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Albert Szent-Györgyi Medical School

Doctoral School of Interdisciplinary Sciences

Telemedicine based physical training monitoring integrated in the physiotherapy of Metabolic syndrome patients

Summary of PhD Thesis

ÉVA MÁTHÉNÉ KÖTELES

Supervisors:

István Kósa M.D., PhD.
Department of Preventive Medicine, Faculty of Medicine,
University of Szeged, Hungary

Mária Barnai PT., PhD.
Department of Physiotherapy, Faculty of Health Sciences and Social Studies,
University of Szeged, Hungary

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1. INTRODUCTION

The last few decades' fast development in the field of Information and Communication Technology (ICT) makes it possible to apply intelligent technologies and "smart" devices during everyday medical practice and healthcare interventions performed by healthcare professionals. The 2015 World Health Organization (WHO) global survey report on eHealth (electronic health) points out, there are about 124 countries in the world where they have some available form of telemedical facilities. In Europe according to the WHO Regional Office for Europe Report on the implementation of eHealth in the WHO European Region, 12 Member States (27%) have a dedicated policy or strategy for telehealth and 36% (16 Member States) refer to telehealth in their national eHealth strategies. Teleradiology was found the most developed telehealth service program and Remote Patient Monitoring (RPM) was declared the second most frequently used telehealth facility and has the highest number of pilots and new solutions in the member state countries. RPM means the monitoring of the different medical or vital bioparameters of a patient from a distance with asynchronous or "store-and-forward" technique and the transferring of the collected data to the doctor or healthcare professionals. Some forms of telemedical services (e.g., teleconsultations) were used in the Hungarian National Healthcare System previously by only a selected population but with the outbreak of the Covid-19 pandemic the utilization of this field has speeded up, spread over and has been legally approved.

Cardiac rehabilitation all over the world tends to turn from the direction of secondary prevention (management of people with already established CVD) to primary prevention's (management of patients without clinically manifest disease but being at risk of developing CVD) direction. Telemonitoring of the status and physical activity level of patients with cardiovascular diseases (CVD) or other chronic non-communicable diseases such as Type 2 Diabetes Mellitus (T2DM) or Metabolic Syndrome (MetS) are not a common practice in Hungary. International studies suggest, however, that home-based, telemonitored physical training programs can be equally effective as hospital or centre-based programs for CVD patients requiring cardiac rehabilitation. Some of these telemonitored programs were also characterized by better patient satisfaction, training adherence and cost-effectiveness than the conventional inpatient or outpatient solutions.

Complex lifestyle interventions, regular physical activity and healthy diet are the key factors in the prevention and the non-pharmacological treatment of the MetS. The majority of patients require external help, strong coaching and close supervision for the lifestyle changing,

which challenges the Public Health Services. A great proportion of the affected population are in the active working-age group, where their occupational activities prohibit the regular visits to outpatient facilities offering therapeutic physical training programs. A further barrier is the time consumption and cost of regular commuting to and from the nearest outpatient clinic. Since the outbreak of the Covid-19 pandemic we should also consider the potential infection hazards related to institutional group training. Services provided through telemedical technology are preferred in this situation to minimize interpersonal contacts between health care workers and patients as well as between patients.

Review of the evidence shows that MetS is also comorbid with different psychological disorders; obesity (central adiposity) and diabetes (insulin resistance) increase the risk of depression and anxiety but on the other hand after successful weight loss programs the improvement of depression was reported. Furthermore depression, anxiety and MetS all have environmental and behavioural factors in common, increasing their risk of prevalence, such as unhealthy diet, smoking, chronic stress and physical inactivity. Vital exhaustion (excessive fatigue, loss of energy and demoralization) is an independent risk factor of cardiovascular diseases. Few studies have analysed the psychological effects of home-based telemonitored training in cardiac rehabilitation and most of them only measured changes in the QoL and the results are mixed. Some studies have found an improvement in quality of, while other studies have found no significant difference in the increase in quality of life of those treated remotely by using telemedical support compared with the conventional treatment.

2. AIMS OF THE THESIS

Although evidence states that mHealth supported training interventions are effective strategies in the non-pharmacological treatment of the Metabolic syndrome, to date there has been no unitary consensus or clinical practice for their implementation and integration in the physiotherapy of MetS patients in Hungary. Therefore, our purpose was to investigate the physiological and psychological effects of a 12 week, home-based and telemonitored physical training program of MetS patients, to see the changes of different risk factors and parameters of the Metabolic syndrome with using heart rate monitoring, online supervision of the trainings, individual coaching by physiotherapists and weekly feedbacking to the patients. Additionally, we intended to try out the usage of two different types of heart rate monitoring devices during the telerehabilitation. We also kept in the focus of our interest that in case of finding the results positive how to implement and integrate our pilot program into the national physiotherapy practice and spread it over to a greater population in need.

2.1 Hypothesis I.

As a result of a 12-week home-based and telemonitored training program, the anthropometric [waist circumference (WC), hip circumference (HC), weight and body mass index (BMI)] **and body composition parameters** [the total body fat mass (BFM), its ratio referred to the body weight (BFM%), the muscle mass (MM), the fat free mass (FFM), the visceral fat (VF) level in the abdomen, the trunk fat percentage (TF%) and the average basal metabolic rate (BMR)] **of Metabolic syndrome patients will improve**.

2.2 Hypothesis II.

As a result of a 12-week home-based and telemonitored training program the maximal exercise and functional capacity (stress ECG duration time, maximum MET and 6MWD) **and the laboratory parameters** [fasting plasma glucose (FPG) level, HbA1c level, HDL-C level, total cholesterol (TC) level and triglyceride (TG) level] **of Metabolic syndrome patients will improve**.

2.3 Hypothesis III.

As a result of a 12-week home-based and telemonitored training program t**he psychological state of Metabolic syndrome patients** measured by the Shortened Beck Depression Inventory (BDI), the Athens Insomnia Scale (AIS), the shortened Maastricht Vital Exhaustion Questionnaire (MQ) and the WHO Well-Being Scale (WHO-WBS) **will improve**.

2.4 Hypothesis IV.

The achieved results after the 12-weeks telemonitored training program will be independent from the type of the used heart rate monitoring device (Polar M430 "smart" watch or Polar H10 chest strap paired with a mobile phone).

3. MATERIALS AND METHODS

3.1 Participants and study design

Our study was a prospective, non-randomized intervention evaluation study among MetS patients in which we enrolled 59 participants with a confirmed diagnosis of Metabolic syndrome, between the 1st of September 2018 and the 31st of January 2020, from the city of Szeged and the surrounding villages within a 40 km distance. MetS was defined according to the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) MetS criteria system.

3.2 Inclusion and exclusion criteria

Participants (men and women), aged between 25 and 70 years were involved in the study, who practiced only very low level of regular physical activity (self-reported, less than 30

minutes a week), and had at least three risk factors concomitantly present from the followings to qualify for the diagnosis of the MetS:

(a) waist circumference above 102 cm in men and above 88 cm in women,

(b) proved T2DM or FPG level above 5.6 mmol/L,

(c) treated hypertension or spontaneous blood pressure ≥ 130/85 Hgmm,

(d) treated hypertriglyceridemia (HTG) or serum TG level above 1.7 mmol/L,

(e) serum HDL-C level under 1.03 mmol/L in men, under 1.3 mmol/L in women

To manage the telemonitoring devices and data transfer the participants had to have basic informatics skills to be able to use a smartphone or transfer data from the smart watch to the phone, laptop or personal computer through a wired or wireless (Bluetooth) connection.

Participants were excluded with: any upcoming planned invasive cardiological intervention [Percutaneous Transluminal Coronary Angioplasty (PTCA), coronary artery bypass, valve repair or replacement], uncontrolled hypertension (blood pressure >160/100 Hgmm), type 1 diabetes mellitus (T1DM), T2DM which needed more than one dose of insulin per day, chronic heart failure (CHF), chronic renal failure where the estimated Glomerular Filtration Rate (eGFR) < 60 ml/min), oncological diseases, serious cognitive disfunction, lack of cooperation, any known disease or condition that seriously affected the mental and legal capacity, any other conditions preventing regular physical trainings.

3.3 Baseline and follow-up patient assessments

3.3.1 Anthropometric measurements

Waist circumference (cm) was measured at two levels: at navel level (WC_{navel}) and at the narrowest part of the midriff ($WC_{midriff}$), between the lower margin of the last palpable rib and the top of the iliac crest. Hip circumference (HC; cm) was measured at the level of the greater trochanter (around the widest portion of the buttocks), with a tape measure, in standing, at the end of the exhalation. Body height (cm) and body weight (kg) were measured in the standardized ways.

3.3.2 Functional capacity

The functional capacity was measured during the 6MWT, in accordance with the American Thoracic Society (ATS) guideline, outside on a 30-meter-long marked track. The distance (m) reached by the highest pace walking in six minutes (6MWD) was measured and documented.

3.3.3 Maximal exercise capacity

Under cardiologist's supervision a twelve channel ECG (CardioSys, MDE Diagnostic, Walldorf, Germany) was performed at rest and during exercise using an incremental loading in

accordance with the Modified Bruce Protocol until the age predicted maximal heart rate, where this target heart rate was calculated based on the 220-age formula. The maximal capacity in Metabolic Equivalent of Task (MET; ml/kg/min), the maximal heart rate (bpm), systolic and diastolic blood pressure (Hgmm) and the duration of the Stress-ECG test (min) were measured and documented.

3.3.4 Body composition analysis

The body composition was measured by a Bioelectrical Impedance Analysis (BIA) method using a segmental body composition analyzer device (Tanita BC-418, Japan. During the measurement the exact bodyweight (kg), the total body fat mass (BFM) in kilograms (kg), its ratio referred to the body weight (BFM%), the muscle mass (MM) in kilograms (kg), the fat free mass (FFM) in kilograms (kg) were detected and analyzed. The visceral fat level (VF) in the abdomen and the trunk fat percentage (TF%) were measured by an abdominal fat analyzer device (Tanita ViScan AB-140, Japan). The Body Mass Index (BMI; kg/m2) and the average basal metabolic rate (BMR) in Joule (J) were calculated by the device and were documented.

3.3.5 Medical evaluation and laboratory parameters

Anamnesis, detailed medical history, available laboratory data, current drug treatment and inclusion and exclusion criteria were reviewed and documented at the time of the initial medical evaluation. Routine echocardiographic evaluation was also performed using a Vivid-e (Boston, Massachusetts, US) cardiac ultrasound machine.

3.3.6 Psychological questionnaires

During the initial and the final visits, the participants were asked to fill in (self-report) the following standardized psychological questionnaires: Shortened Beck Depression Inventory (BDI), Athens Insomnia Scale (AIS), Shortened Maastricht Vital Exhaustion Questionnaire (MQ), WHO Well-Being Scale (WHO-WBS).

3.3.7 Intervention: Home-based telemonitored physical trainings

The participants were informed about the details and features of the trainings and the monitorings. They were given an information sheet and each participant received a 15–30-minute individual patient education on the usage of the given training monitor device and the procedures of the data transfer. The participants were asked to perform 3-5 trainings (minimum 30 minutes per session) individually at home, aiming to a minimum of 150 minutes per week for 12 weeks. There were no restrictions regarding what type of trainings they performed at home (walking, running, cycling, swimming etc.) but they were informed about the recommended and beneficial training types and intensity (aerobic endurance training combined with resistance training, minimum 150 minutes per week) suitable for Metabolic Syndrome

patients. The target heart rate zone for the home-based training was calculated individually, based on the exercise capacity of the patients and the perceived level of exhaustion in the 60-80% range of the maximal predicted heart rate. Patients were asked to keep their heart rate within this target zone during the physical activities they performed at home.

3.3.8 Heart rate and training monitoring

During the home-based physical activities and trainings, the heart rate was monitored by two different types of devices that were allocated to the patients at the initial visit. Both devices were available in the commercial market for reasonable price. One of them was an electric heart rate sensor with a chest strap (Polar H10, Kempele, Finland,) and a wirelessly connected android smartphone (Meizu M5c, China). For patients using this type of device data collection was initiated and stopped through the free to download fitness application (Polar Beat) on the paired smartphone. Training duration, distance, intensity and heart rate zones could be reviewed by the patient on the smartphone online as well as after completing the training. At the end of the training the data were also synchronized automatically to a cloud based integrated system for reviewing and coaching. The other type of heart rate monitor we used was a smart watch with an optical heart rate sensor (Polar M430 GPS running watch, Kempele, Finland) that could start and end the trainings by itself, but the synchronization of training data was not automatic. Patients using this type of sensor had to upload the training data by manually building up a wired connection to a PC running the Polar Flow website, or through initiating a wireless connection to a patient owned smartphone running the Polar Flow application by pressing a button on the smartwatch. The browser-based review process was identical for the two groups. The assignment of devices to the patients was not random, we should take the patient's individual preferences into consideration in some cases, and upon our experience patients dispreferred the chest strap, because it caused discomfort and tightness on the chest. The remote training monitoring was asynchronous (not in real-time). The physiotherapists reviewed the training activities of every patient weekly and contacted them individually via phone or email giving feedback and trying to motivate them.

3.3.9 Data collection and statistical analysis

Power analysis for the study was performed using the software G* Power (Version 3.1.9.2) for power-and-sample size calculation (University of Düsseldorf, Germany). Statistical data were reported as the mean±standard deviation (SD). Paired t-test was used to analyse the effect of the training on several parameters, whereas we used correlation analysis to measure the strength of connection between two continuous variables. For the subgroup analysis, repeated measures variance analysis (RM-ANOVA) was applied for the measured parameters

before and after physical training where the grouped variables were the CSP+P and SW subgroups. For pairwise comparisons, Bonferroni correction was used. Statistical tests were performed using R statistical software (R version 3.6.2). Values of $p<0.05$ were considered significant.

4. RESULTS

4.1 Subject population

Altogether 59 MetS patients (37 men and 22 women, mean age 49.35±8.51 years) were enrolled in the study. 4 participants (2 men and 2 women) dropped out from the program, although they have started and had been allocated a heart rate monitor device but did not finish the program and refused to take part in the final medical and physiotherapy assessments. The dropout rate was 6.8%. Finally, 55 patients (35 men and 20 women, mean age 49.19±7.93 years, completed the 12-week home-based telemonitored program. Out of those patients who completed the program, in 4 cases the final exercise ECG test and in 1 case the final 6MWT could not been performed even because of health-related issues (acute knee injury and pain that limited the walking and cycling ability) or technical problems.

The weekly average heart rate monitored training time was 152±116.2 minutes. Out of the 55 participants who completed the program, 22 patients (40%) performed the recommended 150 minutes or more physical activity time during a week.

4.2 Results supporting Hypothesis I.

4.2.1 Waist circumference changes

After the 12-week telemonitored training program the average WC measured at the narrowest part of the midriff ($WC_{midriff}$, 106.17±14 cm to 103.88±13.5 cm, $p<0.001$) and the average WC measured at navel level (WC_{navel}, 112.8±14.8 cm to 110.6±15.5 cm, $p=0.001$) significantly reduced.

4.2.2 Hip circumference change

Post intervention the average HC decreased from 114.73±13.75 cm to 112.15±13.2 cm ($p<0.001$).

4.2.3 Body weight and BMI changes

Both the average body weight and the BMI of the participants decreased slightly but statistically significant. The body weight decreased from 98.72±21.7 kg to 97.45±21.76 kg ($p<0.01$) and the calculated BMI decreased from 32.98±6.69 to 32.58±6.73 ($p<0.01$).

4.2.4 Body composition parameter changes

We have found some parameters showing improving tendencies but have not found any changes that were statistically significant in the measured body composition parameters except

the muscle mass, which has decreased (MM, 62.4±12.6 kg to 61.8±12.5 kg, p=0.049). The overall average body fat mass (BFM) and the average body fat mass relative to the body weight (BFM%) has decreased, but not significantly. The average fat free mass (FFM) has also showed a decreasing tendency but not changed significantly. The average basal metabolic rate (BMR) calculated by the device has decreased significantly from 8239.56±1694.38 J to 8150.02±1653.45 J (p=0.037). The visceral fat (VF) level in the abdomen and the trunk fat percentage (TF%) have decreased but not significantly.

4.3 Results supporting Hypothesis II.

4.3.1 Stress-ECG duration time change

The average stress-ECG duration time significantly increased after the exercise program (n=51), from 13.74±3.29 minutes to 15.66±2.64 minutes (p<0.001).

4.3.2 Maximum exercise capacity (in METs) change

The average maximal exercise capacity improved significantly post intervention (n=51), from 11.02±2.6 MET to 12.14±2 MET (p<0.001).

4.3.3 Six Minute Walk Distance change

We have found statistically significant change in the average six-minute walk distance (n=54), the 6MWD increased from 539.69±78.62 m to 569.72±79.96 m (p<0.001). A positive correlation was found between the average weekly training time and the increase of 6MWD (r=0.3; p=0.029).

4.3.4 Laboratory parameters changes

We have documented statistically significant changes in the average HDL-C level (n=45), it decreased from 1.28±0.31 mmol/L to 1.68±0.36 mmol/L (p<0.001), and in the FPG level (n=47), which decreased from 6.16±1.26 mmol/L to 5.44±1.31 mmol/L (p=0,001). We have found a weak correlation tendency between the average weekly training time and the HDL-C level increase (r=0.23; p=0.137). In 41 patients we have managed to document the HbA1c level and its level significantly decreased from 6.22±0.68 % to 5.87±0.78 % (p=0.01), There was a declining trend in the triglyceride (TG) level (n=47), and an increase in the total cholesterol (TC) level but the change did not reach significant level.

4.4 Results supporting Hypothesis III.

Out of the 55 patients who finished the monitored training programme we managed to collect the completed, self-reported psychological questionnaires from 38 patients (roughly 70%) who were included in the statistics.

4.4.1 Level of depression

We have not found any statistically significant changes in the scores of the BDI questionnaire. The overall scores decreased from 2.32±2.78 points to 2.18±3.52 points (p=0.709).

4.4.2 Insomnia

We have not found any statistically significant changes in the scores of the AIS questionnaire. The overall scores increased from 2.47±3.20 points to 2.61±4.07 points (p=0.695).

4.4.3 Level of vital exhaustion

We have found statistically significant decrease of the overall scores of the MQ scale (n=38), from 3.37±2.97 points to 2.63±2.70 points ($p<0.05$).

4.4.4 Well-being

Post intervention there was a significant increase of the overall scores of the WHO-WBS scale (n=38) from 9.92±2.59 points to 10.61±2.76 points ($p<0.05$).

4.5 Results supporting Hypothesis IV.

We performed a subgroup analysis in the statistics comparing the patients' results in the two different type heart-rate monitoring groups despite the fact that the two groups cannot be considered randomly classified. Group SM (smart watch) included 23 participants [mean age 49.78±6.65 years, 15 men (65.22%) /8 women (33.78%). Group CS+P (chest strap+phone) included 31 patients [mean age 48.48±8.77 years, 20 men (64.52%) /11 women (35.48%)]. There was no significant difference between the groups regarding the age (p=0.555), and the sex (p=0.999). One patient led a training diary because she was not able to use neither the smart watch nor the smartphone properly, therefore we had to exclude her data from the subgroup analysis, but not from the whole population's statistics.

4.5.1 Anthropometric parameter changes

At baseline, the body height, the body weight, the BMI, the HC and the $WC_{midriff}$ were without significant difference between the subgroups. WC_{navel} was significantly bigger in the smart watch group (Group SW baseline vs Group CS+P baseline, 117.28±17.55 cm vs 108.66±10.65 cm, p=0.044). After the training program the waist- and hip circumferences, the body weight and BMI have decreased significantly in Group CS+P, whereas in Group SW only the HC decreased significantly.

4.5.2 Body composition parameter changes

At baseline, the BFM, BFM%, FFM, MM, BMR, VF level and BF% body composition parameters were without significant difference between the groups. After the training program, there were no significant between group differences regarding most of the body composition parameters, but the BFM has decreased significantly in Group CS+P.

4.5.3 Exercise tolerance and functional capacity parameters

At baseline, the average Stress-ECG duration time was significantly lower in Group SW (14.84±1.93 min vs 12.33±4.04 min, p=0.01), the maximal exercise tolerance was without significant between group difference. Stress-ECG duration time and maximal exercise capacity increased significantly only in Group SW, while the 6MWD has increased significantly in both groups. The average weekly training time achieved tended to be higher in Group SW, but due to considerable dispersal of individual data this difference was statistically not significant.

4.5.4 Laboratory parameters

At baseline, the FPG, HbA1c and TG values were not significantly different between the groups. After the training program HDL-C increased significantly in both groups, while the FPG decrease in Group SW and the HbA1c decrease in Group CS+P was significant.

4.5.5 Psychological questionnaires

There was no statistically significant difference between the two groups regarding the average scores of the used psychological questionnaires at baseline. After the training program the MQ scale has decreased significantly in Group SW, but not in Group CS+P.

5. DISCUSSIONS, CONCLUSIONS AND NEW RESULTS

Main findings of our study are that a 12-week home-based and telemedically supported training program had a positive effect on many core parameters and components of the Metabolic syndrome. We demonstrated in our study, that the home-based physical exercise training monitored by widely available heart rate monitors and open access software application can produce significant changes in a series of anthropometric, exercise capacity and laboratory parameters, and in the quality of life of cardiometabolic patients within 12 weeks. Therefore, we can say that our study was successful and we were able to establish an interventional architecture which can be integrated in the health care system and can effectively influence central obesity, exercise capacity and psychological state of MetS patients. The body weight, the BMI and all the measured circumferences (waist- and hip) significantly decreased, but the waist circumference must be highlighted, as abdominal or central obesity is a key component of the MetS, and that can be defined by the increased waist circumference. Thus, lowering the

waist circumferences and decreasing the body weight positively affect abdominal obesity and are proven to decrease further risk factors of MetS, like the elevated plasma glucose level and T2DM as well. After evaluation of the results in the anthropometric parameters we can say that their positive and significant changes support our Hypothesis I. Regarding the body composition parameters, we have not found significant changes (except the MM), although in some parameters we have seen positive tendencies, but these were not enough to support Hypothesis I.

Our Hypothesis II. regarding the cardiorespiratory fitness parameters was confirmed, as we were able to detect positive significant changes in the maximal exercise capacity, the Stress-ECG duration time and in the 6MWD as well after the 12 weeks telemonitored program. Regarding the laboratory parameters, the HDL-C level significantly increased, which is proved to decrease the risk of cardiovascular diseases. Besides this the FPG and HbA1c levels significantly decreased, by which we could influence another independent risk factor of the MetS, that is proved to decrease the risk of T2DM.

Our Hypothesis III. regarding the improvement of the psychological state of our patient, has been partially confirmed as in two of the measured psychological factors (out of four) we have detected significant positive changes. We must emphasize that the level of vital exhaustion - one of the most important indicators of chronic stress - decreased significantly, which means that one potential psychological risk factor of the MetS could be positively influenced. The level of depression and the level of insomnia did not change significantly, but their before training values were considered normal.

In Hypothesis IV. we assumed that the usage of two different types of monitoring devices will produce similar results in the two user groups, therefore the type of heart rate monitoring device used will not have a significant effect on the results. The evidence we found just partly supports this hypothesis, as we have detected significant after training differences between the two different device user groups in some of the parameters. Most of the measured anthropometric parameters and the body fat mass significantly changed in the chest strap plus phone group (except HC, as it changed significantly in both groups), while the exercise tolerance parameters mainly changed in the “smart” watch group (except the 6MWD, as it changed significantly in both subgroups).

Both heart-rate monitor devices worked well for their purposes and were suitable for distant monitoring of MetS patients; could be integrated in the physiotherapy program. The distribution of the given-out measuring devices was not random, in some cases we took the patients’ preferences into consideration. Patients reported a dislike towards the chest strap

because they felt it caused discomfort and tightness on the chest. Independent from this we should support the utilization of chest strap instead of smart watches in patients tolerating both type of devices, however smart watches are viable alternative for patients not tolerating chest strap. Further studies are required to evaluate arm worn optical heart rate monitors promising better patient comfort as well as accuracy higher than that of wrist worn optical devices.

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