Effectiveness of a Primary Care Program to Increase Physical Activity in People With Dementia and Their Family Caregivers (AFISDEMYF Study).

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Abstract

**Aim:** To evaluate the effectiveness of an intervention in primary health care designed to increase physical activity in people with dementia and their family caregivers.

**Methods:** A cluster-randomized multicentre clinical trial was carried out.

**Participants:** 140 people with dementia (median age 82 years; 63.6% women) and 176 caregivers (median age 62 years; 72.7% women). Seventy patients and 80 caregivers were assigned to the Control Group (CG) and 70 patients and 96 caregivers to the Intervention Group (IG). The physical activity was measured with the pedometer and with the IPAQ-SF questionnaire. The intervention consisted of applying in primary care the program promoting physical activity (PEPAF) for 3 months. The changes observed at 6 months were analyzed.

**Results:**

In people with dementia, in the pedometer assessment a decrease was observed in both groups, but it was larger in the CG both in the total number step/day lower in the IG than in the CG and in the aerobic steps/day (52.89 vs -615.93). The activity reported with the IPAQ-SF decreased more in IG, both in the MET/min/week (-258.470 vs -148.23) and in the MVPA min/week. In caregivers the pedometer assessment showed that total steps/day increased more in the IG, as did aerobic steps/day (356.91 vs -12.95). The IPAQ-SF a smaller increase in global activity was declared in the IG than in the CG (545.25 MET/min/week vs 609.55), but the increase in vigorous activity was greater.

No differences were found in changes in the functional status and the cognitive performances of people with dementia nor in the mental health in the caregivers, but systolic blood pressure, the Family APGAR and overload in the IG did improve.

**Conclusions:** The results suggest that the intervention carried out may be effective on physical activity in both patients and caregivers. It can also improve systolic blood pressure, the Family APGAR and overload in caregivers. This is the first study to implement a primary care intervention aimed at simultaneously increasing physical activity in people with dementia and their relatives. These results reinforce the importance of using objective measures in clinical trials in people with dementia.

**Trial registration number:** NCT 02044887.

Background

Population ageing has led to a rise in chronic diseases, as well as disability, and this requires greater dedication to care by family members [1]. Dementias, as the main cause of loss of disability-adjusted life years in women, are a major health problem [2]. More than two thirds of people suffering from dementia continue to live at home, impacting significantly on their families [3], and worsening the quality of life both of those with dementia and their family caregivers [4]. These challenges are exacerbated by a
shortage of dementia care specialists, which places an increasing burden on primary physicians to provide care for people living with dementia [5]. It is known that people with dementia (PWD) have a less active lifestyle in comparison to their peers without health problems [6]. They highly depend on their caregivers to do any physical activity[5]. Because of this, informal caregivers have a great interest when it comes to physical activity intervention for people who suffer from dementia.

A caregiver is someone who gives support and takes care of someone else who lives with dementia. Unpaid caregivers are usually closed family members of the patient and it is known that more than 30% of PWD have an average of three caregiver members of their family [1]. However, most interventions focus only on the patient and just one caregiver, not taking into account the family functionality [5].

In addition, the sedentary lifestyle that PWD present has a negative influence on executive functions [7]. Physical activity (PA) is a highly protective factor for cognitive functions and also a promising psychosocial strategy for the protection of cognition in older people [8]. However, measuring PA in this group of subjects is not easy. As far as we know, practically all the studies carried out on PWD evaluate PA using questionnaires instead of objective measures such as the pedometer [9]. Furthermore, whether the questionnaires are filled out by PWD or their caregivers is not specified, so it is difficult to assess the discrepancy between performed and reported PA [10].

Caring for a family member often has a negative impact on physical and psychological health [11]. Moreover, caregivers have been found to have a greater tendency towards a sedentary lifestyle than non-caregivers [12], which can exacerbate negative mental health effects [13], cardiovascular morbidity [14, 15], and increase overall mortality [16]. PA is a beneficial intervention for healthy older people, increasing functional capacity and the control of cardiovascular disease risk factors [8, 17, 18], as demonstrated in the program promoting physical activity (PEPAF), a randomized controlled clinical trial developed in primary health care which has been effective in increasing PA in sedentary people, especially in people over 50 years of age [19]. Even though physical activity interventions may have a positive impact on PWD, these types of interventions are a big challenge for people living with dementia. They also require the participation of caregivers and sometimes they might have negative secondary effects on the patient, such as behavioral and psychological symptoms, pain, confusion, agitation, feelings of malaise and higher likelihood of falls. In a review by Lamotte et al. [12] only 4 controlled trials which developed interventions for patients in dyads were taken into account, focused both on the patient and his or her caregiver [20-23].

The conclusion of these trials is that physical activity interventions are feasible and may have a positive effect on the patient, promoting his functional independence and making it easier for the caregiver [23]. However, there is not enough evidence on the benefits of these interventions with dyads with regard to cognitive performance and the behavioral and neuropsychiatric symptoms in participants with dementia.

Finally, interventions aimed at increasing PA in groups of PWD and their relatives, in a primary care setting, have not yet been published since most of the interventions so far have been carried out only on the patient with dementia or only with a family caregiver [24].
THE STUDY

Aim/s

The objective of this study is therefore to evaluate the effectiveness of a primary health care intervention for increasing the PA of PWD and their relative caregivers with objective and subjective measures.

The effects of the intervention on PWD regarding their cognitive status and level of dependence, and on caregivers in terms of mental health, overload and family functionality were also estimated.

Design / Methodology

Field trial with two health centres (clusters) randomly assigned to the intervention group (IG), and two more centres to the control group (CG), where normal care was to be maintained. The protocol has been published with the sections of the methodology shown below [25] and registered in Clinical Trials.gov (AFISDEMYF study, NCT 02044887; date: 24/01/2014). Assessments were made at baseline and after 6 months between January 2016 and December 2018 (Figure 1).

Setting and Participants

The study was carried out in four primary care centres in Spain. Using the morbidity registry of PWD of the primary care physicians participating in the study, those PWD meeting the inclusion criteria were selected. A detailed description of the inclusion and exclusion criteria have been published in the study protocol [25]. A list of PWD was created, including family members who were involved in the care of the patient on at least two days a week, and it was suggested that at least one family member and up to three caregivers participate in the study. Those who accepted and met the inclusion/exclusion criteria had to sign the informed consent document before the initial assessment at the health centres. Finally, 140 PWD and 176 caregivers were included. Figure 1 (flow chart) shows the subjects assessed, causes of exclusion and drop-outs at 6-month follow-up. The study was completed by 48.6%, with “did not want to continue” being the main reason given for dropping out. Twelve months assessment allowed us to have complete information about 22 PWD (11 IG and 11 CG) and 35 caregivers (16 CG and 19 IG). Because of a high sample loss (84.29% of PWD and 80.45% of caregivers), effectiveness results were obtained with 6 months assessment data.

Sample size

Accepting a 0.05 alpha risk and a beta risk of 0.2 in a bilateral contrast, 67 participants in the control group and 67 in the intervention group are needed to detect a difference equal to or greater than 600 steps/day (1/2 SD) between the 2 groups. It is assumed that the common standard deviation is 1200 steps. Therefore, we consider that the 140 subjects included are sufficient to test the hypotheses of the study.

Intervention
The intervention was carried out by health workers (medics and nurses) who regularly care for PWD at the health centre. Caregivers and PWD may have had different family doctors. In a first interview, participating health workers carried out an assessment of the morbidity situation, lifestyles, functionality and care plans of PWD. The intervention carried out in the IG was the one recommended in the PEPAF study [26], consisting of an interview lasting 15-20 minutes, in which possible problems regarding exercise anticipated by the patient and caregiver are addressed and a focused Physical Activity Plan is negotiated in compliance with the recommendations of the Centers for Disease Control and Prevention (CDC). Benefits of doing physical activity and international recommendations about weekly physical activity were explained. Finally, a recommendation was made of 30 min of moderate activity during five days a week or 20 min of vigorous activity just three days a week. Participants are instructed to do PA autonomously, preferably by walking around their neighbourhood. To support the intervention, PEPAF recommendations were handed out in writing (a diptych) to both PWD and caregivers. During the following 3 months, interviews of about 15 minutes were carried out every 3 weeks to reinforce the performance of PA and offer support in case of any difficulties they may have encountered when exercising.

The health workers participating in the IG received a four-hour training session at the beginning of the study in the protocol for prescribing PA and were offered support during the study period to complete information or reinforce intervention content. No records other than those used in the care the care provided in primary care to PWD (medical history) were requested to avoid overloading the attention of the participants. The CG health workers performed the normal care and delayed any systematic intervention on PA until the end of the study, unless the reason for the consultation or the health problems of the PWD and caregivers were directly related to PA.

Data collection

Variables and measurement instruments

1- Primary measurement variable

The measurement of objective PA was carried out with a pedometer, which was used for 7 days, and subjective PA was assessed with a PA questionnaire, covering the same days as the pedometer. The two measurements were made at the beginning of the study and at 6 months with the dementia sufferers and caregivers in the two groups.

1) Digital pedometer (Omron Hj-321 lay-UPS):

The pedometer was previously validated [27]. Its piezoelectric sensors use multi-position sensing technology. It shows total steps, aerobic steps, distance covered and calories consumed, and stores the results of the last 7 days. The pedometer was worn by PWD and caregivers for 9 consecutive days in order to record 7 full days. The application was configured with the participant's data (sex, age, weight and height, step length).
2) The international physical activity questionnaire short form (IPAQ-SF)

The subjective PA record was collected for 7 days using the 9-item version of the IPAQ-SF questionnaire [28]. The IPAQ-SF is a general measure of PA which has been recognized as a valid and reliable tool. The sum of the products of the hours dedicated to each activity and the estimated energy expenditure (MET) provides an estimate of the kilocalories per kilogram used per day (kcal * kg⁻¹ * d⁻¹). The physical exercise dose is estimated in METs per minute per week (METS/min/week).

2- Secondary measurement variables:

A questionnaire was created to collect demographic variables of age, marital status, educational level, number of people living together at home, number of living children and caregiver's occupation. Anthropometric variables, functionality measured with the Barthel test [29, 30], the Lawton and Brody test [31] and morbidity were reported from the medical history by the health workers who regularly attended the PWD. The research team collected the responses to different questions regarding the care received by the patient, the number of months that caregivers had been caring for the family member, also asking whether the caregiver and the patient lived in the same home [32], and carried out the evaluation of the following questionnaires:

1) ADAS-Cog:

This is a brief cognitive battery composed of several scales assessing memory, learning and recognition, language, visuo-constructive skills, ideational practice, and temporal-spatial orientation. Errors are counted and scoring can range from 0 (best) to 70 (worst). It is the most widely used general cognitive measure in AD clinical trials [33].

2) Mini – Mental State Examination (MMSE):

This comprises 20 items and explores the functions of temporal-spatial orientation, attention, memory, language and constructive practice. The total score is a summation of all item scores, with 0 being the maximum error and 30 being the maximum success [34].

3) The clock drawing test:

In this test, the subject is instructed to draw a clock with all the numbers and to place the hands at ten past eleven. Visuo-constructive, visuospatial, planning and organization skills are assessed. The maximum total score is 7 points [35].

4) The 12-item General Health Questionnaire (GHQ-12)

The assessment of perceived mental health was carried out with the GHQ-12 [36], a self-administered screening questionnaire designed to be used in a clinical setting to detect individuals with psychiatric disorders. The total score is obtained by adding the scores between 1 and 4 of the 12 items: the higher the score, the worse the state of mental health. The cut-off point is set at 12 points.
5) The Family APGAR:

This questionnaire assesses the functionality of the family through five components: Adaptation, Partnership, Growth, Affection and Resolve. It consists of five questions, with five possible answers: never, rarely, sometimes, quite frequently, almost always, scored from 0 to 4. A score of 10-12 indicates moderate dysfunction, 13-16 mild dysfunction, and 17-20 normal functionality [37].

6) The short-form Zarit test:

The short-form Zarit test was applied to evaluate the caregiver's burden [38]. It consists of 7 questions with 5 possible responses (never, rarely, sometimes, quite frequently, almost always), scored from 1 to 5, giving a total scoring range of 7-35. The cut-off point is set at 17 points, with higher scores representing overload situations.

Ethical considerations

The Ethics Committee for Drug Research in the Salamanca health area (Spain) approved the project on 11/04/2013. Participants were informed of the project's objectives, as well as the risks and benefits of the actions taken and informed consent was obtained from all participants. They signed an informed consent in accordance with the Declaration of Helsinki. All methods were carried out in accordance with Declaration of Helsinki.

Validity and reliability

The study follows the recommendations of the CONSORT guidelines. The computer program (Epidat 4.0) was used to randomize the primary care centres (two to the IG and two to the CG) to avoid possible contamination due to the interaction of participants from the same centre. Randomization was carried out by researchers other than those performing the assessment, and the researcher in charge of carrying out the analyses was also blinded. Due to the nature of the study, subjects could not be masked. Participants from both groups were able to participate freely in other activities during the intervention period and were able to continue participating in those activities they had previously started.

Data analysis

Data are expressed as means and standard deviations or medians and interquartile ranges for continuous variables, and number and percentages for categorical variables. Normality was assessed using the Kolmogorov–Smirnoff normality test. When comparing categorical variables with each other, the χ² test was used. Comparisons of continuous variables between groups were performed using Student's t-test for independent samples or Mann-Whitney U test to evaluate differences by control and intervention group. PWD and caregivers were analyzed separately. To analyze the changes at 6 months with respect to the baseline evaluation in the outcome variables within the same group, the Student's t-test of paired data or the Wilcoxon test was used. The statistical analyses were carried out using IBM® SPSS® v.26 software (IBM Corp, Armonk, NY).
Results

Baseline characteristics of the participants and follow-up

One hundred and forty PWD (median age = 82.00 (IQR: 78.00-85.00; 63.6% women) and 176 carers (median age = 62.00 (IQR: 52.00-78.00; 72.7% women) participated in the study. Seventy PWD and 80 caregivers, and 70 PWD and 96 caregivers were distributed across the CG and IG respectively.

The second evaluation was taken by 61.43% (n=43) of the PWD in the IG and 35.71% (n=25) in the CG (Figure 1), and by 73.08% of the caregivers in the IG and 62.24% in the CG. A comparison of PWD who dropped out with those who participated in the second evaluation did not show differences regarding sex and PA, although there were differences in age: more older PWD dropped out (84.07 ± 5.78 years vs 80.42 ± 6.18; p = 0.016). Similarly, there were no differences in terms of sex and PA measures between the caregivers who dropped out and those who took the second evaluation in CG and IG. However, there were differences with respect to age, with younger caregivers dropping out more in the IG (57.49 ± 14.05 vs 64.67 ± 14.46 years; p = 0.020). The pedometer measurements were repeated on 8 PWD and on 3 caregivers because they did not obtain valid records during the week that they had to wear it, and 6 PWD who lost the pedometer explicitly refused to put it on again.

Tables 1 and 2 compare the sociodemographic and clinical characteristics of PWD and caregivers across IG and CG. A difference was found between the groups in caregiver overload, which was greater in the CG (p < 0.001). No differences were observed when comparing the PA of the CG with the IG in the baseline assessment, both in PWD and caregivers.

More than one caregiver participated in 32.4% of the cases in the intervention group and in 10% in the control group (TABLE 3). All PCDs who had 3 caregivers participating in the study performed at least 2 evaluations. The highest percentage of losses was observed in the group of PCD who had only one caregiver and belonged to the control group, since they represented 62.9% (44/70). Among the PCD who only carried out the initial evaluation, had only one caregiver the 97.8% in the control group and 85.2% in the intervention group. The number of PCD who participated in the third evaluation was the same in both groups, 11 (15.7%).

Changes in physical activity

In PWD, in the pedometer assessment a decrease was observed in both groups, but it was larger in the CG both in the total number step / day lower in the IG than in the CG (-646.37 v. -898.46) and in the aerobic steps / day (52.89 vs -615.93). However, the activity reported with the IPAQ-SF decreased more in IG, both in the MET / min / week (-258.470 vs -148.23) and in the MVPA min / week. However, statistical significance was not reached in any of the cases (Table 4).

Regarding caregivers, the pedometer assessment showed that total steps/day increased more in the IG (569.41 vs 377.23), as did aerobic steps/day (356.91 vs -12.95). In the activity reported with the IPAQ-SF,
a smaller increase in global activity was declared in the IG than in the CG (545.25 MET/min/week vs 609.55), but the increase in vigorous activity was greater (495.14 MVPA min/week v. 124.68) (Table 5).

Table 1.- Comparison of control and intervention groups at baseline: people with dementia.
### Demographic characteristics:

| Variables                  | Control (n=70) | Intervention (n=70) | p value |
|----------------------------|----------------|---------------------|---------|
| Age (years)                | 82.00(78.00-85.00) | 81.50(78.00-86.25) | 0.446   |
| Gender: Women              | 41(58.6)       | 48(68.6)            | 0.219   |
| Years of schooling.        | 8.00(6.00-8.00) | 8.00(6.00-8.00)     | 0.532   |
| Marital status: Married    | 36(65.5)       | 41(70.7)            | 0.551   |
| Lives with One person      | 53(75.7)       | 48(68.6)            | 0.346   |
| Two or more                | 17(24.3)       | 22(31.4)            |         |
| Classification Number of children |         |                     | 0.145   |
| No children                | 3(4.3)         | 8(11.4)             |         |
| One child                  | 13(18.6)       | 8(11.4)             |         |
| Two children               | 17(24.3)       | 24(34.3)            |         |
| Three or more children     | 37(52.2)       | 30(44.8)            |         |

### Clinical characteristics:

| Variables                  | Control (n=70) | Intervention (n=70) | p value |
|----------------------------|----------------|---------------------|---------|
| Abdominal perimeter (cm)   | 92.07(10.96)   | 95.24(14.54)        | 0.331   |
| Systolic blood pressure (mmHg) | 128.50(122.50-138.50) | 132.00(118.50-145.50) | 0.997   |
| Diastolic blood pressure (mmHg) | 73.00(66.75-82.00) | 74.00(65.00-84.00)  | 0.652   |
| Body Mass Index (kg/m2)    | 27.34(6.28)    | 26.99(4.50)         | 0.755   |
| Hypertension               | 24(34.3)       | 36(51.4)            | 0.040   |
| Hipercholesterolemia       | 29(41.4)       | 28(40.0)            | 0.863   |
| Melliteus Diabetes         | 12(17.1)       | 13(18.6)            | 0.825   |
| Smoking                    | 1(3.4)         | 4(6.6)              | 0.810   |
| Obesity                    | 6(20)          | 16(25.8)            | 0.540   |
| Barthel Index              | 70 (55-80)     | 75 (45-85)          | 0.639   |
| Lawton-Brody Index         | 1 (0-3)        | 3 (1-3)             | 0.009   |
| ADAS-Cog                   | 48.50 (42.00-62.75) | 45.00 (39.00-60.50) | 0.561   |
| Mini Mental State Examination | 15.44(7.51) | 18.06(7.68)       | 0.095   |
| The clock drawing test     | 1 (0-4)        | 2 (0-5)             | 0.483   |
**Number of months receiving care:**

|                                |       |       |
|--------------------------------|-------|-------|
| Less than 18                   | 12 (18.5) | 18 (28.1) |
| Between 18 and 36              | 13 (20.0) | 18 (28.1) |
| Between 37 and 68              | 19 (29.2) | 12 (18.8) |
| More than 68                   | 21 (32.3) | 16 (25.0) |

**Pedometer**

|                                |       |       |
|--------------------------------|-------|-------|
| Total Steps/day                | 3340.89 (2831.53) | 4384.52 (4988.75) |
| Aeróbics Steps/day             | 1697.97 (1695.99) | 2316.95 (3011.92) |
| Kilocaloríes/day               | 100.01 (49.68-151.84) | 111.29 (54.85-165.86) |
| Total Steps                    |       | 0.407 |
| Less than 7000                 | 19 (82.6) | 43 (78.2) |
| Between 7000-10000             | 4 (17.4) | 8 (14.5) |
| More than 10000                | 0 (0.0) | 4 (7.3) |

**IPAQ-SF**

|                                |       |       |
|--------------------------------|-------|-------|
| METS/min/week                  | 1052.47 (926.56) | 1412.00 (1391.72) |
| MVPA_min/week                  | 16.77 (54.74) | 28.88 (123.95) |
| Physical Activity Intensity    |       | 0.405 |
| Light                          | 7 (28) | 22 (38.6) |
| Moderate                       | 17 (68) | 30 (52.6) |
| Intense                        | 1 (4) | 5 (8.8) |

Notes: IPAQ-SF International Physical Activity Questionnaires -Short Form; MET: metabolic equivalent. Values expressed as mean (± standard deviation), Mean (SD), Median (IQR) or frequencies (percent). Chi-squared test and Mann-Whitney U test is used to test differences in all measures excepting Short Zarit where Student-t is applied.

Table 2.- Comparison of control and intervention groups at baseline: caregivers.
| Variables                  | Control (n=78)          | Intervention (n=98) | p value |
|----------------------------|-------------------------|---------------------|---------|
| **Demographic characteristics** |                         |                     |         |
| Age (years)                | 69.00(53.00-78.00)      | 59.00(51.00-76.00)  | 0.120   |
| Gender: Women              | 52(66.7)                | 76(77.6)            | 0.107   |
| Years of schooling.        | 9(8-13)                 | 12(8-15)            | 0.119   |
| Marital estatus: Married   | 65(83.3)                | 82(83.7)            | 0.952   |
| Lives with                |                         |                     | 0.960   |
| Alone                      | 3(4.1)                  | 3(3.3)              |         |
| One person                 | 40(54.1)                | 48(53.3)            |         |
| Two or more people         | 31(41.9)                | 39(43.3)            |         |
| Current job situation      |                         |                     | 0.343   |
| Housewife                  | 32(41.03)               | 36(36.37)           |         |
| Works                      | 13(16.67)               | 22(24.45)           |         |
| Retired                    | 3(3.85)                 | 9(9.20)             |         |
| Does not work              | 30(38.46)               | 31(31.63)           |         |
| Number of children         | 1.98(1.54)              | 1.95(1.57)          | 0.648   |
| No children                | 17(21.8)                | 19(19.4)            |         |
| One children               | 11(14.1)                | 16(16.3)            |         |
| Two children               | 23(29.5)                | 36(36.7)            |         |
| Three or more children     | 27(34.6)                | 27(27.6)            |         |
| **Clinical characteristics** |                         |                     |         |
| Abdominal perimeter (cm)   | 92.24(15.42)            | 90.94(13.24)        | 0.567   |
| Systolic blood pressure (mmhg) | 130.00(115.25-146.25) | 120.00(110.75-135.00) | 0.026   |
| Diastolic blood pressure (mmhg) | 77.00(70.00-86.00) | 75.50(70.00-84.00) | 0.207   |
| Body Mass Index (kg/m2)    | 26.76(4.94)             | 26.21(4.17)         | 0.430   |
| Hypertension               | 26(33.3)                | 32(32.7)            | 0.924   |
| Hipercholesterolemia       | 25(32.1)                | 34(34.7)            | 0.712   |
| Mellitus Diabetes          | 6(7.7)                  | 9(9.2)              | 0.725   |
| Smoking                    | 14(17.9)                | 18(18.4)            | 0.943   |
|                          | Participating Caregivers | People with dementia | Chi-square | p-value |
|--------------------------|--------------------------|----------------------|------------|---------|
| Obesity                  | 26(33.3)                 | 41(41.8)             | 0.248      |         |
| Anxiety/Depression       | 15(19.2)                 | 21(21.4)             | 0.720      |         |
| Mental Health-GHQ-12     | 1 (0-4)                  | 1 (0-3)              | 0.139      |         |
| Family APGAR             | 15 (11-18)               | 15.50 (13-19)        | 0.070      |         |
| Short Zarit              | 19.96(6.75)              | 15.95(6.41)          | <0.01      |         |

**Pedometer**

|                          | Participating Caregivers | People with dementia | Chi-square | p-value |
|--------------------------|--------------------------|----------------------|------------|---------|
| Total Steps/day          | 6039.32(3211.98)         | 7067.45(3717.84)     | 0.067      |         |
| Aeróbics Steps/day       | 1891.74 (1719.76)        | 2060.35 (1933.64)    | 0.603      |         |
| Kilocalories/day         | 104.21(47.07-164.46)     | 122.71(72.43-187.43) | 0.042      |         |
| Total Steps              |                          |                      | 0.314      |         |

| Less than 7000           | 45(36.4)                 | 46(51.7)             |            |         |
| Between 7000-10000       | 18(25.4)                 | 28(31.5)             |            |         |
| More than 10000          | 8(11.30)                 | 15(16.9)             |            |         |

**IPAQ-SF**

|                          | Participating Caregivers | People with dementia | Chi-square | p-value |
|--------------------------|--------------------------|----------------------|------------|---------|
| METS/min/week            | 2322.43 (1865.04)        | 2273.98 (2273.33)    | 0.883      |         |
| MVPA_min/week            | 97.17 (190.28)           | 112.65 (300.41)      | 0.701      |         |
| Physical Activity Intensity |                      |                      | 0.857      |         |
| Light                    | 11(14.9)                 | 12(13.2)             |            |         |
| Moderate                 | 44(59.5)                 | 61(67)               |            |         |
| Intense                  | 19(25.7)                 | 18(19.8)             |            |         |

Note: GHQ-12: General Health Questionnaire-12. IPAQ-SF International Physical Activity Questionnaires - Short Form; MET: metabolic equivalent. Values expressed as mean (± standard deviation), Mean (SD), Median (IQR) or frequencies (percent). Chi-squared test and Mann-Whitney U test is used to test differences in all measures excepting Short Zarit where Student-t is applied.

*Table 3. Comparison of the number of evaluations carried out by people with dementia with the number of participating caregivers.*
Number of evaluations carried out to the people with dementia:

|                                | Only the initial | 6 months | 12 months | Total |
|--------------------------------|-----------------|----------|-----------|-------|

Number of participating caregivers for each people with dementia:

**Control group:**

| Number of caregivers | 1 caregiver | 2 caregivers | 3 caregivers | Total |
|----------------------|-------------|--------------|--------------|-------|
| 1 caregiver          | 44(97,8)    | 9(64,3)      | 10(90,9)     | 63(90,0) |
| 2 caregivers         | 1(2,2)      | 4(28,6)      | 1(9,1)       | 6(8,6)  |
| 3 caregivers         | 0(0,0)      | 1(7,1)       | 0(0,0)       | 1(1,4)  |
| Total                | 45(100)     | 14(100)      | 11(100)      | 70(100) |

**Intervención group**

| Number of caregivers | 1 caregivers | 2 caregivers | 3 caregivers | Total |
|----------------------|--------------|--------------|--------------|-------|
| 1 caregivers         | 23(85,2)     | 20(62,5)     | 5(45,5)      | 48(68,6) |
| 2 caregivers         | 4(14,8)      | 7(21,9)      | 5(45,5)      | 16(22,9) |
| 3 caregivers         | 0(0,0)       | 5(15,6)      | 1(9,1)       | 6(8,6)  |
| Total                | 27(100)      | 32(100)      | 11(100)      | 70(100) |

Total | 72(51,4) | 46(32,9) | 22(15,7) | 140(100) |

Notes: Values expressed as frequencies (percent). Chi-squared test is used to test.

† p value = 0,007; # p value =0,049) in both groups

**Other changes measured in people with dementia and caregivers**

Table 5 shows that in PWD an improvement in BMI was observed in the IG (0.51 vs. - 0.71; p = 0.011) but the figures of systolic and diastolic blood pressure in the IG were worse. It also shows a deterioration in the Barthel index (p <0.05) and Lawton index in both groups and in the cognitive evaluation (ADAS-cog, MMSE, clock test) but with no differences when comparing the changes between the two groups.

In caregivers, systolic blood pressure figures improved in the IG (0 = 0.001), as well as diastolic blood pressure. Also, an improvement in the Family APGAR was only observed in the IG group (p = 0.018), but not when comparing the changes between both groups. The short-form Zarit test showed an improvement in IG overload (-151 vs. -0.38).

No differences were found in the functional status and the cognitive performances of PWD or in mental health in the caregivers, but systolic blood pressure, the Family APGAR and overload in the IG did
Table 4.- Changes in people with dementia at 6 months compared to baseline.

| Variables                        | Control group (n=32) | Intervención group (n=35) | Mean difference (intervention-control) |
|----------------------------------|---------------------|---------------------------|----------------------------------------|
|                                  | Mean (CI 95%)       | p value †                 | Mean (CI 95%)                           | p value †                           | Mean (CI 95%)                           | p value †                           |
| **Physical Activity**            |                     |                           |                                        |                                     |                                        |                                     |
| Pedometer                        |                     |                           |                                        |                                     |                                        |                                     |
| Total Steps (day)                | -898.46 (-2225.51 - 428.59) | 0.171                     | -646.37 (-1502.21 - 209.48)            | 0.134                               | 252.10 (-1218.33 - 1722.53)            | 0.732                               |
| Aerobic steps (day)              | -615.93 (-1344.33 - 112.47) | 0.087                     | 52.89 (-695.45 - 801.23)               | 0.883                               | 668.82 (-444.27 - 1781.91)            | 0.227                               |
| IPAQ-SF[a]                       |                     |                           |                                        |                                     |                                        |                                     |
| MET/min/week                     | -148.23 (-338.46 - 42.00) | 0.119                     | -258.47 (-870.87 - 353.93)            | 0.396                               | -110.24 (-896.31 - 675.84)            | 0.779                               |
| MVPA_min/week                    | -14.96 (-38.88 - 8.95) | 0.205                     | -31.54 (-101.67 - 38.59)              | 0.366                               | -16.58 (-106.90 - 73.74)             | 0.714                               |
| **Clinical characteristics:**     |                     |                           |                                        |                                     |                                        |                                     |
| Abdominal perimeter (cm)         | 3.44 (-0.915 - 7.80) | 0.114                     | -3.16 (-7.31 - 0.99)                  | 0.130                               | -6.60 (-12.43 - 0.77)                 | 0.031                               |
| Systolic blood pressure (mmHg)   | 5.95 (-3.55 - 15.46) | 0.206                     | -0.73 (-8.68 - 7.219)                 | 0.852                               | -6.69 (-19.07 - 5.39)                 | 0.284                               |
| Diastolic blood pressure (mmHg)  | 4.50 (-1.84 - 10.84) | 0.154                     | -0.70 (-5.52 - 4.11)                  | 0.767                               | -5.20 (3.86 - 12.96)                  | 0.184                               |
| Body Mass Index (kg/m2)          | -0.71 (-1.33 - 0.08) | 0.28                      | 0.51 (-3.55 - 1.08)                   | 0.079                               | 1.21 (0.43 - 0.36)                    | 0.006                               |
| **Functional and cognitive state**|                     |                           |                                        |                                     |                                        |                                     |
| Índice de Barthel                | -15.63 (-26.18 - 5.07) | 0.006                     | -14.64 (-25.75 - 0.54)                | 0.011                               | 0.98 (-15.49 - 17.45)                 | 0.906                               |
| Índice de Lawton-Brody           | -0.20 (-0.98 - 0.58) | 0.599                     | 0.19 (-0.59 - 0.96)                   | 0.625                               | 0.39 (-0.75 - 1.52)                   | 0.496                               |
| ADAS-Cog                         | 5.84 (-3.25 - 14.93) | 0.194                     | 3.00 (-5.51 - 11.51)                  | 0.477                               | -2.84 (-15.54 - )                    | 0.655                               |
Discussion

In this study, we assessed the effectiveness of an intervention to increase the PA of PWD and their family caregivers through a program which was designed, adapted and applied in the field of primary health care.

When analysing the effectiveness of the intervention at 6 months in PWD, in the pedometer assessment a decrease was observed in both groups (IG and CG), but it was greater in the CG. However, the activity reported with the IPAQ-SF decreased more in IG. In caregivers, the tendency in both groups was to report increased physical activity: the pedometer assessment showed that activity increased more in the IG and reporting with the IPAQ-SF, a smaller increase in global activity was declared in the IG than in the CG, but the increase in vigorous activity was greater.

The effectiveness of interventions for increasing PA when applied in the field of primary care is not conclusive [3], nevertheless, in the PEPAF study [19], improvement was achieved at least in those over 50 years of age. It was thus more effective than the results achieved in this study. One of the plausible explanations for the differences could be that the studies were applied to different populations, -the PEPAF study applied to a healthy and sedentary population, which was the aim of that project. In the initial assessment, only 23 caregivers (13% of the total) passed 10,000 steps/day, a recommended goal for healthy adults [39]. Although it was not an aim of the study to show the PA levels of caregivers, in our sample they were observed to be more sedentary than in the study by Loi et al. [40]. Our data can therefore help to highlight the great importance of developing interventions that contribute to increasing the PA of this group of people [12]. Furthermore, the way to measure AF was different: subjective and objective in our study, subjective in the PEPAF study.

It is likely that the expected changes were not achieved because the duration of the intervention was only 3 months, possibly too short a period for this type of participant. It is also probable that in people with serious illnesses such as dementia, healthcare providers pay more attention to aspects related to patient morbidity and to enhancing support for caregivers, rather than implementing healthier lifestyles [3, 5, 41]. If this is the case, we suggest that future studies assess the possibility of supporting them with
Table 5.- Changes in caregivers at 6 months compared to baseline.

| Variables               | Control group (n=55) |     | Intervención group (n=60) |     | Mean difference (intervention- control) |     |
|-------------------------|----------------------|-----|---------------------------|-----|-----------------------------------------|-----|
|                         | Mean (CI 95%)        | p value | Mean (CI 95%)            | p value | Mean (CI 95%)            | p value |
| **Physical Activity**   |                      |       |                           |       |                          |       |
| Pedometer               |                      |       |                           |       |                          |       |
| Total Steps (day)       | 377.23 (-218.28 - 972.73) | 0.208 | 569.41 (-565.57 - 568.38) | 0.319 | 192.18 (-1109.25 - 1493.60) | 0.770 |
| Aerobic steps (day)     | -12.95 (-566.78 - 540.89) | 0.962 | 356.91 (-378.17 - 407.39) | 0.351 | 369.86 (-659.33 - 1399.05) | 0.476 |
| **IPAQ-SF**             |                      |       |                           |       |                          |       |
| MET/min/week            | 609.55 (-53.36 - 1272.46) | 0.071 | 545.25 (-420.38 - 1510.89) | 0.262 | -64.29 (-592.34 - 1240.09) | 0.914 |
| MVPA_min/week           | 124.68 (-153.75 - 403.11) | 0.358 | 495.14 (-59.33 - 1049.62) | 0.074 | 370.46 (253.45 - 150.51) | 0.156 |
| **Clinical characteristics** |                      |       |                           |       |                          |       |
| Abdominal perimeter (cm) | 4.04 (0.59-7.49) | 0.023 | 2.55 (-0.26-5.37) | 0.075 | -1.48 (2,212-(-5.90) | 0.506 |
| Systolic blood pressure (mmhg) | -3.71 (-8.85-1.42) | 0.152 | 6.18 (2.55-9.82) | 0.001 | 9.90 (3.09-3.77) | 0.002 |
| Diastolic blood pressure (mmhg) | 0.13 (-3.29-3.56) | 0.939 | 9.09 (-0.47-4.27) | 0.114 | 1.76 (2.04-(-2.28) | 0.390 |
| Body Mass Index (kg/m2) | 1.51 (-0.03-3.39) | 0.111 | 0.23 (-0.31-0.78) | 0.391 | -1.28 (0.93-<8-3.13) | 0.172 |
| **Mental Health**       |                      |       |                           |       |                          |       |
| Mental Health-GHQ-12     | 0.40 (-0.82 -1.63) | 0.512 | 0.74 (-0.45 -1.94) | 0.218 | 0.34 (-1.36 - 2.04) | 0.691 |
| Family APGAR            | 0.02 (-1.12 -1.16) | 0.970 | 1.38 (0.24 -2.52) | 0.018 | 1.36 (-0.23 -2.95) | 0.093 |
| Short Zarit             | -0.38 (-1.77 -1.00) | 0.582 | -1.51 (-3.44 -0.42) | 0.123 | -1.13 (-3.48 -1.22) | 0.344 |

specialized personnel in the health centre itself or with community resources in the context of
interventions directed at PWD and their caregivers [42]. In addition, it will be necessary to do so with caution, since situations could easily arise in which caregivers and health workers provide care against the will of the PWD, known as involuntary treatment [43].

Likewise, we encountered serious difficulties in the proper use of pedometers by some PWD, with several pedometers even being lost, and participants on other occasions refusing to repeat the assessments. In addition, we encountered the technical limitation that some pedometers did not record the PA performed on a specific day by certain PWD, which reduced the sample obtained. Discrepancies between questionnaires and objective measures were observed to be greater in people with obesity, higher disability scores and with more depressive symptoms [44]. The use of accelerometers and recent digital devices in particular [27, 45] can offer safer and more reliable measurements, but the cost of the different must be considered as well as appropriate strategies for using them correctly with this type of patient so that the devices are not frequently lost. However, the possible biases related to these devices should have been the same in both groups (CG and IG), so they did not modify the validity of the results regarding the effectiveness of the intervention. Objective measures may be the most appropriate, especially in the case of people when they are not in a position to declare reliable information [6]. In such cases, however, the discrepancies observed between the questionnaires and the objective measures may be due to reasons different from those found when comparing the PA reported by healthy participants wearing devices and their PA measurements [46]. The discrepancies between questionnaire and pedometer results are found in caregivers but not in PWD. This is possibly due to the fact that all data were provided by the caregivers and this bias did not show up when reporting the PA of the PWD. A social desirability bias commonly causes participants to respond to PA verification questionnaires too optimistically, and variability in the optimism for achieving goals may influence the ability to respond accurately to questionnaires [47]. We consider that these findings are sufficiently interesting to recommend that they be taken into account in new research on the recording of PA in PWD.

Other changes analyzed through the intervention

Among the PWD, no differences were observed between IG and CG in the changes measured in both the assessment of functional state and cognitive state. However, in both groups we observed that most PWD showed a worsening of their general condition.

Nor wer significant differences found in the changes observed with regard to mental health, burden or Family APGAR in IG and CG caregivers. However, it should be noted that the APGAR family questionnaire and the Short Zarit test found improvement in the IG, suggesting that at least the intervention is not harmful to caregivers. Although no significant differences were reached, it should be noted that this improvement in the stress tests is in line with what was observed in several interventions developed in dyads of PWD to implement PA [48].

Most of the interventions on PA in PWD have been developed in groups of specialized dementia centres (nursing homes, day centres, associations, etc.) [3, 42, 49]. Although the intervention model of this project is based on the PEPAF, in which an individual intervention was performed, given that the AFISDEMYF
study is applied simultaneously to PWD and their family caregivers, we cannot classify this as a typical individual intervention.

Nor is it a group intervention because it was applied in the consultations of the health centre staff with each of the family groups made up of the patient and at least one of the caregivers.

Furthermore, it is not identical to an intervention in dyads, characterized by the fact that only one main caregiver participates with each person with dementia. Since it is known that more than 30\% of PWD are cared for by 3 or more family caregivers, in this study, up to 3 caregivers for each person with dementia were invited to take part. A positive characteristic of this proposal has been reflected in the fact that the proportion of family groups in which more than one caregiver participated in the second evaluation was higher than in the initial one, and especially in those who participated in the 12-month evaluation. It seems to be a promising approach to encourage integrated programs which address the needs and requirements of persons with disabilities and their careers in a multidimensional way \[42\].

**Limitations and Strengths**

It is important to mention the main limitation of the study, which is the sample loss throughout follow-up. Although the study follow-up was planned for up to 12 months, the progress of the disease itself, accompanied as it is by a worsening of general health, meant that the number of PWD who dropped out at 6 months was large. As this would compromise the power of the study, it was decided to analyze the data for this period only. The main reasons for drop-out were refusal to continue the study, and failure to locate the participants. As has been discussed, these are usually the most frequent causes faced by similar population studies with older people \[50\] and is exacerbated when the degree of disability is considerable \[44\]. However, we have observed that participation can be improved if more than one caregiver is included for each person with dementia, which may represent a strength in the study methodology.

The CG did not show differences with regard to age, sex and PA level in those caregivers and PWD who participated in both assessments and those who dropped out of the study. However, there were differences with respect to age in the IG, where it was the older PWD and the younger caregivers who dropped out. It is possible that caregivers under 65 years of age felt more overburdened with other activities (including work) and did not value prioritizing PA in the context of the care plan offered to PWD, and that older PWD felt less motivated to implement PA. The fact that caregivers presented a higher level of burden was also likely to have contributed to the considerable drop-out rate in the CG, since it is the only characteristic in which a difference was found between the IG and the CG in the initial caregiver assessment (Table 2).

To our knowledge, this is the first study to implement a primary care intervention aimed at simultaneously increasing PA in PWD and their relatives. In order to reach clinically relevant conclusions regarding the potentially significant effects of the intervention on PA and the other aspects, a longer intervention would
be necessary, and to achieve this, specific measures would be required to avoid substantial drop-out rates [12, 44].

Conclusions

The results suggest that the intervention carried out may be effective on physical activity in both PWD and caregivers. It can also improve systolic blood pressure, the Family APGAR and overload in caregivers. This is the first study to implement a primary care intervention aimed at simultaneously increasing physical activity in PWD and their relatives. These results reinforce the importance of using objective measures in clinical trials on PWD.

Abbreviations

PWD: People with dementia; CG: Control Group; IG: Intervention Group; CDC: Centers for Disease Control and Prevention; IPAQ-SF: The international physical activity questionnaire short form; MMSE: Mini – Mental State Examination; GHQ-12: The 12-item General Health Questionnaire; PA: Physical activity; PEPAP: program promoting physical activity.

Declarations

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Author contributions:

ERS, LGO and MAG contributed to the conception and design of the study. ERS and LGO had full access to all of the data in the study and takes responsibility for the integrity of data and the accuracy of data analysis. ERS, LGO and MPA contributed to the drafting of the paper and ERS had the primary responsibility for the final content. ERS and LGO contributed as senior authors in the manuscript. ERS, LGO, MPA and MAGM contributed to the analysis and interpretation of the data. EDR, SGS, JR, OTM, SMS and JUA contributed to the critical review of the paper for important intellectual content. EDR, SGS, OTM and JUA were responsible for the collection and assembly of data. All authors have read and approved the manuscript.
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No conflict of interest was declared by the author(s).

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The Ethics Committee for Drug Research in the Salamanca health area (Spain) approved the project on 11/04/2013. Participants were informed of the project's objectives, as well as the risks and benefits of the actions taken and informed consent was obtained from all participants.

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to them still being used for analyses but are available from the corresponding author on reasonable request.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Figures
Figure 1

Study flowchart: enrollment of participants and completion study