Short-term effectiveness of a smartphone application in increasing physical activity and adherence to the Mediterranean diet in primary care: a randomized controlled trial. The EVIDENT II study.

Short title: **Short-term effectiveness of a smartphone application in improving healthy lifestyles**

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Abstract

Background: The use of smartphone applications (APPs) for improving lifestyles has become generalized in the population, though little is still known about their effectiveness in improving health.

Objectives: To evaluate the effect after three months of adding an APP to standard counseling in terms of increased physical activity and adherence to the Mediterranean diet.

Design: A randomized, controlled, multicenter clinical trial was carried out.

Setting: Six primary care centers in Spain.

Participants: A total of 833 subjects from family practice offices were recruited through random sampling: 415 in the APP + counseling group (APPG) and 418 in the counseling group (CG).

Intervention: Counseling on the Mediterranean diet and physical activity was given in both groups. The APPG subjects additionally received training in the use of an APP designed to promote the Mediterranean diet and physical activity over a three-month period.

Measurement: Physical activity was measured with the 7-day Physical Activity Recall (PAR) questionnaire and an accelerometer, and adherence to the Mediterranean diet was assessed using the MEDAS questionnaire (primary endpoints). Age, sex, blood pressure, lipids, blood glucose, body mass index, motivation and adherence to APP were measured.

Results: Leisure time moderate / vigorous physical activity (MVPA) as assessed with the 7-day PAR was seen to increase in APPG (29 [95%CI: 5 to 53] min/week; $p<0.05$) but not in CG (17.4 [95%CI: -18 to 53] min/week; $p>0.05$), without differences on comparing the increase between the two groups, except as regards leisure time moderate activity among female university students (75.4 [95%CI: 2.3 to 148.5] min/week; $p<0.05$). The accelerometer recorded a decrease in physical activity after three months in both groups. Adherence to the Mediterranean diet increased to a similar extent in both groups (8.4% in APPG and 10.4% in CG), with an increase in score of 0.42 and 0.53 points, respectively.

Limitation: The nature of the trial precluded blinding of the participants to the intervention.

Conclusion: Leisure time MVPA as assessed with the 7-day PAR increased in APPG, particularly among female university students. Counseling accompanied by printed materials appears to be effective in improving adherence to the Mediterranean diet, though the APP does not increase adherence.

Trial registration: Clinical Trials.gov Identifier: NCT02016014

Keywords: Physical activity, Food, Information and communication technologies, Arterial aging.

INTRODUCTION

Regular physical activity offers considerable physical and psychological health benefits (1), reducing overall and cardiovascular mortality in a dose dependent manner (2, 3) among subjects at high cardiovascular risk and also in the general population (4, 5). Despite this fact, most of the population in developed countries do not follow the international recommendations on physical activity (6, 7). This situation was also seen in phase 1 of the EVIDENT trial (8), where the proportion of active individuals was found to be very low (31%). On the other hand, interventions designed to promote physical activity have revealed a small to moderate effect – better results being obtained when such interventions are targeted to change behavioral habits in people who are insufficiently active (9).

The Mediterranean diet (MD) has been shown to be effective in preventing cardiovascular disease (10), and moreover exerts a preventive effect against other disorders such as type 2 diabetes (11). It has also been associated to a decrease in different types of cancer (12, 13) and to a reduction in proinflammatory markers (14). Despite the above, adherence to the MD is low, as documented by the EVIDENT trial, where adherence among the participants was found to be 33% (15). Interventions designed to improve adherence to the MD show nutritional counseling to achieve moderate improvements in food habits, reducing the intake of saturated fats and increasing the consumption of fruit, vegetables and fiber. Those interventions characterized by more frequent contacts or with periodic reinforcements appear to be more effective than less intensive interventions (16).

Information and communication technologies are currently one of the supporting elements that may facilitate such reinforcement and contribute to improve health and change lifestyles (17).

Many smartphone applications (APPs) have been developed with this aim in mind, though the supporting evidence is generally limited (18). Furthermore, the results are not always uniform, with positive effects in terms of body weight loss (19, 20), but few or contradictory effects upon physical activity (21, 22). However, few studies have examined effectiveness in large population samples using an APP combining physical activity and food habits.

The present study evaluates the short-term (three months) effects of adding an APP in support of standardized counseling in order to increase physical activity and adherence to the MD.

METHODS

Design overview

A randomized, controlled, multicenter clinical trial with two parallel groups was carried out in 6 Spanish primary care centers, with a follow-up period of 12-months (the EVIDENT II study) (23). Assessments were made at baseline and after three months between January 2014 and December 2015, with evaluation of the 12-month period in 2016.

Setting and participants

The study included 6 primary care groups of the Spanish Research Network for Preventive Activities and Health Promotion in Primary Care (RedIAPP). The study population was selected from the EVIDENT I study (24), comprising 1553 subjects randomly selected in 6 primary care centers from family practice offices. Eligibility criteria included age between 18-70 years. Subjects over 70 years of age were excluded, as were those unable to do exercise or follow the Mediterranean diet, as well as those individuals meeting any of the exclusion criteria of the EVIDENT I study. These were: known coronary or cerebrovascular atherosclerotic disease; heart failure; moderate or severe chronic obstructive pulmonary disease; musculoskeletal disease

that limited walking; advanced respiratory, renal, or liver disease; severe mental disease; and treated oncological disease diagnosed in the previous 5 years (23).

Screening and randomization

Of the 1553 subjects recruited in the EVIDENT I study, 250 were excluded due to age over 70 years, while 85 failed to meet the inclusion criteria, 325 declined to participate, and 60 were not included due to other reasons. We thus finally recruited 833 subjects (Figure 1), which were randomized in proportion 1/1 on a centralized basis from Salamanca, using the Epidat 4.0 software package: counseling + APP group (APPG) 415 subjects, and counseling group (CG) 418 subjects. In order to minimize contamination of the CG, the investigator performing randomization and intervention was different from the investigator conducting evaluation. The investigator performing data analysis was blinded. Due to the nature of the study, the subjects could not be blinded to the intervention.

Intervention

A research nurse performed a common intervention in both groups, comprising standardized counseling in physical activity and the Mediterranean diet, with the delivery of printed supporting material (leaflet) on the session.

Physical activity counseling: Both groups received counseling with the current recommendations on physical activity in the general population. This intervention has demonstrated its effectiveness in the PEPAF study (25). Counseling consisted of an individual visit lasting 15 minutes in which an explanation was given of the health benefits of physical activity, with the recommendation to perform at least 30 minutes of moderate activity 5 days a week, or 20 minutes of vigorous activity three days a week. ***Nutritional counseling****:* Both groups

146 received nutritional counseling aimed at favoring adherence to the MD. This intervention has
147 been shown to be effective in the PREDIMED study (26). Counseling consisted of an individual
148 visit lasting 15 minutes in which the concepts of the MD were explained, with insistence upon
149 the importance of complying with each of the recommended points.
150 ***Specific intervention of the counseling + APP group:*** The subjects in APPG moreover received
151 training in the use of a smartphone application (EVIDENT II) designed to promote the
152 Mediterranean diet and increase physical activity over a three-month period. The APP was
153 designed by software engineers in collaboration with dietitians and physical activity experts,
154 with an easy-to-use interface for logging food and exercise. The APP can be used to quickly
155 evaluate the adaptation of living habits to healthy lifestyle recommendations referred to both
156 eating and physical activity. A first visit lasting 15 minutes was used to provide training in the
157 use of the device, which was employed daily for the full three-month period of the
158 intervention. The investigator instructed the participants on the use of the tool that evaluates
159 food intake; on how to enter the information and receive the recommendations; and on how to
160 use of the accelerometer and read the generated information – with the recommendation to
161 reach a total of 10,000 daily steps. The subjects were instructed to enter food intake (breakfast,
162 lunch, afternoon snack, and dinner) on a daily basis, selecting the dishes and foods from the
163 application menu. An evaluation was made of the quantity and quality of food intake according
164 to standardized references, with the purpose of assessing adaptation of the eating habits of the
165 individual to the Mediterranean diet. Based on adequate proportions of primary food elements,
166 a personalized recommendation was produced, depending on the entered intake
167 characteristics. Regular physical activity was recorded with the accelerometer of the device,

together with due registry of those activities performed without the smartphone (swimming, football, etc.). Lastly, the final daily summary was reviewed, with a balance of food intake and physical activity, and the device in turn generated a recommended plan for the following days, with a view to improve eating habits and increase physical activity. A new visit took place one week after supplying the device, in order to confirm that it was being used correctly, and to clarify any possible doubts. The smartphone was returned after three months, coinciding with the common review visit. The information was stored in the device and was downloaded on occasion of the control visits for subsequent analysis. Adherence to the smartphone APP was assessed by the number of days of recordings in the device.

Outcomes and follow-up

The primary outcome was the change in physical activity and adherence to the Mediterranean diet at three months in APPG compared with CG. Data on secondary outcomes were also collected, including blood pressure, waist circumference, body mass index and laboratory parameters. A detailed description has been published elsewhere of how the clinical data were collected, the anthropometric measurements were made, and of how the analytical parameters were obtained (23)

Main outcomes

Physical activity: Physical activity was measured with an accelerometer and using the 7-day physical activity recall (7-day PAR). ActiGraph GT3X accelerometers (ActiGraph, Shalimar, FL, USA) were used to evaluate the physical activity primary endpoint, and have been previously validated (27-29). ActiGraph is a monitor that uses a piezoelectric acceleration sensor to filter and convert the signals produced from the sensor in samples collected at a preset frequency in

Hertz. The samples were summed over a user-specified time sampling interval, called an "epoch". Output from the ActiGraph is in the form of activity "counts," where one count is equivalent to 16 milli-g per second, and where g is equal to 9.825 m · s − 2, the acceleration of gravity. Activity "counts" were recorded to the internal memory of the accelerometers by converting acceleration units over a given epoch (30). Subjects wore the accelerometer fastened with an elastic strap to the right side of the waist for 7 consecutive days with habitual physical activity, except for bathing and performing activities in the water. All subjects were verbally instructed on how to use the accelerometer. The accelerometer was set to record physical activity data every minute. Sequences of 10 or more consecutive zero counts were regarded as non-wearing time and were excluded from the analyses. Inclusion criteria were a minimum of 5 days of recording, including at least one weekend day and at least 600 registered minutes per day. The first and last day were excluded, to analyze full days only, and the uptime was adjusted to 7 days. The main outcome variable from the activity monitor was the average intensity of physical activity (counts/minute), calculated with equal weighting given to each day (regardless of registered time per day). The intensity of physical activity was rated according to the cut-off points proposed by Freedson (31) as sedentary (<100 counts/minute), light (100–1952 counts/minute), moderate (1952–5724 counts/minute) vigorous (>5724 counts/minute) or very vigorous (>9498 counts/minute). Moderate / vigorous activity was considered as activity accumulated from all bouts lasting at least one min.

The 7-day PAR is a general measure of physical activity that has been recognized as a valid and reliable tool in recent years, and is widely used in epidemiological, clinical and behavioral change studies. It consists of a semi-structured interview (10-15 minutes) in which participants

provide an estimate of the number of hours dedicated to physical or occupational activities requiring at least a moderate effort in the past 7 days. The categories collected are moderate, vigorous and very vigorous physical activity. The amount of time dedicated to each activity was multiplied by the mean metabolic equivalents (METs) of each category: light activity 1.5, moderate activity 4, vigorous activity 6, and very vigorous activity 10. The sum of the products of the hours dedicated to each activity and its estimated mean energy expenditure (METs) provides an estimation of the kilocalories per kilogram used per day (kcal*kg-1 * d-1). The dose of physical exercise was estimated in METs/minute/week. Active individuals were considered as those doing at least 30 minutes of moderate activity 5 days a week, or at least 20 minutes of vigorous activity three days a week (32). Subjects not reaching this level of physical activity were regarded as sedentary.

Nutrition: Adherence to the Mediterranean diet, as nutrition primary endpoint, was measured using the validated 14-point Mediterranean Diet Adherence Screener (MEDAS) (33), developed by the PREDIMED study group. The MEDAS is a valid instrument for rapid estimation of adherence to the Mediterranean diet, and may be useful in clinical practice. The 14-item screener includes 12 questions on food consumption frequency and two questions on food intake habits considered characteristic of the Spanish Mediterranean diet. Each question was scored as 0 or 1, and the total score ranged from 0-14. Adequate adherence to the Mediterranean diet was assumed when the total score was ≥ 9 points.

Other measurements

Laboratory determinations: Venous blood sampling was performed between 08:00 and 09:00 hours after the individuals fasted and abstained from smoking and the consumption of alcohol

and caffeinated beverages for the previous 12 hours. Blood samples were collected in the respective health centers, and all were analyzed at the hospital of the city. Fasting plasma glucose, glycosylated hemoglobin and lipids were measured.

Anthropometric measurements: Body weight was determined on two occasions using a homologated electronic scale (Seca 770; Medical scale and measurement systems, Birmingham, United Kingdom) following due calibration (precision ± 0.1 kg); readings were rounded to 100 g. Height in turn was measured with a portable system (Seca 222), recording the average of two readings. Body mass index (BMI) was calculated as weight (kg) divided by height squared (m2). A value of > 30 kg/m2 was taken to define obesity. Waist circumference was measured using a flexible graduated measuring tape following the Spanish Obesity Society recommendation (34). The subjects wore light clothing and were shoeless.

Office or clinical blood pressure: Office blood pressure measurement comprised three measurements of systolic blood pressure (SBP) and diastolic blood pressure (DBP), using the average of the last two measurements, employing a validated OMRON model M10-IT sphygmomanometer (Omron Health Care, Kyoto, Japan), and following the recommendations of the European Society of Hypertension (35).

Analysis of motivation to change: We classified the motivation stages as pre-contemplation, contemplation, determination, action and maintenance as specified by the model of Prochaska and Diclemente (36).

Ethical considerations

The study was approved by the Clinical Research Ethics Committee (CREC) of the health care area of Salamanca ("*CEIC de Area de Salud de Salamanca*", 21 June 2013), as reference

Committee. In addition, the study was approved by the Ethics Committees of the 5 collaborating centers ("*CEIC de Aragón (CEICA), CEIC de IDIAP Jordi Gol, CEIC de Euskadi (CEIC-E), CEIC de Castilla la Mancha, CEIC de Area de Salud de Valladolid Oeste*"). All subjects signed the informed consent form prior to inclusion in the study, in accordance with the Declaration of Helsinki (37).

Statistical analysis

Estimation of sample size was made for the main study endpoints. Regarding physical activity, assuming $\alpha = 0.05$ and $ß = 0.20$, with a standard deviation (SD) of 154 counts/minute, we would need 828 subjects (414 per group) to detect an increase of 30 counts/minute in APPG versus CG. In turn, regarding the MD, assuming $\alpha = 0.05$ and $ß = 0.20$, with a standard deviation (SD) of 2 points, we would need 504 subjects (252 per group) to detect an increase of 0.5 points in the MD questionnaire in APPG versus CG. We considered it sufficient to include 833 subjects in order to detect clinically relevant differences in the main study endpoints.

The results were expressed as the mean ± standard deviation for quantitative variables, and as the frequency distribution for qualitative variables. Analysis of the results was made on an intent-to-treat (ITT) basis. The Chi-squared test and Fisher test were used to analyze the association between independent qualitative variables, while the McNemar test was applied to assess changes within one same group. The Student t-test was used for the comparison of means between two groups, and the paired t-test was applied to assess changes within one same group. Analysis of variance (ANOVA) was used for the comparison of means between more than two groups. In order to analyze the effect of the intervention, comparisons were made of the changes observed in CG versus APPG. To evaluate the effect of adherence to the

tool referred to the physical activity by accelerometer measurements, we performed a multivariate analysis based on the general lineal model (GLM), adjusting the results for age and sex. The contrasting of hypotheses established $\alpha = 0.05$. The data were analyzed using the IBM SPSS version 23.0 statistical package for MS Windows (IBM Corp, Armonk, NY, USA). A value of $p<0.05$ was considered statistically significant.

Role of the funding source

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RESULTS

Baseline characteristics of the participants and follow-up

The participants were predominantly females in both APPG (n=249; 60%) and in CG (n=268; 64%), with a mean age of 51.4 (12.1) and 52.3 (12.0) years, respectively ($p>0.05$). Likewise, no differences were observed between the two groups in terms of the rest of the demographic and clinical characteristics (Table 1). According to the trans-theoretical model of the stages of change of Prochaska and Diclemente, over one-half of the subjects were under maintenance conditions referred to both physical activity (57.6% in APPG vs 54.4% in CG) and food habits (66.7% in APPG vs 68.8% in CG).

Regarding physical activity evaluated with the 7-day PAR, we found APPG to reach 864.6 METS-min/week while CG reached 865.8 min/week – 27.5% of the subjects being active in the first group versus 28.2% in the second ($p>0.05$). In the case of the parameters analyzed with the

accelerometer, the results were similar in both groups. Of note is a mean number of daily steps of 9992 in APPG and 9708 in CG ($p>0.05$), these figures being very close to the target of 10,000 daily steps (Table 2). As regards adherence to the MD, the mean score was 7.6 in APPG and 7.4 in CG, with an adequate adherence rate of 34% in the first group versus 28% in the second ($p>0.05$)(Table 3).

Of the 833 subjects included in the study, 36 were seen to have been lost on the visit after three months in the first group (8.6%) versus 32 in the second group (7.6%). The reasons for these losses are detailed in the flow chart (Figure 1). Thus, evaluation after three months was based on 765 subjects (379 in APPG and 386 in CG). In the case of the accelerometer, the remaining number of patients was 679 (335 in APPG and 344 in CG).

Changes in physical activity and adherence to the Mediterranean diet

Based on the data of the 7-day PAR, both groups were seen to increase their physical activity after three months, though only APPG reached statistical significance in relation to leisure time moderate activity (28 min/week [95%CI: 6 to 50]) and leisure time moderate / vigorous and very vigorous activity (29 min/week [95%CI: 5 to 53]). However, although the increase in activity in APPG was greater than in CG for all the analyzed variables, no significant differences were observed on comparing the two groups (Table 4). In relation to physical activity evaluated with the accelerometer, we recorded a decrease in daily steps, counts/min and times at the different levels of activity, except for vigorous / very vigorous activity, with an increase in sedentary time in both groups – no differences being observed on comparing the changes between them (Table 4). Both groups increased adherence to the MD to a similar degree after three months versus baseline (8.4% in APPG and 10.4% in CG), with an increase in overall score

of 0.42 points (95%CI: 0.24 to 0.60) in APPG and 0.53 (95%CI: 0.35 to 0.71) in CG. The behavior referred to the different questionnaire items was similar in both groups, except as regards the decrease in meat intake in CG and the increase in fish consumption in APPG. In no case were significant differences observed between the groups (Table 5).

Adherence to the smartphone application

Fifty-seven percent of the subjects in APPG used the smartphone more than 60 days. Although there was a decrease in physical activity after three months as evaluated by the accelerometer in both groups, the decrease was less pronounced in the group that used the smartphone most (> 60 days), with a net increase in the time of moderate physical activity of 42.9 (95%CI: 1.8 to 83.9) min/week and moderate / vigorous physical activity of 44.0 (95%CI: 2.1 to 86.0) min/week, and a net decrease in sedentary time of 126.1 min/week (95%CI: 18.9 to 233.4). We also recorded a net increase in counts/min of 766.6 (95%CI: 26.2 to 1506.9). No differences were observed in relation to the 7-day PAR questionnaire or adherence to the MD (Figure 2).

Analysis by subgroups

No relevant differences were observed in the effect of the intervention in the analysis by subgroups with respect to the different motivation phases, age groups, sex or other sociodemographic and clinical variables analyzed. Only in the female university students subgroup did we observe an increase in leisure time moderate physical activity as evaluated with the 7-day PAR in APPG versus CG (increment 75.4 [95%CI: 2.3 to 148.5] min/week)(supplementary material).

Discussion

Although some randomized, controlled clinical trials have analyzed the effect of smartphone applications (APPs) in promoting healthy lifestyles, the EVIDENT II trial is the study that has included the largest number of subjects (n=833), and with the longest follow-up. The main findings at short term (three months) were an increase in physical activity as evaluated by the 7 day-PAR in both groups (though greater in APPG), and especially in the time dedicated to leisure time moderate / vigorous activities. Nevertheless, on comparing the two groups, statistical significance was only reached in the subgroup of female university students. However, assessment with the accelerometer revealed a similar decrease in physical activity in both groups. On the other hand, adherence to the MD was seen to increase in both groups, as evidenced by both the overall score and percentage good adherence. Lastly, in the accelerometer analysis, the subjects in APPG that most used the APP showed a net increase in MVPA time and a net decrease in sedentary time.

At this time, there is still no conclusive evidence of the effectiveness of APPs for smartphones in improving lifestyles. In this regard, the metaanalysis published by Flores et al. (19) found that interventions with APPs had some impact in terms of weight loss (0.43 kg/m^2), though no improvement in terms of increased physical activity was observed. Partridge et al. (38), in a series of 250 subjects between 18-35 years of age, evaluated physical activity using the IPAQ questionnaire, with results similar to those obtained in our study with the 7-day PAR. In both cases there was a greater increase in physical activity in the intervention group versus the controls, though the differences between them were not significant. In turn, Laing et al. (20), in a randomized, controlled study of 212 overweight individuals with a mean age of 43 years, found the use of an APP (MyFitnessPal) to have no impact in terms of either weight loss or

365 increased physical activity as assessed by means of a questionnaire. Likewise, Duncan et al. (39)
366 compared a group with a mobile + web device versus another group that received written
367 recommendations, and found physical activity to increase in both groups, with no significant
368 differences between them. These results are very similar to those obtained by the EVIDENT
369 study, where as we have mentioned physical activity increased to a greater extent in APPG -
370 particularly as regards leisure time MVPA (17.4 min/week) - than in CG, though here again the
371 differences between them were not significant.
372 However, the SMART MOVE study (40), involving 90 subjects (45 in each group) in which
373 physical activity was assessed from the steps estimated by the smartphone pedometer, an
374 increase was recorded after 8 weeks in the intervention group (1631 steps), while a decrease
375 was observed in the control group (-386 steps) – the baseline values in the two groups being
376 4365 and 5138 steps/day, respectively. In the baseline evaluation of the EVIDENT II study, the
377 mean number of steps/day as determined with the accelerometer was 9992 in APPG and 9708
378 in CG. This was followed by a decrease in both groups after three months, possibly because the
379 baseline values were very high. We have found no studies involving accelerometer
380 interventions in adults – the published data being limited to younger subjects. Direito et al. (21)
381 compared two APPs with a control group. Physical activity as evaluated with the accelerometer
382 decreased in both the control group and in one of the intervention groups after 8 weeks, in
383 coincidence with the findings of the EVIDENT study, with practically no changes in the data
384 assessed with the PAQ-A questionnaire. The decrease in accelerometer recordings is probably
385 attributable to a Hawthorne effect associated to utilization of the device - being more evident
386 at baseline with a possible increase in usual activity than after three months, due to a certain

loss of effect. This circumstance could limit the usefulness of the accelerometer in evaluating the effect of the interventions, despite the fact that the method is objective.

In the EVIDENT trial, nutritional counseling was seen to increase the overall score of adherence to the MD. Counseling was standardized in both groups – all participants receiving an informative leaflet (23). This type of nutritional counseling has shown improvements in food habits, with a moderate increase in the consumption of fruit, vegetables and fiber, especially when written materials are supplied in support of counseling (16). However, the added use of an APP did not result in significant differences between the overall groups or subgroups. There is little evidence of the effectiveness of APPs in improving food habits, and in general the results obtained are modest and come from studies with small sample sizes (41).

Nevertheless, the use of new technologies achieved some change in a study of young individuals between 18-35 years of age, with a slight increase in vegetable intake and a decrease in the consumption of sugared beverages (38). Furthermore, a lesser calorie and fat intake was recorded, resulting in increased weight loss (41). More discrete results were obtained in a population with type 2 diabetes, where a slight increase in fiber intake was documented (42). On the other hand, Coughlin et al. (41) considered that heterogeneity in the functional characteristics of the different APPs makes it more difficult to draw conclusions and to estimate the magnitude of their effect. In turn, Wang et al. (43) suggested that effectiveness can be increased by orienting these tools towards personalized needs such as self-education and the gaining of awareness of personal food intake. In this regard, one of the novelties of the EVIDENT APP is the incorporation of weekly notifications on the benefits and characteristics of the consumption of vegetables, fruit, olive oil, fish and tomato sauce prepared with vegetables

409 and olive oil – all these being traditional ingredients of the MD. This feature appears to exert
410 some effect, since these are the elements that improved most in APPG.
411 Our study also has several limitations. On one hand, the nature of the intervention precludes
412 blinding of the participants, and this could influence the results obtained. On the other hand,
413 the main findings of the study are based on self-reported information referred to both
414 adherence to the MD and to physical activity. Lastly, the recorded loss rate of close to 20% may
415 have biased the study sample composition to some extent, since certain populations may have
416 experienced difficulties using the APP and consequently decided to leave the study.
417 In sum, counseling accompanied by printed materials appears to be effective in improving
418 adherence to the MD, though the APP for smartphones does not increase effectiveness.
419 Physical activity, evaluated with the 7-day PAR, increases in APPG in reference to leisure time
420 MVPA, particularly in the subgroup of female university students. Improved adherence to the
421 APP appears to be associated to better results in terms of physical activity evaluated with the
422 accelerometer. Further studies are needed to determine which population subgroups may
423 benefit most from interventions based on information and communication technologies.
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Figure captions:

Figure 1:

Study flow chart: Enrollment of the participants and completion of the study.

Figure 2:

Changes in physical activity evaluated with the accelerometer, according to adherence to the smartphone application (number of days with a record in the application)**.** Higher adherence (> 60 days): 57%. Lower adherence (≤ 60 days): 43%; (0-6 days: 18%, 7-30 days: 10%, 31-60 days: 15%).

January 2014

Assessed for eligibility (n=1553)

Enrollment

Excluded (n=720)

Excluded by older age than 70 years (n=250)

Not meeting inclusion criteria(n=85)

Declined to participate(n=325)

Other reasons (n=60)

May 2015

Randomised (n=833)

Allocated to Counseling+APP intervention (n=415)

Received allocated Counseling intervention (n=415)
Received allocated APP intervention (n=403)

Allocation

Allocated to Counseling intervention (n=418)

Received allocated Counseling intervention(n=418)

Lost to follow-up (n=36)

Address change (n=4)

Illness (n=3)

Lack of time (n=13)

Did not want to continue (n=14)

Others (n=2)

Follow-up

Lost to follow-up (n=32)

Address change (n=2)

Illness (n=6)

Lack of time (n=8)

Did not want to continue (n=12)

Others (n=4)

December 2015

Analysed (n=415)

Analysis

Analysed (n=418)

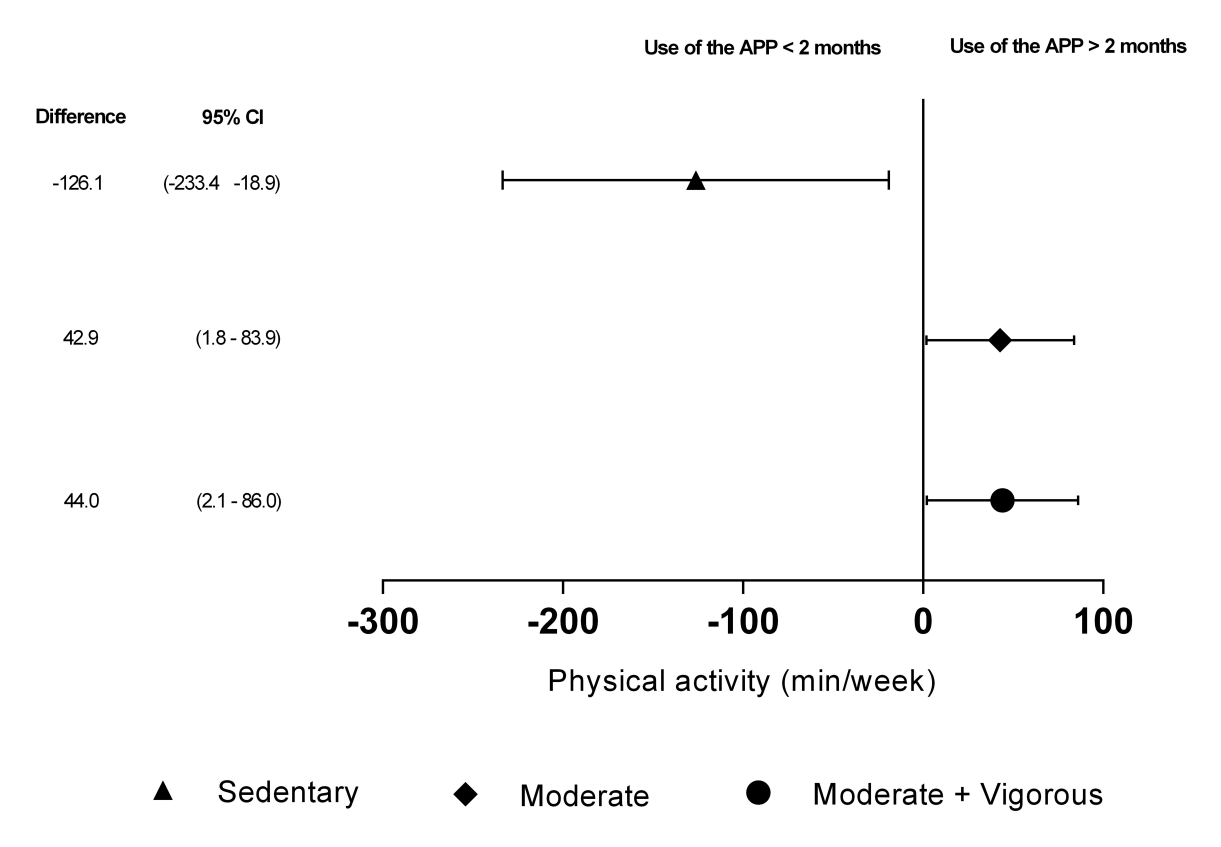
Use of the APP < 2 months
Use of the APP > 2 months
Difference
95% CI
-126.1
(-233.4 -18.9)
42.9
(1.8 - 83.9)
44.0
(2.1 - 86.0)
-300
-200
-100
0
100
Physical activity (min/week)
Sedentary
Moderate
Moderate + Vigorous

Table 1: Baseline characteristics of the study population

		APPG (415; 49.8%)		CG (418;50,2%)		
Variable		Mean/N	SD/(%)	Mean/N	SD/(%)	p
Age (years)		51.4	12.1	52.3	12.0	0.287
Females (n,%)		249	(60.0)	268	(64.1)	0.226
Work situation (n,%)	Works outside of home	228	(54.9)	203	(48.6)	0.246
	Homemaker	53	(12.8)	72	(17.2)	
	Retired	77	(18.6)	89	(21.3)	
	Student	10	(2.4)	8	(1.9)	
	Unemployed	47	(11.3)	46	(11.0)	
Educational level (n,%)	University studies	117	(28.2)	132	(31.6)	0.417
	Middle or High school	208	(50.1)	208	(49.8)	
	Elementary school	90	(21.7)	78	(18.7)	
Smoking (n,%)	Non smoker	190	(45.8)	166	(39.7)	0.203
	Smoker	94	(22.7)	108	(25.8)	
	Former smoker	131	(31.6)	144	(34.4)	
Waist circumference (cm)		95.2	13.2	94.8	6	0.708
BMI mean (Kg/m^2)		28.1	5.1	27.6	4.59	0.142
BMI Categories (n,%)	BMI<25	117	(28.2)	131	(31.3)	0.501
	BMI 25-30	172	(41.4)	173	(41.4)	
	BMI > 30	126	(30.4)	114	(27.3)	
Systolic blood pressure (mmHg)		124	16	124	17	0.749
Diastolic blood pressure (mmHg)		76	10	76	10	0.409
Total Cholesterol (mg/dl)		202	35	206	37	0.086
Triglycerides (mg/dl)		112	63	107	67	0.290
Glycated Haemoglobin (%)		5,5	0.5	5.5	0.6	0.870
Hypertension (n,%)		145	(34.9)	133	(31.8)	0.341
Dyslipidemia (n,%)		116	(28.2)	113	(27.3)	0.766
Diabetes (n,%)		32	(7.7)	30	(7.2)	0.769
Medication use (n,%)	Antihypertensive drugs	108	(26.0)	95	(22.7)	0.294
	Lipid Lowering drugs	90	(21.7)	74	(17.7)	0.163
	Antidiabetics drugs	24	(5.8)	28	(6.7)	0.668
Physical activity stage of change (n,%)	Precontemplation	57	(14.0)	73	(17.7)	0.347
	Contemplation	28	(6.9)	38	(9.2)	
	Preparation	58	(14.2)	51	(12.4)	
	Action	30	(7.4)	26	(6.3)	
	Maintenance	235	(57.6)	224	(54.4)	
Dietary habits stage of change (n,%)	Precontemplation	34	(8.3)	34	(8.2)	0.911
	Contemplation	26	(6.3)	20	(4.8)	
	Preparation	59	(14.3)	57	(13.8)	
	Action	18	(4.4)	18	(4.3)	
	Maintenance	275	(66.7)	285	(68.8)	

APPG: Counseling+APP group, CG: Counseling group. APP: Smartphone application. BMI: Body mass index. Categorical variables are expressed as number (n) and (%) and continuous variables as mean ± standard deviation (SD). p: statistically significant differences ($p < 0.05$). T-Student, Chi square and Fisher tests. Stage of change by Prochaska and Diclemente model.

Table 2: Baseline physical activity by 7-day PAR questionnaire and accelerometer

	APPG (415; 49.8%)		CG (418;50,2%)		
7- day PAR	Mean/N	SD/(%)	Mean/N	SD/(%)	p
Total minutes moderate activity	152.7	264.8	154.9	258.2	0.903
Total minutes moderate activity in leisure time	131.2	213.1	148.0	249.4	0.295
Total minutes vigorous/very vigorous activity	29.9	99.2	30.0	106.2	0.982
Total minutes vigorous/very vigorous activity in leisure time	28.0	97.1	27.9	98.2	0.995
Total minutes moderate vigorous/very vigorous activity	182.6	293.0	184.9	284.7	0.906
Total minutes moderate vigorous/very v. activity in leisure time	159.1	228.9	175.9	271.6	0.335
METS minute/week	864.6	1407.8	865.8	1330.6	0.990
METS minute/week in leisure time	764.4	1119.7	825.6	1263.3	0.460
Active (n,%)	114	(27.5)	118	(28.2)	0.817
Accelerometer					
Step / day	9992.3	3847.3	9708.3	3930.9	0.310
Counts minute/week	69.0	70.4	65.9	69.4	0.539
Sedentary minute /week	8327.0	540.4	8341.4	526.0	0.708
Light minute /week	1298.3	436.9	1307.2	423.2	0.774
Moderate minute /week	438.0	205.4	413.3	212.6	0.100
Vigorous very v. minute /week	16.7	38.9	18.2	45.8	0.624
Total MVPA minute /week	455.4	215.9	432.7	222.5	0.149
METS/ minute /week	1850.8	891.7	1762.6	922.0	0.177
> 450 METS minute /week (n,%)	368	(96.6)	373	(94.4)	0.153

APPG: Counseling+APP group, CG: Counseling group. APP: Smartphone application. 7-day PAR:7-day physical activity recall questionnaire. METS: metabolic equivalents. Active were considered as those doing at least 30 minutes of moderate activity, five days a week, or at least 20 minutes of vigorous activity, 3 days a week. MVPA: Moderate Vigorous/very vigorous physical activity. Categorical variables are expressed as number (n) and (%) and continuous variables as mean ± standard deviation (SD). p: statistically significant differences ($p < 0.05$). T-Student test and Fisher test.

Table 3: Baseline adherence to the Mediterranean diet

	APPG (415; 49.8%)		CG (418;50,2%)		
Criteria mediterranean diet	N	(%)	N	(%)	p
1. Using olive oil as the principal source of fat for cooking	389	(94)	394	(94)	0.772
2. ≥4 T (1 T=13.5 g) of olive oil/d (eg, used in frying, salads, meals eaten away from home)	154	(37)	135	(32)	0.146
3. 2 or more servings of vegetables/d	166	(40)	151	(36)	0.254
4. 3 or more pieces of fruit/d	180	(43)	177	(42)	0.780
5. 1 serving of red meat or sausages/d	347	(84)	355	(85)	0.635
6. 1 serving of animal fat/d	378	(91)	379	(91)	0.904
7. 1 cup (1 cup=100 mL) of sugar-sweetened beverages/d	356	(86)	363	(87)	0.687
8. ≥7 servings of red wine/week	79	(19)	70	(17)	0.416
9. ≥3 servings of legumes/week	98	(24)	81	(19)	0.152
10. ≥3 servings of fish/week	163	(39)	183	(44)	0.206
11. <2 commercial pastries/week	206	(50)	195	(47)	0.406
12. ≥3 servings of nuts/week	149	(36)	123	(29)	0.055
13. Preferring white meat over red meat?	282	(68)	261	(62)	0.109
14. ≥2 servings/wk of a dish with a traditional sauce of tomatoes, garlic, onion, or leeks sautéed in olive oil	220	(53)	223	(53)	0.945
Study participants with a total score ≥ 9 points (n,%)	142	(34)	119	(28)	0.086
Score for adherence to Mediterranean Diet (mean± SD)	7.6	2.1	7.4	2.0	0.091

APPG: Counseling+APP group, CG: Counseling group. APP: Smartphone application. Categorical variables are expressed as number (n) and (%) and continuous variables as mean ± standard deviation (SD). p: statistically significant differences ($p < 0.05$). T-Student test and Fisher test.

Table 4: Changes in physical activity and sedentary lifestyle at 3 months compared to baseline

	Changes in APPG (n=379)			Changes in CG (n=386)			Mean difference (APPG – CG)		
7-day PAR	Mean	95% CI	p	Mean	95% CI	p	Mean	95% CI	p
Total minutes moderate activity/week	20.6	(-8.1 to 49.2)	0.159	8.3	(-18.6 to 35.2)	0.542	12.2	(-27.0 to 51.5)	0.540
Minutes moderate activity in leisure time/week	28.4	(6.0 to 50.8)	**0.013**	12.8	(-13.2 to 38.8)	0.334	15.6	(-18.8 to 49.9)	0.373
Total minutes vigorous/very vigorous activity/week	2.8	(-7.6 to 13.1)	0.603	-0.7	(-10.0 to 8.7)	0.889	3.4	(-10.5 to 17.4)	0.631
Minutes vigorous/very v. activity in leisure time/week	0.7	(-9.5 to 10.9)	0.894	-1.1	(-10.3 to 8.1)	0.818	1.8	(-11.9 to 15.5)	0.799
Total minutes MVPA/week	23.3	(-5.4 to 52.1)	0.111	7.7	(-19.8 to 35.2)	0.584	15.7	(-24.0 to 55.3)	0.439
Minutes MVPA in leisure time/week	29.1	(4.9 to 53.3)	**0.018**	11.7	(-14.6 to 38.1)	0.382	17.4	(-18.4 to 53.1)	0.340
METS minute/week	88.8	(-42.8 to 220.3)	0.185	14.5	(-108.7 to 137.8)	0.817	74.2	(-105.7 to 254.1)	0.418
METS minute/week in leisure time	110.5	(-5.0 to 225.9)	0.061	26.9	(-90.3 to 144.2)	0.652	83.6	(-80.7 to 247.9)	0.318
Accelerometer									
Step / day	-1042.1	(-1401.7 to -682.6)	**<0.001**	-584.2	(-961.2 to -207.1)	**0.002**	-458.0	(-978.5 to 62.6)	0.085
Counts minute/week	-12.9	(-18.6 to -7.3)	**<0.001**	-6.8	(-13.3 to -0.3)	**0.041**	-6.1	(-14.7 to 2.5)	0.162
Sedentary minute /week	167.7	(114.9 to 220.5)	**<0.001**	125.6	(73.7 to 177.6)	**<0.001**	42.1	(-31.9 to 116.0)	0.265
Light minute /week	-113.0	-(154.4 to -71.6)	**<0.001**	-96.6	(-137.3 to -55.8)	**<0.001**	-16.4	(-74.4 to 41.6)	0.578
Moderate minute /week	-51.3	(-71.3 to -31.4)	**<0.001**	-26.3	(-47.0 to -5.5)	**0.013**	-25.1	(-53.8 to 3.7)	0.088
Vigorous very v. minute /week	-3.4	(-6.9 to 0.2)	0.062	-2.8	(-6.7 to 1.0)	0.153	-0.6	(-5.8 to 4.7)	0.827
Total MVPA minute /week	-55.3	(-75.8 to -34.9)	**<0.001**	-30.1	(-51.8 to -8.4)	**0.007**	-25.2	(-55.0 to 4.5)	0.096
METS minute /week	-229.3	(-313.2 to -145.4)	**<0.001**	-118.6	(-208.6 to -28.7)	**0.010**	-110.7	(-233.6 to 12.2)	0.078

APPG: Counseling+APP group, CG: Counseling group. APP: Smartphone application. Changes in APPG and CG= data at 3 months – baseline. CI: Confidence interval. 7- day PAR:7-day physical activity recall questionnaire. METS: Metabolic equivalents. MVPA: Moderate vigorous/very vigorous physical activity. p: statistically significant differences ($p < 0.05$).T-Student independent and paired test.In accelerometer measurement, 335 subjects in APPGand 344 in CG.

Table 5: Changes in the Mediterranean diet at 3 months compared to baseline

	Changes in APPG (n=379)			Changes in CG (n=386)			Mean difference (APPG – CG)		
Criteria mediterranean diet	% Mean	95% CI	p	% Mean	95% CI	p	%Mean	95% CI	p
1. Using olive oil as the principal source of fat for cooking	3.2	(0.9 to 5.5)	**0.007**	2.6	(0.4 to 4.8)	**0.018**	0.6	(-2.6 to 3.7)	0.719
2. ≥4 T (1 T=13.5 g) of olive oil/d (eg, used in frying, salads, meals eaten away from home)	0.5	(-4.4 to 5.5)	0.833	2.1	(-2.8 to 6.9)	0.400	-1.6	(-8.5 to 5.4)	0.659
3. 2 or more servings of vegetables/d	8.2	(3.1 to 13.3)	**0.002**	12.3	(7.2 to 17.4)	**<0.001**	-4.1	(-11.3 to 3.2)	0.269
4. 3 or more pieces of fruit/d	8.0	(3.5 to 12.4)	**<0.001**	7.6	(2.9 to 12.2)	**0.001**	0.4	(-6.0 to 6.8)	0.901
5. 1 serving of red meat or sausages/d	1.6	(-2.6 to 5.8)	0.454	3.6	(0.1 to 7.2)	**0.043**	-2.1	(-7.5 to 3.4)	0.460
6. 1 serving of animal fat/d	0.8	(-2.2 to 3.8)	0.602	0.8	(-2.1 to 3.7)	0.591	0.0	(-4.1 to 4.1)	0.997
7. 1 cup (1 cup=100 mL) of sugar-sweetened beverages/d	2.1	(-1.2 to 5.4)	0.206	1.3	(-2.1 to 4.8)	0.457	0.8	(-4.0 to 5.6)	0.739
8. ≥7 servings of red wine/week	-0.3	(-3.4 to 2.9)	0.870	0.3	(-2.1 to 2.6)	0.828	-0.5	(-4.5 to 3.4)	0.793
9. ≥3 servings of legumes/week	-3.4	(-8.1 to 1.2)	0.144	-1.6	(-5.5 to 2.3)	0.432	-1.9	(-7.9 to 4.1)	0.540
10. ≥3 servings of fish/week	5.3	(0.5 to 10.1)	**0.029**	3.9	(-0.8 to 8.6)	0.104	1.4	(-5.3 to 8.1)	0.684
11. <2 commercial pastries/week	6.9	(1.5 to 12.2)	**0.012**	8.6	(3.6 to 13.7)	**0.001**	-1.7	(-9.1 to 5.6)	0.643
12. ≥3 servings of nuts/week	2.1	(-2.9 to 7.1)	0.405	4.7	(-0.2 to 9.5)	0.058	-2.6	(-9.5 to 4.4)	0.469
13. Preferring white meat over red meat?	6.4	(1.4 to 11.3)	**0.012**	10.4	(6.3 to 14.6)	**<0.001**	-4.1	(-10.5 to 2.4)	0.219
14. ≥2 servings/week of a dish with a traditional sauce of tomatoes, garlic, onion, or leeks sautéed in olive oil	3.4	(-1.8 to 8.7)	0.201	-0.5	(-5.9 to 4.9)	0.850	4.0	(-3.6 to 11.5)	0.304
Study participants with a total score ≥ 9 points	8.4	(3.4 to 13.5)	**0.001**	10.4	(5.0 to 15.8)	**<0.001**	-1.9	(-9.3 to 5.5)	0.611
Difference Mediterranean diet score (Mean)	0.42	(0.24 to 0.60)	**<0.001**	0.53	(0.35 to 0.71)	**<0.001**	-0.11	(-0.37 to 0.15)	0.395

APPG: Counseling+APP group, CG: Counseling group. APP: Smartphone application. Changes in IG and CG= data at 3 months – baseline. CI: Confidence interval. p: statistically significant differences ($p < 0.05$). T-Student independent and paired test, and Mc Nemar and Fisher test.