Master's thesis

NTNU
Norwegian University of Science and Technology

Sarah Nilsen Evensen

Effect of wearable activity trackers on physical activity levels in obese- and overweight individuals during a rehabilitation process

Master's thesis in Bevegelsesvitenskap
Supervisor: Lene Aasdahl

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Abstract

Background: With a global obesity-and overweight challenge, treatments targeted to reduce obese-and overweight related risk, such as diabetes type 2 and hypertension, are in high demand. Institutional rehabilitation has become a globally approved treatment for obese and overweight individuals. However, new additional approaches to successfully increase obese and overweight's physical activity and therefore reduce obesity related risks have been requested.

In this study we investigated if feedback from a wearable activity tracker would influence obese and overweight individual's physical activity levels more than without feedback, while at home during a rehabilitation process.

Method: In this randomized controlled trial, 37 consenting adults with obesity or overweight (Mean age 51 years, 78% women, mean BMI 39) were randomized into two groups, an intervention group (N=18) and a control group (N=19). The intervention group received feedback on their physical activity levels while wearing an activity tracker, while the control group did not receive any feedback while wearing the same activity tracker. The participants were instructed to follow the scheduled rehabilitation program while at the institution and self-monitor while at home.

The primary outcome was between group difference in total PAI (Personal Activity Intelligence, measurement on physical activity levels) in two home weeks. Due to fall outs related to use of activity trackers, only 26 participants had some or all activity data to be included in the analysis.

Results: There was no difference in total PAI between groups in either of the two home weeks (mean difference first home week 1.7, 95% CI: -50.3 to 53.7, $p = 0.95$, mean difference second home week -35.3, 95% CI: -86.6 to 16.9, $p = 0.17$). Likewise, the change in secondary outcomes did not differ between groups. There was no difference in change between groups in weight (mean difference in change 1.3, 95% CI: -0.8 to 3.3, $p = 0.21$), BMI (mean difference in change 0.4, 95% CI: -0.3 to 1.1, $p = 0.23$) and VO_{2max} (mean difference in change 0.1, 95% CI: -4.2 to 4.7, $p = 0.96$).

Conclusion: There were no difference in physical activity levels in the two home weeks between the intervention group receiving feedback and the control group not receiving feedback. With challenges related to inconsistencies in data and few participants completing wear time, this study questions if the technological solution was suitable.

Sammendrag

Bakgrunn: Med et globalt fedme- og overvekts problem, har behandlingsetterspørselen for å redusere fedme- og overvekts relaterte risikoer som diabetes type 2 og hypertensjon, økt. Rehabilitering på institusjon har blitt en globalt anerkjent metode for behandling av fedme- og overvekts pasienter. Etterspørselen er allikevel stor etter en behandlingsmetode som sikrer økt fysisk aktivitetsnivå og dermed reduserer fedme- og overvekts relaterte risikoer.
I denne studien undersøkte vi om bruk av bærbar teknologi med feedback påvirket fedme-og overvekt pasienters aktivitetsnivå mer enn uten feedback, i en hjemme periode under en rehabiliteringsprosess.

Metode: I denne randomiserte kontrollerte studien, ble 37 samtykkende voksne med fedme eller overvekt (Gjennomsnitt alder 51 år, 78% kvinner, gjennomsnitt BMI 39) randomisert i to grupper, en intervensjonsgruppe (N=18) og en kontrollgruppe (N=19). Intervensjonsgruppen fikk feedback på det fysiske aktivitetsnivå fra en aktivitetsmåler. Kontrollgruppen fikk ikke feedback til tross for at dem brukte samme aktivitetsmåler. Deltakerne fikk beskjed om å følge rehabiliterings opplegget på institusjonsukene og benytte seg av selvovervåking i ukene hjemme. Målet med studien var å se på forskjellen i total PAI (Personlig Aktivitets Intelligens, mål på aktivitetsnivå) mellom gruppene i to hjemmeuker. Grunnet stort frafall grunnet lite bruk av aktivitetsmåler, var det totalt 26 deltakere som hadde noe eller all aktivitetsdata.

Resultat: Det var ingen forskjell i total PAI mellom gruppene i noen av hjemmeukene (gjennomsnitt forskjell første hjemmeuke 1.7, 95% CI: -50.3 to 53.7, p = 0.95, gjennomsnitt forskjell andre hjemmeuke -35.3, 95% CI: -86.6 to 16.9, p = 0.17). Likt hovedmålet med studien, var det heller ingen forskjell mellom gruppene på de sekundære målene. Det var ingen forskjell i endring mellom gruppene på vekt (gjennomsnitt forskjell i endring 1.3, 95% CI: -0.8 to 3.3, p = 0.21), BMI (gjennomsnitt forskjell i endring 0.4, 95% CI: -0.3 to 1.1, p = 0.23) og VO_{2max} (gjennomsnitt forskjell i endring 0.1, 95% CI: -4.2 to 4.7, p = 0.96).

Konklusjon: Det var ingen forskjell i aktivitetsnivå i de to hjemmeukene mellom intervensjonsgruppen som fikk feedback og kontrollgruppen som ikke fikk feedback. Grunnet manglende data og lite total gjennomføring fra deltakerne, stiller denne studien spørsmålstegn ved om den teknologiske løsningen var passende.

Acknowledgements

I would like to express a special thanks to my supervisors Lene Aasdahl and Marius Steiro Fimland for contributing with their knowledge and guidance throughout this project.

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Finally I want to thank my partner, my family and my friends for their continuous support during my studies and helping me finalizing this thesis.

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Background

According to the Worlds Health Organization in 2016 almost 40% of the world's population was overweight and an additionally 13% of the world's population was obese. The worldwide prevalence of obesity has nearly tripled in the last forty years, and though in some regions the obesity is slightly decreasing, the worldwide overweight and obesity problem have never been more substantial (1). In Europe alone obesity is responsible for 2-8% of all health cost as well as 10-13% of all deaths across the region (1) Excess bodyfat is strongly associated with several chronic conditions and noncommunicable diseases such as cardiovascular disease, diabetes 2, hypertension, asthma and multiple cancers (2-5). Obesity and overweight also increases risks of heart failure, stroke and overall mortality (4, 6, 7). Furthermore, obesity and overweight are associated with reduced quality of life as well as several psychiatric disorders such as mood disorders, anxiety and depression (8).

The majority of the obese and overweight population fail to reach the recommended physical activity level at 150 minutes (or more) per week in moderate- to vigorous-intensity as well as having increased sedentary behavior (9-12). Sedentary behavior is associated with increased risk of diabetes 2, cardiovascular disease as well as all-cause mortality, and the less time spent sedentary and more time spent physically active these behavior associated risk can be reduced (13). A newer study including over one million participants showed that all-cause mortality associated with sedentary behavior could be eliminated with high levels (60-75minutes per day) of moderate intensity physical activity, while the currently recommended moderate physical activity levels may not be sufficient in reducing the risks (14). Other studies show that regular physical activity may decrease obesity-related measures such as high blood pressure, cholesterol, risks of heart failure, and metabolic risks while further attenuate, or even eliminate risks related to sedentary behavior if the intensity and amount of physical activity is high enough (15-17). Unfortunately, increasing the physical activity levels and the exercise intensity on an already sedentary group with low motivation compared to already physically active and normal weight individuals, has shown to be difficult (18, 19).

Interventions created to increase physical activity in general have consisted of several modalities such as in-person (both individually and groups), telephone and a variety of Web-based

counselling-and coaching concepts (20-22). Rehabilitation institutions have become more common and offer advanced programs for various groups, including obese and overweight individuals. Some rehabilitation programs offer hourly-meetup, others with a day-to-day offer and inpatient programs that require an extended stay over several days, weeks or even months at an institution (23).

At a typical inpatient rehabilitation institution, patients with obesity and overweight are offered 1-3 weeks within the institution. The length of the rehabilitation process varies between institutions, where some only lasts a few weeks other stretches over months or even years. The institutions often have several institutional stays, with home-periods between the institutional weeks, allowing the patients to experiment with their new behavioral techniques at home in their natural environment (24). It is a universal agreement that conservative treatment (no surgery) of obesity and overweight should include behavioral modification of lifestyle and eating habits as well as regular physical activity (25). In institutional rehabilitation of obese and overweight patients these elements have become the primary focus during their rehabilitation, and they are highly encouraged and recommended to maintain these modifications during their home periods. Across rehabilitation institutions one of their primary goals for their obese and overweight patients are to promote a variety of different indoor and outdoor physical activities with a transferability to the patients everyday routines at home (24). Though there are many interventions aiming to change physical activity and eating behaviors, they have different amount of success in treating overweight and obesity. Shorter interventions, typically 6-months or shorter, shows increased physical activity levels and weight loss (26). However, the effect of lifestyle interventions in the long term have a small to moderate effect on physical activity levels and weight loss (27). Such face-to-face or institutional interventions is quite costly and requires professional personnel (28). Therefore, developing low-cost yet effective interventions to increase physical activity, reduce sedentary time and increase the amount of successful weight losses has become a public health priority. This is one reason for the recently growing interest among physical activity- and diet behavior researchers in mobile health interventions using mobile devices and wearable technology such as smartphones, tablets, apps and,- watches (29).

There are several different programs and devices on the marked targeting dietary change, physical activity and sedentary behavior. Some are already being used in rehabilitation, and have

an overall very high success rate, such as the dietary application Lifesum (30). Technology targeted towards physical activity and sedentary behavior have become huge commercially and some well-established brands are frequently used in research projects, but have yet to be included in rehabilitation (31). The most common devices used in research are pedometers, accelerometers and pulse monitors designed to work like a watch or armband, often accompanied by an application that can provide the user with customized feedback. The landscape in wearable technology are in constant change with new devices and brands released every year (31). While most activity trackers are made commercially, others are created for research and treatment purposes. A newer system developed at NTNU based on data from the large population-based HUNT-study called PAI (Personal Activity Intelligence) was created for this purpose. Calculated by the wearers pulse, feedback on activity levels in total PAI-points are provided through the PAI-application. Reaching the 100 PAI goal per week is associated with decreased risk in health-related measurements and overall mortality (32). Technologies such as these are typically favored in studies and interventions due being portable, cost-effective, convenient, accessible, gives the user a feeling of being in control while providing a more accurate measurement of activity levels than other methods, such as questionnaires and other self-report methods (31, 33, 34). Further, evidence suggests that wearable technology is an effective tool that can result in improved weight loss, increased physical activity and decreased sedentary time as an addition to rehabilitations programs as well as independent of face-to-face interaction (35, 36). The motivational aspects of receiving personal feedback and competing with yourself to improve are some of the factors affecting physical activity levels while wearing a activity device (37).

There is several studies where both face-to-face behavioral change interventions and wearable tools have been used simultaneously (22, 38). Where there are several interventions with obese and overweight individuals wearing activity trackers, there are less studies where the obese and overweight individuals partake in a full-time rehabilitation program (38). There has been conducted studies on individuals wearing activity trackers at home. These studies have provided evidence that wearing activity trackers at home have little to no impact on physical activity levels and sedentary time, and while the motivational effect may increase physical activity levels temporarily, the effect wears off with time (39, 40). However, there is a scarcity in published literature on the effect of wearable activity trackers influence on obese and overweight

individual's activity levels during a rehabilitation process where they are at home after an institutional stay.

The purpose of this study was to examine the effect of constantly available feedback from wearable activity trackers on physical activity levels in obese and overweight participants in a home-period during a rehabilitation process. The primary objective of this study was to compare any differences in physical activity levels between participants wearing activity trackers with feedback (intervention group) and participants wearing activity trackers without feedback (control group). The study lasted 6-10 weeks and included two institutional stays as well as the targeted home period between the institutional stays. Secondary objectives were to examine any change in body weight, BMI and VO_{2MAX} between the two groups from baseline to follow-up. The study aim was to test if the PAI system could contribute to an already existing rehabilitation program through increasing obese and overweight individual's physical activity levels during their home period. We hypothesized that the intervention group with feedback from the activity trackers would show a greater increase in physical activity levels at home than the control group.

Method

Study design

A randomized controlled feasibility study design was chosen to evaluate the effect of wearable activity trackers on physical activity levels in adults in rehabilitation with obesity and overweight. The study was a parallel group randomized controlled trial where obese and overweight in rehabilitation received either no intervention (control group) or intervention through continuous feedback on their physical activity (intervention group). All participants wore a wearable activity tracker though the study period. Both groups were to take part in the same rehabilitation program during the study period.

The primary outcome measure was difference between groups in total PAI in the home-weeks. The study was approved by the Regional Committee for Medical and Health Research Ethics in Central Norway (no. 2019/799) and the trial is registered in https://clinicaltrials.gov/ (No.: NCT04031079).

Participants and recruitment

The study's inclusion criteria were that that the participants had to partake in inpatient rehabilitation at Unicare Helsefort Rehabilitation center for overweight and obesity as well as having been referred from a hospital outpatient obesity clinic, which all patients at the institution are. The participants needed to be ≥18 years old and have a BMI≥30 to be referred to rehabilitation. However, due to participants being included at different times of their rehabilitation, and could therefore possibly have loosen weight already, participants were included if their BMI≥25. The exclusion criteria were if the patient did not have a smartphone with operation systems' requirements for the PAI-system and LYNK2 watch. Patients in wheelchairs would also be excluded due to the technology not being able to measure physical activity correctly.

The participants were recruited at Unicare Helsefort near Trondheim, Norway between August and November of 2019. The rehabilitation at the institution are group based and includes as many as 12 patients in each group. A total of 6 groups was included all recruited at their first or second institutional stay. On arrival at Unicare the participants were provided with a written information letter about the study. The following day started with an informative meeting, allowing the participant to ask questions and get a further introduction to the PAI activity tracking system. The main goal of this meeting was to defuse any discomfort, stress or anxiety towards the project and make the patients comfortable signing the info sheet and become participants in our study, knowing that they at any moment could withdraw their consent and discontinue the participation in the study without it effecting their rehabilitation. The participants interested then provided a written consent at the bottom at said information letter.

Intervention

The rehabilitation treatment was divided in 4 institutional stays, with a home period between each stay. The first institutional stay is the longest being 2-3 weeks, while the next 3 institutional stays are 1 week. There were about 4-6.5 weeks between the first and second stay, 6-8 weeks between the second and third stay and 8-10 months between the third and the fourth stay. The treatment consists of exercise, and behavioral modification towards lifestyle and eating habits and is an institutional in-person rehabilitation process. During the home weeks between the institutional stays, the participants were executing self-monitoring combined with their daily

routines and did not receive a specific eating-and exercise program.

The participants was divided in 2 groups, one intervention group that would receive feedback and one control group that would not receive feedback. Both groups completed a series of anthropometrical measurements, including a submaximal ergometer cycle test, before receiving a wearable activity tracker. The intervention group and the control group both had customized apps for each group, preventing the control group from getting feedback. Other than different apps with either no feedback or with feedback, both groups got the same information about how the watch and app functioned. Physical activity levels and sedentary behavior were objectively measured by a LYNK2 watch which is a wrist worn, waterproof pulse monitor with a 7-day memory accompanied with a mobile application, more specifically the PAI-system. PAI is short for Personal Activity Intelligence and is based on an algorithm that calculates your physical activity levels through pulse and give you feedback in PAI score. The PAI score is from 0 to 100, where 100 gives the best health benefits. PAI is earned through increased pulse detected by a wearable device and with 1-hour high intensity exercise (80% of max pulse) a week the 100 PAI goal will be reached. Study personnel made the watch ready for use by creating a user for each participant and connecting this user to each participant's private smartphone and then with the LYNK2 watch. When the watch was ready for use study personnel demonstrated how the watch were to be synchronized with the PAI-app and explained the provided feedback on the participants' activity levels in the app. Both groups were told that to gain "PAI" they needed to be active. High intensity was not required to achieve PAI, however, they were told that it took more time in low and moderate intensity to achieve the same amount of PAI as in high intensity. The participants were also told that they could achieve more "PAI" then the 100 PAI goal, but it did not correlate with further decreased risk of lifestyle diseases (32). The study personnel showed the participants how to wear the LYNK2 watch and the participants in both groups were advised to wear the watch tightly on the wrist or the upper arm in the daytime. Synchronization of the watch with the app was advised to be at least twice per week to prevent the "oldest" data to be deleted when the watch's storage became full. Participants that went several days without synchronizing was contacted and reminded of this. They were also advised to wear the watch one night or more each week to determine exact resting heartrate (this to optimize the PAI algorithm). The participants were also recommended to charge the LYNK2 watch regularly to prevent it from

running out of battery and activity data not being measured.

The LYNK2 watch is a no-screen watch/armband that connects with the PAI-system. Even though the watch does not provide feedback from a screen it provides direct feedback on intensity while exercising. This happens with different color lights indicating different intensity (blue lights=low intensity, green lights= moderate intensity, red= vigorous intensity) on the watch. The trial began immediately after the participants were physically tested, randomized and had received their activity trackers.
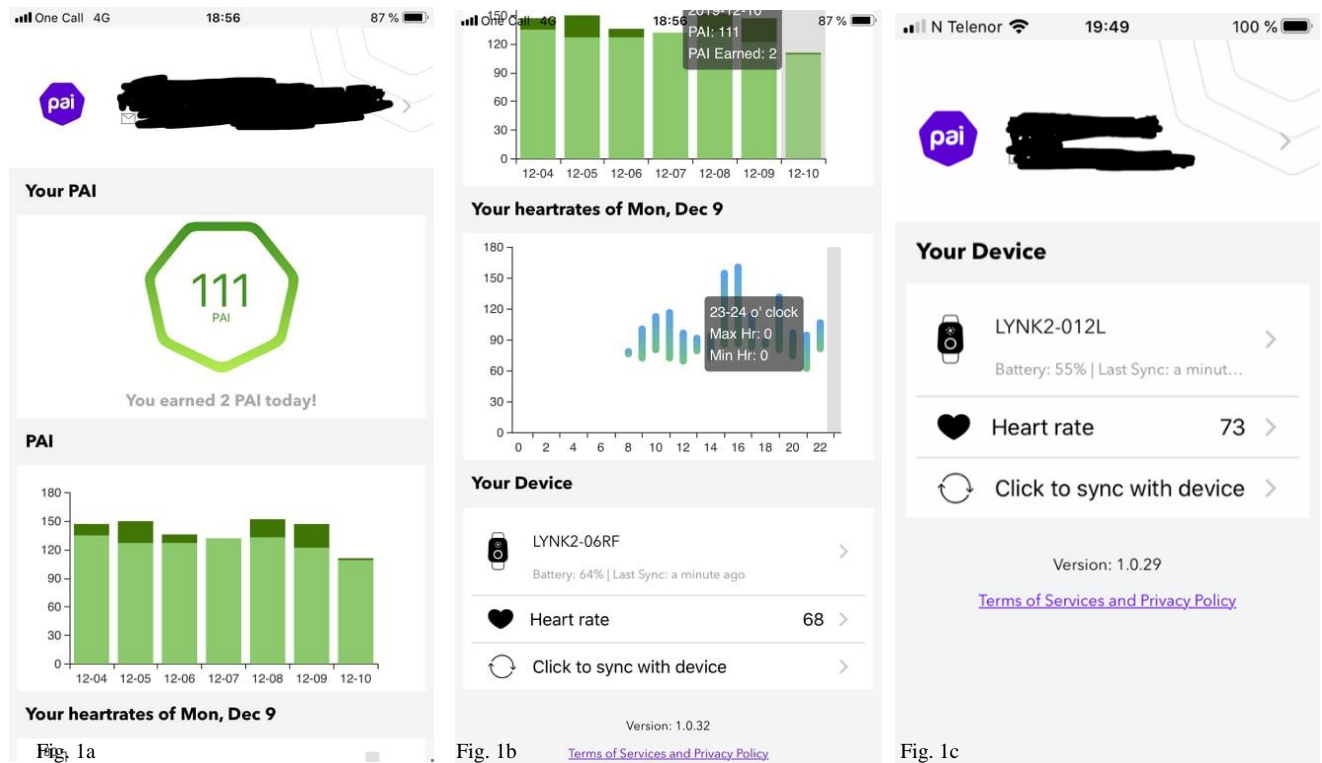

Fig. 1a

Fig. 1b

Fig. 1c

Fig. 1a, Feedback application part 1. Describes total PAI the current week and PAI earned in the 7 previous days.

1b, Feedback application part 2. Shows maximum and minimum heartrate each hour of the 7 previous days. Shows total battery, when last synchronized as well as current heart rate. At the bottom the application will synchronize when pressed.

1 c, No-feedback application. Shows total battery, when last synchronized as well as current heart rate. At the bottom the application will synchronize when pressed.

Randomization and blinding

During the test appointment the participants were allocated (allocation ratio 1:1) to either intervention group or control group. Randomization was performed after testing and was

conducted by the same study personnel also responsible for the physical testing and neither the participants nor the study personnel were blinded. The Unit of Applied Clinical Research (third party) provided a web-based randomization solution for clinical research at NTNU, and their WebCRF3 platform was used in this study. A list of computer-generated numbers was used to distribute the participants into "feedback" which was the intervention group or "regular" which was the control group.

Measurements
Activity measurements

To each subject's app there was health data required to create a user in the PAI-system. The health data required; sex, birth date, resting heart rate (measured sitting still at ergometer cycle before warm-up and testing), maximum heart rate (220-age), height and weight. These data were as well as the pulse measurements provided by the LYNK2 is used by the algorithm to determine physical activity levels. The PAI-system collects these data and based on them, provides the participants with feedback described in Figure 1. Further data such as total PAI each week, PAI earned each day, minutes in low, moderate- and high intensity each day and PAI achieved in each of the 3 intensities per day was available for study personnel.

Physical performance measurements

At baseline as well as at the end of the trial, physical performance was measured. The study personnel collected measurements on height (self-reported), weight (Soehnle Body Control Contour F3, Germany), age (self-reported), and ergometer seat height (the participants had a slightly bent knee in the extended position) and was measured and noted before test-protocol. The 6-minutes submaximal ergometer cycle, Åstrand-Ryhming test was used to estimate the participants VO_{2MAX}. A slightly modified version of the ACSM-protocol was used (41). The participants were instructed to pedal at a pedal rate 50±5 during the entire test and was corrected if needed. The participants started pedaling at 0 watts for a few minutes as a short warm up while the study-personnel had a short run-down of the test. The watt was adjusted to a comfortable level before the test was started (between 45-75watts depending on the participant). The watt was further increased during the first couple of minutes of the test to achieve an exercise heartrate between 120-170bpm (test requirement). The heart rate needed to be stable (≤5 beats difference

between the fifth and the sixth minute) for the test to be validated (41). The test was conducted using a Premium Heart Rate Monitor (Garmin, USA) on a Monark exercise and test cycle (Monark Sport and Exercise, Sweden). The test estimates maximal oxygen uptake (ml/kg/min) based on the final test measurements on heart rate, watt, gender, age, height and body weight with the formula:

VO_{2MAX} (mL*kg-1*min-1) = $VO_2$1 [(220 – age – 73 – (G * 10))/(HR – 73(G * 10))]

where

$VO_2$1 (submaximal workload) = [(1,8 * work rate)/body weight in kilogram] + 7

Work rate = watt * 0,10197162129779 * 60

G = 0 for women and 1 for men

HR = steady-state heart rate in beats per minute (bpm).

The ergometer cycle settings were noted and copied at both tests, as well as if the participants are wearing shoes or not during weighing and cycling. The pulse monitor was placed either around the participant's waist or around the chest depending on signal strength and stability. The final placement was repeated at the second test.

The test appointments were scheduled to be at the same time for both pre- and posttest. This to further prevent any biased results. There were no restrictions on the participants eating, drinking, nicotine, or caffeine intake before the test appointment. The Åstrand-Ryhming test was executed by study personnel at the rehabilitation center's test room where all patients completed according to test-protocol unless otherwise specified.

Primary Outcomes

The Primary outcomes of this study were to unveil any difference in activity levels in the home period between the intervention group and the control group. This was done by comparing the mean number of PAI points achieved each week of the two first weeks in said home period between the intervention and control group. Another primary outcome was to compare the number of participants achieving the 100 PAI goal per week in the home period in the intervention group and the control group.

The secondary outcomes were change in submaximal oxygen uptake as well as change in body weight and Body Mass Index (BMI) score between groups. The time frame was set from inclusion to the end the second stay.

Statistical analysis

Sample size was not determined. A convenience sample was chosen and the available partients at the institution during the study period was invited to participate. Each participant's total PAI in the first institutional week and the first 2 home weeks was determined by using the last total PAI score for each week. Only participants with PAI data in 3 or more days per week was included in the analysis. One participant was excluded due to a previously not mentioned medication effecting the participant's pulse. Due to few participants wearing the LYNK2 watch enough through their home-period only the first 2 weeks of their home-period and the first institutional week was analyzed. The difference in total PAI per week between the intervention group and the control group was analyzed using an independent sample t-test.

The Fisher's Exact test was used to compare the number of participants in each group reaching the 100PAI goal in both the institutional week and the 2 home weeks. Only participants completing both baseline and follow-up anthropometrical measurements were included in the anthropometrical and the physical fitness analyses. Participants with negative VO_{2max} measurements meaning they did not complete testing, was removed and not included in this analysis. The difference in change between the group's anthropometrics (weight and BMI) and physical fitness (VO_{2max}) measurements was analyzed using an independent sample t-test. The difference in anthropometrics (weight and BMI) and physical fitness (VO_{2max}) measurements between baseline and follow-up were analyzed using a paired samples t-test for each of the two groups. All variables were tested for normality with the Kolmogorov-Smirnov test, as well as histograms and QQ-plots being used. The results were analyzed with statistic software IBM SPSS Statistics 26 for Windows. Precision of the estimates was assessed by 95% confidence intervals (CI) and a p value below 0,05 (two-tailed) was considered statistically significant.

Results

The flow of participants is illustrated in Figure 2. Between August and December 2019, 49 potential participants at Unicare Helsefort was invited to participate in the study. 11 potential participants declined the invitation while 1 was excluded based on exclusion criteria. The personal reasons whom 7 of the participants declined due to was things such as anxiety towards ergometer testing, skepticism around application use, and pain limiting their movement and activity levels. Of the 37 who accepted the invitation 18 was randomized to the intervention group and 19 was randomized to the control group.

It was 35 participants in total, 94% in the intervention group and 95% of the control group that had some or all data to be included in the final analyzes. Out of the 35 participants included in the analyzes only 10 (56%) from the intervention group and 7 (37%) from the control group had both PAI and anthropometrical data. A total of 26 participants, 13 (72%) from the intervention group and 13 (68%) from the control group had 1 week or more in PAI data. As for the anthropometrical data there was 27 participants, 15 (83%) from the intervention group and 12 (63%) from the control group that completed both baseline and follow-up measurements. The participants lost to follow up, 1 in the intervention group and 1 in the control group, both lacked PAI data and neither had completed both baseline and follow-up measurements in anthropometrical data.
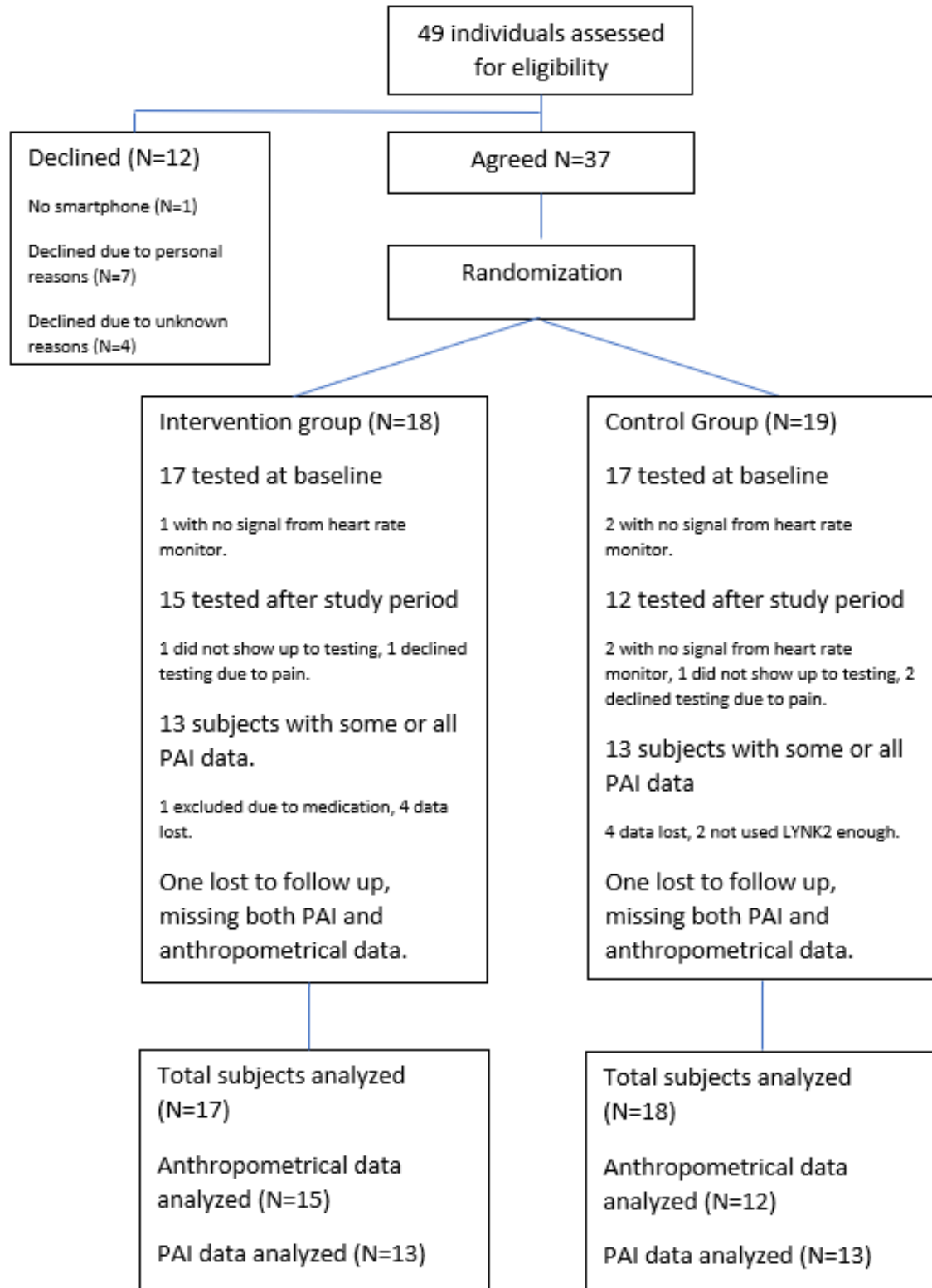
Fig. 2 Flow of participants for 6-10 weeks randomized controlled physical activity trial.

Participant characteristics

The mean age of the participants was 51 (SD 12.8) where the majority of the participants were women (78.4%). The mean of the participant's weight and BMI was 110.6kg (SD 20.1) and 38.7 (SD 5.6). The participants estimated physical fitness (VO_{2max}) mean was 28.3 (SD 7.7). Baseline characteristics for the intervention group and the control group were similar between groups (Table 1).

Table 1. Baseline characteristics of the study participants (n=37)

	Intervention group (N=18)	*Control Group (N=19)*
Women	N=14 (77.8%)	N=15 (78.9%)
Men	N=4 (22.2%)	N=4 (21.1%)
Age, years	52.4 (11.9)	50.6 (13.9)
Height, cm	168.7 (7.5)	168.7 (7.8)
Weight, kg	112.7 (19.4)	108.6 (21.1)
BMI, kg/m^2	39.5 (5.8)	37.9 (5.4)
Estimated aerobic fitness, ml/min/kg	28.4 (6.8) *	28.3 (8.8) *

Values are mean (SD).
* N=17

Total PAI

Table 2 describes the mean total PAI for both groups in 3 individual weeks, showing no statistically significant differences between groups, except a moderate, not statistically significant difference between groups in the first institutional week (mean difference -58.4, 95% CI: -122.4 to 5.6, p = 0.072). Only 19 (73%) participants had complete data from all tree weeks, 9 (69%) of the intervention group and 10 (77%) of the control group. In the first home week only 3 (30%) of the intervention group and 4 (40%) of the control group reached the 100PAI goal (Fisher's Exact Test, p = 1.000). The second home week 3 (30%) of the intervention group and 1 (9%) of the control group achieved the 100PAI goal (Fisher's Exact Test, p = 0.311). 11 (92%) of the intervention group and 6 (50%) of the control group reached the 100PAI goal in the first institutional week (Fisher's Exact Test, p = 0.069).

Anthropometrics and physical fitness change

Table 3 shows anthropometrical and physical fitness data, describing a not statistically significant difference in change between groups from baseline to follow-up, as well as in-group change from baseline to follow-up in both groups.

Table 2. Total PAI per week during study period (N=26)

	Intervention Group (N=13)	Control Group (N=13)	Mean Difference between groups (95% CI)	p-value [a]
PAI, first home week	69.2 (52.4) ***	70.9 (58.1) ***	1.7 (-50.3 to 53.7)	0.946
PAI, second home week	77.4 (73.2) ***	42.0 (37.2) **	-35.3 (-86.6 to 16.9)	0.173
PAI, first institutional week	165.7 (64.6) *	107.3 (85.1) *	-58.4 (-122.4 to 5.6)	0.072

Values are mean (SD).
[a] Independent samples t-test for the mean difference between groups.
13 participants were included in the total for each group..
* - (N=12), ** - (N=11), *** - (N=10)

Table 3. Anthropometrics and physical fitness (N=27)

	Intervention Group (N=15)				Control Group (N=12)					
	Baseline	6-10weeks	Mean difference (95% CI)	p-value [a]	Baseline	6-10weeks	Mean Difference (95% CI)	p-value [a]	Mean difference between groups (95% CI)	p-value [b]
Weight, kg	111.2 (19.8)	108.13 (20.1)	-3.02 (-4.2 to 1.8)	<0.000	109.7 (20.3)	105.3 (20.3)	-4.3 (-6.2 to -2.4)	<0.000	1.3 (-0.8 to 3.3)	0.208
BMI, kg/m^2	39.4 (5.6)	38.31 (5.8)	-1.08 (-1.5 to -0.6)	<0.000	38.5 (5.9)	37.0 (6.0)	-1.5 (-2.1 to -0.8)	<0.000	0.4 (-0.3 to 1.1)	0.232
VO2$_{max}$, ml/min/kg	29.1 (6.8) *	32.47 (8.5) *	3.33 (-0.2 to 6.9) *	0.063	30.4 (9.0)	33.6 (9.9)	3.2 (0.7 to 5.8)	0.017	0.1 (-4.2 to 4.7)	0.963

Values are mean (SD).
[a] Paired sample t-test for the change within the group over the study period.
[b] Independent samples t-test for the mean difference in the change from baseline to 6-10weeks between the intervention and the control group.
* - (N=14)

Discussion

Based on the study's results there was no additional effect in wearing a physical activity tracker with feedback to increase the physical activity levels of an obese and overweight group in a home period during a rehabilitation process.

Even though there was no statistically significant difference between the groups in any of the three analyzed weeks, there were some indications that the intervention group had more PAI then the control group in the institutional week. This indicates that the intervention group was in either more physical activity or had more vigorous intensity while exercising in this week.

In addition, there was no significant difference between groups in either weight, BMI or VO_{2max} after 6-10 weeks. However, there was a statistically significant in-group difference between the baseline and the follow up measurements in both groups, but this indicates an effect of the rehabilitation program and not the wearable activity trackers.

This is one of the first interventional studies on overweight and obese individuals wearing a physical activity monitor with feedback during a rehabilitation process. While this study's focus was primarily on the home period of the rehabilitation process, the majority of similar studies have conducted research on the institutional period and have few to no results from the home period. In a previous and somewhat similar study, a 24-month trial, obese and overweight adults underwent a lifestyle intervention targeting weight loss, physical activity levels and sedentary time while using and receiving feedback from a wearable activity monitor both at an institution and at home (38). The study found no differences between the feedback and control group in weight or BMI after being home. While both the feedback group and the control group increased their physical activity levels during their home stay, there was no difference between the groups (38). This somewhat support the findings in the current study. While the current study found a small increase in physical activity levels during the second home week for the intervention group, there were no statistically significant difference between groups. However, in contrast to the current study, the intervention period in the previous study was substantially longer in comparison.

In other shorter studies, conducted on individuals wearing activity trackers with feedback at home without rehabilitation and institutional stays have inconsistent results in physical activity levels and sedentary behavior (26, 42). Some studies that all investigates the effect of feedback

from physical activity monitors shows an effect in feedback on physical activity levels and somewhat in weight and BMI (42-44). A study conducted on young Finnish men wearing activity monitors with feedback showed a short-term positive effect on physical activity levels and sedentary time (45). Another study investigated the effect in feedback from a wearable activity device on activity levels in young, sedentary adults (43). The study found that the feedback group had significantly increased their physical activity levels compared to the control group. The same effect have been shown in a physical activity intervention in overweight women receiving feedback from a activity tracking device (46). However, these studies have several distinctions compared to the current study. The Finnish study is conducted on a completely different population as well as the participants is not undergoing a rehabilitation (45). The two remaining studies both had somewhat the same population as the current study, and even if both the feedback groups and the control groups underwent a physical activity intervention neither of the studies participants was in rehabilitation with an institutional stay and a home period (43, 46).

In the current study there was indications, however not statistically significant, that the feedback group had higher physical activity levels in the institutional week compared to the control group. This is in line with a previous study conducted on overweight and obese adults wearing an activity tracking device with feedback that showed an significant increase in moderate-and vigorous intensity activity in the feedback group compared to the control group (44). The same effect was revealed in 6-month behavioral weight loss trial in obese individuals. The group that received feedback from a wearable activity tracker had more minutes in moderate-and vigorous intensity compared with the control group not receiving feedback (26). Furthermore, the indication from the current study is substantiated by another study who investigated a physical activity enhancements effect on the physical activity levels in severely obese individuals during a 6-month behavioral weight loss trial (47). The results from previous studies support the indicational find from the current study. However, in contrast to the present study, the participants was not in an institutional rehabilitation, but received face-to-face guidance at least once per week during the study period (26, 44, 47).

The current study found no evidence that feedback improved weight loss, BMI and VO_{2max} more compared to controls. Similar results have been found in previous studies (38, 42). A study conducted on obese participants during an in-person, behavioral weight loss intervention, found

no additional weight loss in the group receiving feedback from a activity monitor (42). A previously mentioned study also found no additional weight loss or increased physical fitness in the feedback-receiving group (38). While both of these studies have the same population and institutional in-person approach as the current study, both studies are substantially longer than the current study, with one being 12 weeks and the other 24 months (38, 42).

While the first home week in the current study had no difference between groups, there seems to be a small difference between groups in the second home week, however not statistically significant. Where other studies find an immediate increase in physical activity after an intervention (48), at least in the short term, the current study does not. With no similar studies showing the same indicational results on physical activity levels during the home period the possible explanations may be many. One explanation may be a "back-to-routines" mechanism where work, kids, friends, housekeeping, and other everyday activities is prioritized the first week after being away for a period of time, and therefore not prioritizing physical activity despite receiving feedback or not. This could possibly change during the second home week, where the intervention group are reminded through feedback and again prioritizing physical activity, while the control group does not. Another explanation may be that the participants takes a needed break after an intensive institutional stay, and where the feedback group starts to exercise again the control group continue their break. Both these explanations are just speculations, and with no similar findings in other studies it will be difficult to determine the exact mechanism.

The difference between the group's physical activity levels in the institutional week for the current study are also interesting and corresponding with similar studies. While at the institution both groups followed the same standardized rehabilitation program and in theory both groups conducted the same amount of exercise. Therefore, it can be speculated if the feedback group had a higher intensity while exercising to achieve more PAI in a shorter amount of time, while the control groups didn't make this connection due to no feedback. These findings are supported by findings from similar studies(43, 44, 47). Individuals receiving feedback from a wearable device have more minutes in moderate-and vigorous intensity compared to individuals not receiving feedback (43, 44, 47) . If the current study had results of minutes in different intensities it would be easier to determine the exact cause of the higher PAI-levels in the intervention group.

The current study found no differences between groups in weight, BMI or VO_{2max}, which is

concurrent with findings from other shorter studies (42, 43). However, there is a statistically significant change from baseline to follow-up in both groups which shows that the rehabilitation program influenced the participants independent of group. In similar studies, with longer intervention periods, findings indicates that participants receiving feedback from a activity tracker have a bigger weight loss compared to participants not receiving feedback from a activity tracker (26, 47). Therefore, it can be speculated if the current study had had a longer intervention period there could have been a difference in weight loss and possibly physical fitness between groups.

It became apparent that there were inconsistencies in the collected activity data in the current study. Where the intention was to examine the entire home period, the data collected revealed severe inconsistencies where several participants did not wear or synchronize the activity tracker. Even after eliminating several weeks from the analysis there was a substantial fall-out with limited registered data in the remaining 3 weeks, where only 26 (70.3%) participants had data in at least one of the three weeks. This percentage of participation can be seen in other studies, where activity data were not analyzed due to similar inconsistencies (37). Dean et al. (37) mentions some "pros and cons" noted by the participants related to wearing the activity tracker. The main "con" mentioned from these participants were the synchronization process and resulted in several of the participants stopped wearing the activity tracker (37). Despite different activity tracking monitors used in the current and previous study it can be speculated if the synchronization process caused the similar inconsistencies in activity data. If so, it needs to be evaluated if such interventions need better technological solutions and if they are feasible on this population.

The main strengths of this study were the randomized, controlled design and the objective activity data. Other strengths were the choice of activity tracking system and device. With a pulse monitoring activity tracker, data from movement, typically seen in monitors such as pedometers and accelerometers are avoided.

This study had several limitations where the most prominent were the inconsistencies in the activity data. Much data was lost due to few participants completing the 6-10-week study period

while wearing their activity trackers. With several participants lost to follow up, from both groups, the groups may not be equal in the analysis, like they were after randomization. This may have affected the results in a way where only the motivated participants in the groups had data to be included in the analysis and could have biased the results.

During the analysis it became clear that to investigate the time in moderate- and vigorous intensity as intended was not feasible. Where PAI-data build on top of the previous week, the minutes in each intensity went day by day. Therefore, if participants did not synchronize each day the minutes in each intensity were lacking in the missing days, where PAI were not. Limitations related to the LYNK2 watch and the use of this device is also prominent. How much the watch has been used each day by the participants was not possible to determine and therefore it can be differences in total wear time. The LYNK2 watch also provided feedback on intensities during exercise through different color lights on the watch, which unfortunately affected both groups. This became a limitation because the control group was not supposed to receive feedback of any kind, and even if this was attempted to be corrected it could not be done. The application also showed the participants current pulse, which also affected both groups. However, this pulse was not seen in context with other feedback measures for the control group and have been considered to have had little impact on physical activity levels.

Because of limited available time during the rehabilitation process as well as a high drop-out chance a quick, convenient and manageable physical test was chosen. The Åstrand-Ryhming ergometer test provides an estimated VO_{2max} and should be used cautiously when compared to results from other studies. However, the Åstrand-Ryhming ergometer test provides measures that can easily be used to detect change in individuals. A limitation to this test was that either the participants nor the study personnel were blinded, which possibly could have influenced the performance in the follow up measurements. Another limitation to the ergometer test was that there were no dietary restrictions. Where the Åstrand-Ryhming test protocol recommend no eating, drinking, nicotine or caffeine before testing (41), the participants was allowed to eat during the scheduled meals at the institution. However, the participants was tested at the same time at both baseline and follow up to get the same physical adaptations both times and standardize the test.

Because the intervention only lasted a maximum of 10 weeks it was not designed to detect larger

physiological changes over time. Furthermore, without any sample size calculations we do not know if the study was able to detect a possible difference between groups, which limits the study's results.

In conclusion there were no observed differences in physical activity levels during the home period of a rehabilitation process between the intervention group receiving feedback from an activity tracker and the control group not receiving feedback in obese and overweight individuals. With complications and challenges related to inconsistencies in data, it can be questioned the technological solution was suitable for this population. Further research, possibly with a more suitable technological solution, are needed.

References

1.   WHO. Obesity and overweight. 2020.

2.   Bassuk SS, Manson JE. Epidemiological evidence for the role of physical activity in reducing risk of type 2 diabetes and cardiovascular disease. J Appl Physiol (1985). 2005;99(3):1193-204.

3.   Eheman C, Henley SJ, Ballard-Barbash R, Jacobs EJ, Schymura MJ, Noone AM, et al. Annual Report to the Nation on the status of cancer, 1975-2008, featuring cancers associated with excess weight and lack of sufficient physical activity. Cancer. 2012;118(9):2338-66.

4.   Malnick SD, Knobler H. The medical complications of obesity. Qjm. 2006;99(9):565-79.

5.   Stenehjem JS, Hjerkind KV, Nilsen TIL. Adiposity, physical activity, and risk of hypertension: prospective data from the population-based HUNT Study, Norway. J Hum Hypertens. 2018;32(4):278-86.

6.   Bhaskaran K, Dos-Santos-Silva I, Leon DA, Douglas IJ, Smeeth L. Association of BMI with overall and cause-specific mortality: a population-based cohort study of 3.6 million adults in the UK. Lancet Diabetes Endocrinol. 2018;6(12):944-53.

7.   Flegal KM, Kit BK, Orpana H, Graubard BI. Association of all-cause mortality with overweight and obesity using standard body mass index categories: a systematic review and meta-analysis. Jama. 2013;309(1):71-82.

8.   Avila C, Holloway AC, Hahn MK, Morrison KM, Restivo M, Anglin R, et al. An Overview of Links Between Obesity and Mental Health. Curr Obes Rep. 2015;4(3):303-10.

9.   Gine-Garriga M, Sansano-Nadal O, Tully MA, Caserotti P, Coll-Planas L, Rothenbacher D, et al. Accelerometer-measured sedentary and physical activity time and their correlates in European older adults: The SITLESS study. J Gerontol A Biol Sci Med Sci. 2020.

10.   Heath GW, Brown DW. Recommended levels of physical activity and health-related quality of life among overweight and obese adults in the United States, 2005. J Phys Act Health. 2009;6(4):403-11.

11.   Asvold BO, Midthjell K, Krokstad S, Rangul V, Bauman A. Prolonged sitting may increase diabetes risk in physically inactive individuals: an 11 year follow-up of the HUNT Study, Norway. Diabetologia. 2017;60(5):830-5.

12.   WHO. Information sheet: global recommendations on physical activity for health 18 - 64 years old 2011 [Available from:

https://www.who.int/dietphysicalactivity/publications/recommendations18_64yearsold/en/.

13.   Grontved A, Hu FB. Television viewing and risk of type 2 diabetes, cardiovascular disease, and all-cause mortality: a meta-analysis. Jama. 2011;305(23):2448-55.

14.   Ekelund U, Steene-Johannessen J, Brown WJ, Fagerland MW, Owen N, Powell KE, et al. Does physical activity attenuate, or even eliminate, the detrimental association of sitting time with mortality? A harmonised meta-analysis of data from more than 1 million men and women. Lancet. 2016;388(10051):1302-10.

15.   Lin WY, Chan CC, Liu YL, Yang AC, Tsai SJ, Kuo PH. Performing different kinds of physical exercise differentially attenuates the genetic effects on obesity measures: Evidence from 18,424 Taiwan Biobank participants. PLoS Genet. 2019;15(8):e1008277.

16.   Marques A, Santos DA, Peralta M, Sardinha LB, Gonzalez Valeiro M. Regular physical activity eliminates the harmful association of television watching with multimorbidity. A cross-sectional study from the European Social Survey. Prev Med. 2018;109:28-33.

17.   Werneck AO, Silva DR, Oyeyemi AL, Fernandes RA, Steene-Johannesen J, Andersen LB, et al. Physical activity attenuates metabolic risk of adolescents with overweight or obesity: the ICAD multi-country study. Int J Obes (Lond). 2020;44(4):823-9.

18.   Hansen BH, Holme I, Anderssen SA, Kolle E. Patterns of objectively measured physical activity in normal weight, overweight, and obese individuals (20-85 years): a cross-sectional study. PLoS One. 2013;8(1):e53044.

19.   Jakicic JM, Davis KK. Obesity and physical activity. Psychiatr Clin North Am. 2011;34(4):829-40.

20.   Verreijen AM, Engberink MF, Memelink RG, van der Plas SE, Visser M, Weijs PJ. Effect of a high protein diet and/or resistance exercise on the preservation of fat free mass during weight loss in overweight and obese older adults: a randomized controlled trial. Nutr J. 2017;16(1):10.

21.   Kurscheid T, Redaelli M, Heinen A, Hahmann P, Behle K, Frobose I. [App-controlled feedback devices can support sustainability of weight loss. Multicentre QUANT-study shows additional weight loss and gain of QoL via multiple feedback-devices in OPTIFAST(R)52-program]. Z Psychosom Med Psychother. 2019;65(3):224-38.

22.   Cheatham SW, Stull KR, Fantigrassi M, Motel I. The efficacy of wearable activity tracking technology as part of a weight loss program: a systematic review. J Sports Med Phys Fitness. 2018;58(4):534-48.

23.   Unicare. Våre rehabiliteringstilbud [Available from:
https://unicare.no/tjenester/rehabilitering/vare-rehabiliteringstilbud/.

24.   Yanovski SZ, Yanovski JA. Toward Precision Approaches for the Prevention and Treatment of Obesity. Jama. 2018;319(3):223-4.

25.   Hainer V, Toplak H, Mitrakou A. Treatment modalities of obesity: what fits whom? Diabetes Care. 2008;31 Suppl 2:S269-77.

26.   Pellegrini CA, Verba SD, Otto AD, Helsel DL, Davis KK, Jakicic JM. The comparison of a technology-based system and an in-person behavioral weight loss intervention. Obesity (Silver Spring). 2012;20(2):356-63.

27.   Hillsdon M, Foster C, Thorogood M. Interventions for promoting physical activity. Cochrane Database Syst Rev. 2005(1):Cd003180.

28.   Butryn ML, Webb V, Wadden TA. Behavioral treatment of obesity. Psychiatr Clin North Am. 2011;34(4):841-59.

29.   Norman GJ, Zabinski MF, Adams MA, Rosenberg DE, Yaroch AL, Atienza AA. A review of eHealth interventions for physical activity and dietary behavior change. Am J Prev Med. 2007;33(4):336-45.

30.   Ferrara G, Kim J, Lin S, Hua J, Seto E. A Focused Review of Smartphone Diet-Tracking Apps: Usability, Functionality, Coherence With Behavior Change Theory, and Comparative Validity of Nutrient Intake and Energy Estimates. JMIR Mhealth Uhealth. 2019;7(5):e9232.

31.   Henriksen A, Haugen Mikalsen M, Woldaregay AZ, Muzny M, Hartvigsen G, Hopstock LA, et al. Using Fitness Trackers and Smartwatches to Measure Physical Activity in Research: Analysis of Consumer Wrist-Worn Wearables. J Med Internet Res. 2018;20(3):e110.

32.   Nes BM, Gutvik CR, Lavie CJ, Nauman J, Wisløff U. Personalized Activity Intelligence (PAI) for Prevention of Cardiovascular Disease and Promotion of Physical Activity. Am J Med. 2017;130(3):328-36.

33.   Thomas JG, Bond DS. Review of innovations in digital health technology to promote weight control. Curr Diab Rep. 2014;14(5):485.

34.   Bacigalupo R, Cudd P, Littlewood C, Bissell P, Hawley MS, Buckley Woods H. Interventions employing mobile technology for overweight and obesity: an early systematic review of randomized controlled trials. Obes Rev. 2013;14(4):279-91.

35.   Chambliss HO, Huber RC, Finley CE, McDoniel SO, Kitzman-Ulrich H, Wilkinson WJ. Computerized self-monitoring and technology-assisted feedback for weight loss with and without an enhanced behavioral component. Patient Educ Couns. 2011;85(3):375-82.

36.   Tang J, Abraham C, Greaves C, Yates T. Self-directed interventions to promote weight loss: a systematic review of reviews. J Med Internet Res. 2014;16(2):e58.

37.   Dean DAL, Griffith DM, McKissic SA, Cornish EK, Johnson-Lawrence V. Men on the Move-Nashville: Feasibility and Acceptability of a Technology-Enhanced Physical Activity Pilot Intervention for Overweight and Obese Middle and Older Age African American Men. Am J Mens Health. 2018;12(4):798-811.

38.   Jakicic JM, Davis KK, Rogers RJ, King WC, Marcus MD, Helsel D, et al. Effect of Wearable Technology Combined With a Lifestyle Intervention on Long-term Weight Loss: The IDEA Randomized Clinical Trial. Jama. 2016;316(11):1161-71.

39.   Marttinen R, Daum D, Fredrick RN, 3rd, Santiago J, Silverman S. Students' Perceptions of Technology Integration During the F.I.T. Unit. Res Q Exerc Sport. 2019;90(2):206-16.

40.   Le A, Mitchell HR, Zheng DJ, Rotatori J, Fahey JT, Ness KK, et al. A home-based physical activity intervention using activity trackers in survivors of childhood cancer: A pilot study. Pediatr Blood Cancer. 2017;64(2):387-94.

41.   ACSM's Guidelines for Exercise Testing and Prescription: American College of Sports Medicine.; 2017. Available from:
https://books.google.no/books?hl=no&lr=&id=hhosAwAAQBAJ&oi=fnd&pg=PP1&ots=ljIa5GZXWy&sig=pDLBKOvSXC9FpYJdcPbZ17Q07QE&redir_esc=y#v=onepage&q&f=false.

42.   Polzien KM, Jakicic JM, Tate DF, Otto AD. The efficacy of a technology-based system in a short-term behavioral weight loss intervention. Obesity (Silver Spring). 2007;15(4):825-30.

43.   Barwais FA, Cuddihy TF, Tomson LM. Physical activity, sedentary behavior and total wellness changes among sedentary adults: a 4-week randomized controlled trial. Health Qual Life Outcomes. 2013;11:183.

44.   Wang JB, Cadmus-Bertram LA, Natarajan L, White MM, Madanat H, Nichols JF, et al. Wearable Sensor/Device (Fitbit One) and SMS Text-Messaging Prompts to Increase Physical Activity in Overweight and Obese Adults: A Randomized Controlled Trial. Telemed J E Health. 2015;21(10):782-92.

45.   Jauho AM, Pyky R, Ahola R, Kangas M, Virtanen P, Korpelainen R, et al. Effect of wrist-worn activity monitor feedback on physical activity behavior: A randomized controlled trial in Finnish young men. Prev Med Rep. 2015;2:628-34.

46.   Cadmus-Bertram LA, Marcus BH, Patterson RE, Parker BA, Morey BL. Randomized Trial of a Fitbit-Based Physical Activity Intervention for Women. Am J Prev Med. 2015;49(3):414-8.

47.   Unick JL, O'Leary KC, Bond DS, Wing RR. Physical activity enhancement to a behavioral weight loss program for severely obese individuals: A preliminary investigation. ISRN Obes. 2012;2012.

48.   Lynch BM, Nguyen NH, Moore MM, Reeves MM, Rosenberg DE, Boyle T, et al. Maintenance of physical activity and sedentary behavior change, and physical activity and sedentary behavior change after an abridged intervention: Secondary outcomes from the ACTIVATE Trial. Cancer. 2019;125(16):2856-60.