-1.05)	1.03 (0.96-1.11)
Female sex	1.02 (0.38-2.48)	1.75 (0.91-3.37)	1.36 (0.63-2.95)
Education			
Primary education	3.32 (0.52-16.93)	0.69 (0.24-1.95)	0.41 (0.11-1.47)
Secondary education	3.45 (0.86-13.93)	0.92 (0.41-2.03)	0.93 (0.37-2.29)
Number of comorbidities			
One comorbidity	2.41 (0.50-11.71)	0.75 (0.30-1.84)	0.47 (0.17-1.32)
Two or more comorbidities	3.87 (0.82-18.30)	0.86 (0.35-2.15)	0.45 (0.16-1.28)
BMI categories			
Underweight	0.71 (0.06-8.35)	0.85 (0.16-4.60)	2.08 (0.28-15.67)
Overweight	0.84 (0.23-2.98)	1.25 (0.49-3.22)	1.22 (0.39-3.82)
Obese	0.55 (0.15-2.03)	1.36 (0.50-3.68)	2.98 (0.94-9.49)
Poor appetite	3.52 (1.00-12.43)†	1.09 (0.39-3.01)	0.27 (0.07-0.98)†
Poor nutritional state		0.34 (0.7-1.74)	4.17 (0.87-8.85)
Presence of prefrailty	0.42 (0.10-1.73)	1.00 (0.42-2.37)	4.09 (1.60-10.44)†
Physical activity			
Inactive/ Low activity	2.31 (0.45-11.75)	1.16 (0.35-3.89)	1.05 (0.25-46)
Somewhat active	0.72 (0.16-3.20)	0.70 (0.25-1.95)	2.76 (0.86-8.85)
Active	0.64 (0.19-2.20)	0.81 (0.36-1.83)	1.94 (0.69-5.47)

MCS=Mental Component Summary score, PCS= Physical Component Summary Score
[1]Reference categories were: tertiary education, zero comorbidities, normal weight, high physical activity
[§]Underweight: <20 for <70y or <22 for ≥70y; normal weight: 20-24.9 for <70y or 22-24.9 for ≥70y; overweight: 25.0-29.9; obese: ≥30
†*P*<0.05, multivariate linear regression analysis, the variable pilot was also included in the models

7.7 Improvement of dietary intake

The overall score of selected items on dietary intake, combining the number of full meals and the intake of fluid, vegetable and protein intake, did not increase upon the PhysioDom-HDIM intervention (Table 17a). However, at the level of the individual questions protein intake increased both the CYB and WU pilots, and fluid intake decreased for the WU (Table 17b).

Table 17a: Effect of PhysioDom-HDIM on the summary score of four MNA questions on dietary intake

Pilot	Baseline	Month 6	*P*
CST (n=94)	4.37 (0.6)	4.28 (0.6)	0.27
CYB (n=102)	4.36 (0.7)	4.42 (0.8)	0.36
WU (n=45)	4.36 (0.5)	4.44 (0.6)	0.50
Total (n=241)	4.37 (0.6)	4.37 (0.7)	0.96

Table 17b: Effect of PhysioDom-HDIM on selected dietary intakes[1]

	Pilot	Score	Baseline	Month 6		Score	Baseline	Month 6
			n (%)				n (%)	
Full meals	CST	0	3 (3.1%)	1 (1.1%)	**Vegetable intake**	0	20 (20.8 %)	21 (22.3%)
		1	9 (9.4%)	14 (14.9%)		1	76 (79.2%)	73 (77.7%)
		2	84 (87.5%)	79 (84.0%)				
	CYB	0	2 (2.0 %)	2 (2.0%)		0	14 (13.7%)	13 (12.8 %)
		1	20 (19.6 %)	24 (23.5%)		1	88 (86.3 %)	89 (87.3%)
		2	80 (78.4 %)	76 (74.5 %)				
	WU	0	0	1 (2.2%)		0	5 (11.1%)	1 (2.2%)
		1	3 (6.7%)	1 (2.2%)		1	40 (88.9 %)	44 (97.8 %)
		2	42 (93.3%)	43 (95.6%)				
	Total	0	5 (2%)	4 (1.6%)		0	39 (16.0%)	35 (14.6%)
		1	32 (13.2%)	39 (16.2%)		1	204 (84.0%)	204 (85.4%)
		2	206 (84.8%)	198 (82.2%)				
Protein intake					**Fluid intake**			
	CST	0		2 (2.1%)		0	1 (1.0 %)	3 (3.19%)
		0.5	15 (15.6%)	16 (17.0%)		0,5	35 (36.5%)	34 (36.2%)
		1	81 (84.4%)	76 (80.9%)		1	60 (62.5%)	57 (60.6%)
	CYB	0	3 (2.9%)	0		0	0	1 (1.0%)
		0.5	29 (28.4%)	17 (16.6%)		0,5	18 (17.7%)	17 (16.7%)
		1	70 (68.6%)	85 (83.4%)		1	84 (82.4%)	84 (82.4%)
	WU	0	6 (13.3%)	5 (11.1%)		0	0	1 (2.2%)
		0.5	20 (44.4%)	17 (37.8%)		0,5	9 (20.0%)	13 (28.9%)
		1	19 (42.2%)	23 (51.1%)		1	36 (80.0%)	31 (68.9%)
	Total	0	9 (3.7%)	7 (2.9%)		0	1 (0.41%)	5 (2%)
		0.5	64 (26.3%)	50 (20.8%)		0,5	62 (25.5%)	64 (27%)
		1	170 (70%)	184 (76.3%)		1	180 (74.6%)	168 (71%)

[1]questions from the MNA questionnaires.
Full meals: How many full meals does the patient eat daily? Scores: 0=1 meal; 1=2 meals; 2=3 meals
Protein intake: 1) At least one serving of dairy products (milk, cheese, yoghurt) per day; 2) Two or more servings of legumes or eggs per week; 3) Meat, fish or poultry every day. Scores: 0=0/1 yes; 0.5=2 yes; 1=3 yes
Vegetable intake: Consumes two or more servings of fruit or vegetables per day? Scores: 0 = no 1 = yes
Fluid intake: How much fluid (water, juice, coffee, tea, milk...) is consumed per day? Scores: 0.0 = less than 3 cups 0.5 = 3 to 5 cups 1.0 = more than 5 cups

7.8 Intensity of the intervention in relation to outcome measures

The intervention of dietitians, nutritionists, nurses and social workers served as a proxy of intensity of the intervention in PhysioDom. There is no clear relation between the intensity of the intervention and the changes in the QoL dimension scores (Table 18a), the changes in MNA scores and the weight (Table 18b).

Table 18a: Effect of the intensity of intervention on the changes in the quality of life dimensions scores

	CST			CYB		WU		
	0 (n=14)	1-2 (n=40)	> 3 (n=42)	0 (n=92)	1-2 (n=10)	0 (n=38)	1-2 (n=2)	> 3 (n=5)
MCS	0,2	0,6	-1,1	-1	3,7	1	1,5	6,4
PCS	3,8	0	0,8	-0,5	-4,6	1,4	1,9	-3,7
PF	8,9	2,4	0,3	-1	4	2,7	5	5
RP	3,5	-4,4	-3,6	-5,5	-27,5	-3,3	0	-5
BP	13,2	-0,8	1,6	-0,6	-4,9	2,1	25,5	-0,6
GH	-1	0,9	2,2	-1,6	-3,7	10,8	-10,5	-10
VT	12,5	4,7	3,1	-0,9	-0,5	3,3	0	1
SF	7,1	-0,6	-0,6	-1,5	-1,25	0,6	6,3	7,5
RE	-4,8	1,7	-8	-0,4	16,7	5,2	0	26,7
MH	0,3	-0,1	-1,3	-3,6	3,2	0,6	8	8

Table 18b: Effect of the intensity of intervention on the change in nutritional state, weight and the number of chronic diseases

			M0			M6		
			0	1-2	> 3	0	1-2	> 3
		n	Mean (SD)			Mean (SD)		
MNA score	CST	14/40/42	26 (2.4)	27.1 (1.6)	26.7 (1.6)	26.2 (1.7)	27.1 (1.8)	26.9 (1.6)
	CYB	92/10	27.8 (1.7)	26.9 (1.9)		27.8 (1.9)	25.6 (1.5)	
	WU	38/2/5	26.5 (2.3)	20 (4.9)	25.5 (1.6)	26.4 (2.3)	25.5 (0.7)	25.4 (2.8)
Weight	CST	14/40/42	75.7 (12.4)	76.3 (15.4)	76.6 (11.3)	73.4 (9.9)	73.3 (15.8)	76.2 (11.3)
	CYB	92/10	77.3 (13.4)	87.1 (17.1)		77 (13.2)	82.7 (16.9)	
	WU	38/2/5	79.5 (13.4)	75.1 (23.1)	83.3 (15.8)	79.6 (13.2)	74.9 (23.8)	83 (16)

7.9 Hospital admissions and visits

The total number of hospital admissions in the CST pilot were halve as much during the intervention as compared with a six month period one year earlier. The average number of nights dropped from 2.9 in 2015 to zero in 2016 (Table 19a).

The total number of hospital admissions related to the main diagnoses of PhysioDom dropped from one in 2015 to zero in 2016. Compared to one year earlier, the number of visits to a nurse dropped significantly (P=0.0001) during the PhysioDom intervention, while the number of visits to the GP remained stable (P=0.41) (Table 19b).

Table 19a: Hospital admissions in CST during the PhysioDom intervention in 2016 and a 6 month control period in 2015

	2015 control period			2016 intervention period		
	admissions	number of nights		admissions	number of nights	
	n	n	average	n	n	average
All admissions	8	23	2.9	4	0	0
Related to main diagnosis	1	5	5.0	0	0	0

Table 19b: Visits to nurses and GPs during the PhysioDom intervention and 6 month control period in 2015

	2015		2016		*P*
	n	Mean (SD)	n	Mean (SD)	
Visits to GP	129	1.4 (1.5)	123	1.3 (1.8)	0.41
Visits to nurses	191	2.0 (1.8)	120	1.3 (1.1)	0.0001

GP= general practitioner

7.10 Dropouts

Participants who dropped out were significantly older for age those that dropped in each of the three pilot sites. In CYB, participants who dropped out were significantly different from completers in the baseline characteristics gender, BMI and MNA scores (Table 20).

The most frequent reason for dropping out was the persons own decision (40%), followed by technical problems with the system which includes connectivity (17%)(Table 21).

Table 20: Characteristics of the dropouts in the three pilot sites

	CST (n=57)			CYB (n=52)			WU (n=21)		
	n	%	*P*	n	%	*P*	n	%	*P*
Age (years), mean (SD)	73.8 (5.5)		0.04	75.8 (7.5)		0.004	82 (6.4)		0.006
missing							6		
Length (cm), mean (SD)	162 (8)			166 (9)			163 (9)		
Gender, %									
Male	35	61.4	0.53	16	30.7	0.03	5	24	0.43
Female	22	38.6		36	69.3		16	76	
Marital status, (%)									
Married	44	78.5	0.07	23	57.5	0.38	8	38	0.83
Divorced/ Widow(er)/ partner died	10	17.9		15	37.5		12	57	
Single (never married)	2	3.6		2	5.0		1	5	
Living with partner	0	0		0	0		0	0	
missing values	1			12					
Education, n (%)									
Primary education or less	37	82	0.09	4			7	33	0.4
Secondary education	4	9					10	47	
Tertiary education	4	9					4	20	
Comorbidities, %									
No chronic disease	5	9	0.13	19	37	0.84	4	19	0.91
One chronic disease	13	23		19	37		9	43	
Two or more chronic diseases	39	68		14	26		8	38	
BMI, kg/m^2									
Underweight	0	0	0.24	9	17.6	0.03	0	0	0.58
Normal weight	10	17.5		10	19.6		0	0	
Overweight	24	42.1		22	43.1		5	55	
Obese	23	40.4		10	19.6		4	45	
missing				1					
MNA, mean (SD)	26.5 (2.4)		0.49	26.2 (2.6)		0.0003	25.7 (2.4)		0.37
missing	3			2			1		

Table 21: Reasons for dropping out by pilot site

	CST (n=57)	CYB (n=60)	WU (n=21)	Total (n=138)
exclusion criterium		3		3 (2%)
hospitalisation		0	1	1 (1%)
person's own decision	31	19	5	55 (40%)
current health status		11	5	16 (12%)
too difficult	17	3	1	21 (15%)
technical problem	9	9	5	23 (17%)
death	0	1	1	2 (1%)
other (moved, …)	0	3	0	3 (2%)
none	0	11	3	14 (10%)

8. Discussion

To our knowledge, this is the first time that combined nutritional and physical activity monitoring and coaching is provided to home-dwelling elderly populations with the use of telehealth applications.

The main results of the present study were that the dietary and nutritional coaching were effective in keeping nearly all the different outcome measures the HR-QoL dimensions, nutritional status, appetite, weight, proportion of fat mass in female subjects and blood pressure stable over time in each of the pilot sites, while steps remained stable only in CST. Furthermore, PhysioDom-HDIM was effective in improving the QoL dimension scores in those with the poorest scores, the nutritional status in persons at risk of malnutrition, to increase appetite in those with poor appetite and to reduce the APS in subjects with hypertension at the level of the pooled data. Subjects with a poor appetite had a higher chance of increasing their nutritional status with two points and prefrail subjects, defined according to our criteria, had the most chance of increasing their MCS score with three points. Furthermore in CST, the number of hospital admissions and visits to nurses dropped significantly during the intervention as compared with the same period one year ahead.

However, PhysioDom-HDIM was not able to prevent the deterioration of the nutritional status of some of the normally nourished subjects and the APS of some of the subjects with hypertension raised above the critical level.

The fact that the MNA and SF36 dimension scores did not change at the group level was in contrast with previous studies combing both types of intervention programs (physical activity and nutritionl coaching) and evaluating either the nutritional status (13) or HR-QoL dimensions (48, 49). Possible explanations of these differences may lie in the fact that 92.5% of our group of ageing subjects started the study with a good nutritional status, while this was the case for only 54% of the subjects in the study of Luger et al. (2016), and the fact that our population was probably healthier than the population of Kwon et al (2015). Another explanation could be that the counselling through telemedicine applications was perceived as less motivating in changing nutritional and physical activity behaviours than when people are in direct contact with either health professionals or trained volunteers (13). When we looked upon the changes in four selected items on food intake, we perceived only an increase in protein intake in WU and

CYB upon the intervention. Clearly a more sensitive measurement tool is needed to detect changes in food intake, as the MNA is primarily a tool to detect changes in nutritional status, not changes in food intake. Adoption and maintenance of nutritional and physical activity behaviour changes are dependent on multiple factors, among which psychological factors play an important role, but also age, gender (women generally have lower physical activity levels, but have better eating behaviours than men) and education (4). The fact that those with a poor appetite have the highest chance to increase their MNA score with two points shows that it is indeed a good tool to detect those in need to be followed-up to prevent risk of malnutrition (50). Prefrail subjects had the highest change to increase their MCS score. In a future study subjects should be screened for frailty with validated measures to see if this result is reproducible (47, 51).
The fact that those with the poorest QoL dimension scores increased, while those with normal scores on the QoL dimensions decreased after 6 months may be an effect of PhysioDom, but may also be explained by the regression to the mean phenomenon (52).

The telemonitoring of the blood pressure in a subpopulation with APS values above 140 mm Hg was effective in reducing those values, which was in agreement with the results of a meta-analysis of randomized controlled trials (53). However, some of the subjects whose values were initially under the critical level, had scores above this level at the end of the study. The patients' acceptance to telemonitoring/telemedicine of high blood pressure seems to be influenced by doctors' timely feedback; lack of feedback may lead to lower motivation for sustained use of telemonitoring system (54). Perhaps the feedback was lower in the group of subjects under the critical level.
By wearing a pedometer, participants become aware of daily levels of physical activity and may enhance their motivation to increase physical activity levels (55). There may be several reasons for the fact that in this study the number of steps remained stable (CST), or even reduced (CYB, WU). In the first place the data should be interpreted with caution as steps were self-reported and participants had enter data manually in HHR-Home.
Apart from that, seasonal effects could have played a role. The start of the intervention was in summer and the end in winter, and outdoor physical activity is generally reduced during the winter months. Also, the fact that the pedometer was not Bluetooth connected may have dissuaded some of the subjects in using it on a daily basis, or even losing interest at all at the course of the study. Attrition could have played a role as well

(56). In the beginning, people are usually very motivated to use the novel system such as HHR Home and read the messages on a regular basis. After a while, people got used to the system and motivation to read all messages might have dropped. Therefore, effort should be put in keeping an Ehealth system attractive and interesting to end-users, also after prolonged use. Furthermore, in spite of the fact that only five days were sufficient to validate a month, 48 subjects could not be included in the analyses on steps. This may particularly have biased the results for CST, and is supported by the fact that average step count was relatively high and 79.3% of the subjects had a high to very high activity level.

The CYB subjects showed the highest adherence to this type of activity tracking, missing only data for 4 subjects. Peer support, where friends and neighbours discussed their progress and set each other targets played a role in the UK.

In spite of this negative finding, still there were also 25% of the 65-74 year olds and 18% of the group over 75 years who increased their step count by 20% (see Metrics of success).

For ageing obese people it is extremely important that weight loss is accompanied by an increase in physical activity, in order not to lose muscle mass and become frail (57). As the weight reduction correlated only moderately (r=0.33) with the fat mass reduction, this weight loss probably concerned for a large part a loss of lean mass (particularly muscle mass), which is not favourable at an advanced age. In a recent intervention study in patients with Type 2 Diabetes Mellitus, personalized messages induced a positive effect on glycated Haemoglobin A1c, in spite of the fact that the monthly step count was much lower than in our population (58).

Limitations of the study

This study had several limitations:

- The intervention period was relatively short allowing only modest, non-significant changes at group level
- The lack of a proper control group makes it difficult to draw conclusions on the effect of the intervention
- There was a lack of power for most of the stratified analyses, making it impossible to test differences on subgroup level

- There was high heterogeneity in baseline characteristics across pilots making it difficult to compare across pilots
- The start of the study was in summer, while the end of the study was in winter. Seasonal effects may have had (negative) repercussions on several of the outcomes, particularly on physical activity level and HR-QoL dimensions

Conclusion

Overall, the outcome measures monitored during PhysioDom remained stable during the intervention study.

However, the results indicate that nutritional and physical activity monitoring and coaching through telehealth applications can help to improve HR-QoL, nutritional status, physical activity and weight and hypertension in the most vulnerable groups.

Recommendations for future research

Future studies should focus on more vulnerable subjects, particularly those with a poor nutritional status. Also, more research should be done on the way to keep Ehealth attractive for various types of population, e.g. by adapting the frequency of the messaging to the needs of the beneficiary.

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Annex I: ISCED 2011 levels of education

For the educational level, the ISCED-2011international classification system was used (http://www.uis.unesco.org/Education/Documents/isced-2011-en.pdf).
Three categories were created: Primary education or less (0,1); Secondary education (2,3,4); tertiary education (5,6,7,8)

Level	ISCED 2011	Description
0	Early childhood Education (01 Early childhood educational development)	Education designed to support early development in preparation for participation in school and society. Programmes designed for children below the age of 3.
0	Early childhood Education (02 Pre-primary education)	Education designed to support early development in preparation for participation in school and society. Programmes designed for children from age 3 to the start of primary education.
1	Primary education	Programmes typically designed to provide students with fundamental skills in reading, writing and mathematics and to establish a solid foundation for learning.
2	Lower secondary education	First stage of secondary education building on primary education, typically with a more subject-oriented curriculum.
3	Upper secondary education	Second/final stage of secondary education preparing for tertiary education and/or providing skills relevant to employment. Usually with an increased range of subject options and streams.
4	Post-secondary non-tertiary education	Programmes providing learning experiences that build on secondary education and prepare for labour market entry and/or tertiary education. The content is broader than secondary but not as complex as tertiary education.
5	Short-cycle tertiary education	Short first tertiary programmes that are typically practically-based, occupationally-specific and prepare for labour market entry. These programmes may also provide a pathway to other tertiary programmes.
6	Bachelor or equivalent	Programmes designed to provide intermediate academic and/or professional knowledge, skills and competencies leading to a first tertiary degree or equivalent qualification.
7	Master or equivalent	Programmes designed to provide advanced academic and/or professional knowledge, skills and competencies leading to a second tertiary degree or equivalent qualification.
8	Doctoral or equivalent	Programmes designed primarily to lead to an advanced research qualification, usually concluding with the submission and defence of a substantive dissertation of publishable quality based on original research.

Annex II: Morbidities

Detailed overview of the single morbidities, clustered in 11 subgroups used as covariates, and to determine the number of chronic diseases

Subgroup	**Morbidities**	**Morbidities Physiodome TO BE USED as COVARIATE**	**Chronic diseases to be counted individually to get Number of Chronic diseases (Tab 1)**
1=Pulmonary	asthma and COPD	ASTHMA; BRONCH; COPD; CNSLD; CATLUNG	ASTHMA; BRONCH; COPD; CNSLD; CATLUNG
2=Cancer		CHEMOTH; CANCER	CHEMOTH; CANCER
3= Cardiovascular disease	myocardial infarction, stroke, heart valve problems, atherosclerosis, thrombosis and pulmonary embolism, cardiac insufficiency	TIA; BRAINHAEM; CATBRAIN STROKE; CEREBINFR CARDINS; HYPERT	TIA; BRAINHAEM; CATBRAIN STROKE; CEREBINFR CARDINS; HYPERT
4=Head	migraine, cataracts and chronic throat/sinus infections	HEARING; VISION	HEARING; VISION
5= Gastrointestinal & Liver	Hepatitis, cirrhosis of the liver, coeliac disease and gallstones, gastrointestinal bleedings	GASTBLEED	
6= Kidney and Bladder	Kidney stones, chronic bladder infection and incontinence	RENALINS; INCONTINENT; PROSTAT	RENALINS
7=Neurological diseases	Epilepsie, multiple sclerosis, spasticity, Parkinson's disease and dementia	PARKIN	PARKIN
8=Blood disorders	anaemia and clotting disorders		
9=Musculoskeletal diseases	fibromyalgia, arthrosis, rheumatic disease, osteoporosis, back or neck hernia, and repetitive strain injury	ARTHRIT; OSTEOP; HIPREP/HIPFRACT; KNEEREP; SPINEPROB; LUPUS; FRACTOTHER	ARTHRIT; OSTEOP; LUPUS
10=Dermatological diseases	Serious acne, eczema and psoriasis		
11=Mental disorders	chronic fatigue syndrome, burnout, depression, panic disorder, social phobia, agoraphobia, other anxiety syndromes, manic depressive syndrome, schizophrenia, eating problems, obsessive/compulsive disorders and ADHD	DEPRESS; ANX	DEPRESS; ANX
12=Hormonal Disorders	Diabetes, thyroid disorders	DIAB, THYROID	DIAB, THYROID

Annex III Results for M-3

Changes in the SF 36 dimension scores between the M-3 and M0 period

	CST (n=96)			CYB (n=102)		
	M-3	Baseline	*P*†	M-3	Baseline	*P*†
	Mean (SD)			Mean (SD)		
MCS	55.0 (8.2)	54.9 (8.0)	0.74	55.7 (7.1)	55.6 (8.0)	0.77
PCS	46.3 (8.9)	46.4 (9.0)	0.9	46.5 (10.5)	47.9 (9.1)	0.48
PF	80.3 (20.4)	79.3 (21.9)	0.83	78.3 (25.1)	80.5 (22.1)	0.45
RP	87.6 (28.9)	88.3 (28.3)	0.84	79.7 (37.7)	86.5 (31.2)	0.09
BP	65.1 (27.1)	66.2 (25.5)	0.98	72.3 (26.1)	75.0 (23.6)	0.35
GH	66.4 (18.5)	65.8 (19.4)	0.68	71.7 (17.6)	72.2 (17.3)	0.59
VT	66.4 (22.8)	67.2 (22.4)	0.55	64.9 (18.3)	66.3 (17.3)	0.37
SF	90.7 (17.4)	89.7 (19.9)	0.81	93.7 (14.3)	93.8 (16.0)	0.8
RE	93.3 (21.0)	93.4 (21.4)	0.63	92.1 (24.1)	90.5 (26.3)	0.8
MH	79.6 (18.3)	79.1 (17.9)	0.8	81.4 (15.3)	83.4 (15.0)	0.23

Annex IV Metrics of success

Summary statistics of the Dietary variables

In Table 1 the metrics of success of the PhysioDom intervention study for the different dietary variables are listed. Data are pooled results of the three pilots.

Table 1: Summary statistics for dietary variables - pooled data of the three pilots

	M0		M6	M6 Results		Success
	n	Score	Expected	n	%	Yes / No
MNA - Undernutrition (change into a more favourable category)	**none**	**n/a**	**30% ****	n/a		n/a
MNA – Risk of Undernutrition (change into a more favourable category)	**18**	22.4±1.8	**40% ****	13	72%	Yes
SNAQ- Poor appetite (change into a more favourable category)	**29**	13.1±1.1	**50% ****	19	66%	Yes
Nb of steps per week - < 75 years (20% of improvement*)	**138**	7530±3346	**40% ****	35	25%	No
Nb of steps per week - ≥ 75 years (10% of improvement*)	**51**	4785±2995	**30% ****	9	18%	No
Pre frailty status (following the criteria – D4.1)	**78**		**20% *****	23	29%	Yes
SF36 (4 points of improvement*) PCS summary score <40 ≥40 MCS summary score <50 ≥50	 **66** **177** **57** **186**	 30.0±6.7 50.2±4.9 40.5±8.2 58.2±3.7	**30% ****	 28 39 34 23	 42% 22% 60% 12%	 Yes No Yes No

Nutritional status (MNA)

At the start of the study:

- None of the subjects was malnourished
- 18 subjects were at risk of undernutrition

At the end of the study:

- 13 (72%) had a normal nutritional status

- Nine (4%) subjects with a good nutritional status were at malnutrition risk
- One subject was malnourished (< 1%)

Conclusion: The PhysioDom intervention was successful for 3/4 of the population at risk for undernutrition. However, we cannot explain why the coaching doesn't prevent all normally nourished subjects from becoming malnourished.

Appetite (SNAQ)

Of the 30 subjects with poor appetite at the beginning of the study, 19 (63%) had normal appetite at the end of the study.
However, 14 (6.5%) subjects moved from normal to poor appetite from the beginning till the end of the study. A follow-up study should be conducted in each of the pilots to help understand the reasons of this failure.

Steps

Data on steps were available for 189 subjects, as only those having registered their steps for at least five consecutive months were considered. The proportion of missing values were 17% and 33% for the <75 and ≥75 years old, respectively.
Although overall the physical activity coaching could not be considered a success, still almost a quarter of the subjects successfully improved their activity. Also, it should be kept in mind that the start of the study was in summer and the end in winter, when walking activity may be lower due to less favourable weather conditions.

Prefrailty

Prefrailty was defined as having one or more of the criteria listed in §6.7 of the main document.
Among the 78 (32%) prefrail subjects in the beginning of the study, 23 (29%) became robust at the end of the study.
However, among the initially robust subjects, 35 became prefrail, thus resulting in 90 (37%) prefrail subjects at the end of the study. One of the reasons of this increase is that 12 people lost more than 5 kg by means of the Physiodom coaching. As the weight reduction correlated only moderately (r=0.33) with the fat mass reduction, this weight loss probably concerned for a large part the lean mass (muscle tissue), which is not favourable at advanced age.
Also, the higher number of people with a positive score on one of the fatigue criteria may, in fact, be a seasonal effect, as in winter people generally feel less bouncy. Additional tests and

examinations (dysphagia, blood analysis...) should be performed to determine if these subjects were or have indeed become prefrail.

Health related Quality of life (SF36 summary dimensions)

Neither in the manual of the RAND-36 questionnaire nor in the literature, an indication what should be considered poor scores and which change in the Health Related Qualtiy of life (HR-QoL) domain scores are relevant. Following the proposal of Slagter et al (2015), to define poor scores, we determined the 25th percentile cut-off scores for the pooled data and separately for both genders for each of the summary domain scores. We evaluated the number of subjects that improved 4 points below and above this cut-off point.

Of the subjects with a poor physical component summary (PCS) score, 42% improved their score with 4 points between the start and the end of the study, whereas this was the case for about one fifth of those with a score above 40.

Of the subjects with a poor mental component summary (MCS) score at baseline 60% improved 4 points, whereas this was the case for 12% of those with a score above 50.

In conclusion, in spite of the fact that the coaching was only six months, it was effective in improving the HR-QoL summary dimensions scores for those with the poorest scores.

Summary statistics of the Clinical parameters

In Table 2 the metrics of success of the Physiodom intervention study for the different clinical parameters are listed. Data are pooled results of the three pilots.

Arterial hypertension

Of the 18 subjects with arterial hypertension (>140 mm Hg) at the start of the study, seven normalized their systolic blood pressure, which can be considered as a successful result.

Renal insufficiency

As the systolic blood pressure of five of the six patients with renal insufficiency finishing the study was lowered or kept stable, we considered the surveillance successful.

BMI

For BMI, we looked upon those subjects that changed into a more favourable category.

A more favourable category was defined as: 1) a change from underweight or overweight into normal weight; 2) a change from obese into overweight or normal weight.

Overall, the BMI category of 13% of the subjects improved. However, four of the normal weight subjects became overweight and one underweight, and five of the overweight subjects became obese. A weight loss of ≥5% was achieved in 11% of the obese subjects.

Table 2: Clinical state improvement - pooled data of the three pilots

	M0	M6 Expected	M6 Results		Success
	n		n	%	Yes / No
Arterial Hypertension[1] (BP in normal range*)	18	**35%****	7	39%	Yes
Renal Insufficiency (BP stabilized)	6	**35%****	5	83%	Yes
BMI (change in more favorable category[2])					
Underweight	9	**20%****	2	22%	Yes
Normal weight	35				
Overweight	112		14	13%	No
Obese	87		11	13%	No
Weight loss[3] (>5% among obese)	87	**50%****	10	11%	No
Fat ratio (reduction, %)					
Male (-3%)					
<30%	24		1	4%	No
≥30%	47	**30%****	3	6%	
Female (-4%)					
<40%	19		1	5%	
≥40%	29		2	7%	

[1]Includes only subjects with hypertension who had APS values out of the normal range at the start of the study (more than three times consecutively ≥ 140 mm Hg)

[2]A more favourable category is defined as: a change from underweight or overweight into normal weight; 2) a change from obese into overweight or normal weight

[3]A loss of weight of ≥5% also occurred in 3 (8.6%) subjects with normal BMI and 8 (7.1%) subjects with overweight

Fat proportion

For the analyses on the proportion of fat, data were available for only 119 subjects. This was due either to a high number of missing values (as the average of three-five measures was taken) or because of incoherent data (structural fluctuation from one day to another).

For the majority of the subjects this short coaching period couldn't improve the subjects' fat proportions.

Conclusion

In conclusion, the PhysioDom intervention was successful for the population at risk for undernutrition, the pre-frails and for the monitoring of blood pressure. However, the coaching doesn't prevent all normally nourished subjects from becoming malnourished nor some of the robust from becoming frail.

A future larger scale study should explore the underlying reasons that some subjects evolve defavourable on some of the parameters.