The provision of simple written material does not significantly improve physical activity rates in a population with musculoskeletal problems, a double-blinded randomised controlled trial

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Word count (excluding title page, abstract, tables, figs, refs): 3612

The author designed the study, collated the results, analysed the data, and wrote the manuscript.

The research received a favourable ethical response from NRES Committee East Midlands - Northampton, study REC number: 11/EM/0208 and received all necessary site permissions from the host NHS Trust before commencing recruitment. A copy of the protocol is hosted at the Trust's R&D Department.

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38 **Conflicts of Interest**
39 The author declares no conflict of interest
40
41 **Funding**
42 No external funding was received for this study
43
44 **Category**
45 Original research – "3 - the relationship between exercise and health, and the exercise prescription"
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ABSTRACT

The provision of simple written material does not significantly improve physical activity rates in a population with musculoskeletal problems, a double-blinded randomised controlled trial

Background: Physical activity has been shown to have significant health benefits to individuals, being effective in the treatment and prevention of multiple different conditions. However, despite these benefits, rates of physical activity remain low in the western world and less than 40% of people in the UK meet physical activity recommendations. Musculoskeletal pain can be a barrier to activity, and patients with pain can stop all activity out of fear of harm. This project seeks to see if simple written advice can influence activity rates and behaviours.

Methods: A double-blinded randomised controlled trial was conducted to assess any impact of simple written material on physical activity rates in patients attending a single UK National Health Service (NHS) Sports Medicine Department. 546 consecutive patients with a range of musculoskeletal problems were randomised to either an "intervention group" (n=235) or "control group" (n=311). Patients in the intervention group received simple written material encouraging of the benefits of physical activity for general aspects of health, including practical steps to increase regular activity in daily life such as commuting, and work.

Results: No significant difference in activity rates were seen between the members of the two groups in any of the outcome measures used. These measures included the short-form/7-day recall version of the International Physical Activity Questionnaire (IPAQ), the General Practitioner Physical Activity Questionnaire (GPPAQ), and the "Vital Signs" questions. There were no differences seen in transport choices. Overall physical activity levels were low among both groups, with only one-third reaching national targets of 150minutes of moderate-level physical activity per week, and one in five patients undertaking no regular physical activity.

Conclusion: The provision of simple written material does not significantly improve physical activity rates in patients referred to this NHS Sports Medicine Clinic in the UK. Consideration must be given to more tailored and individualised approached to physical activity promotion.

Keywords

- Physical Activity
- Exercise
- Patient Education Handout
- Outcome assessment (health care)

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Introduction

Physical activity has a number of health benefits for individuals, however in western countries activity levels are so low that physical inactivity is reported as the biggest public health problem of the 21st century.[1] Physical inactivity is the fourth leading cause of preventable death worldwide, accounting for 5 million people dying each year,[2, 3] and in terms of personal health costs, a week of physical inactivity is equivalent to smoking a packet of 20 cigarettes.[4]

Physical fitness has historically been under-recognised as an independent risk factor despite a range of studies over many decades demonstrating the importance of activity for health.[5-89] Physical activity been shown to reduce the risk of developing high blood pressure, obesity, colon cancer, prostate cancer, diabetes & heart disease, it helps build and maintain bone health, aids immunity, activity may prevent and treat depression, promotes worker productivity and reduces the incidence of dying prematurely from all causes.[10-18] Additional benefits are seen in the elderly where regular physical activity has beneficial effects on osteoarthritis,[19] osteoporosis,[20-22] fall risk,[23, 24] as well as cognitive impairment risk and progression.[25-29] Benefits from physical activity have been found from a wide variety of types of activity. The risk of developing coronary heart disease is reduced by regular walking,[30, 31] cycling to work or other forms of active commuting,[32, 33] or four hours (or 800kcals) of recreational activity per week.[34, 35] The benefits of physical activity are accrued independent of age of onset, with sedentary men who take up activity in their fifties eventually achieving the same benefits as those who have always been active.[36]

In the UK, the current recommendations from the Home Countries' Chief Medical Officers include all adults aiming to be active daily, attaining a minimum of 150 minutes of moderate-level activity per week (or 75mins vigorous activity), undertaking activity to improve muscle strength twice per week, reducing sitting time, and incorporating balance activities twice per week for older adults who are at risk of falls. [37] However, despite the benefits of activity and national guidance, levels of physical activity in the UK remain low across all ages; currently only 37% of men and 24% of women reach UK guidelines.[38-41] The UK is one of only seven countries worldwide found to have less than 40% of the adult population meeting physical activity recommendations.[42]

Due to the low general levels of physical activity in the community and the benefits of physical activity across populations, brief physical activity promotion advice should be given to patients who are seen in primary care as a minimum with more detailed rehabilitation offered to those with chronic medical problems.[43] This should also be the case in secondary care. However research shows that this is rarely addressed in routine clinical practice.[44] This may be explained at least in part as work has shown that the knowledge of the benefits of physical activity, and the use of activity promotion as opposed to other health promotion approaches, remain low in primary care health professionals.[45]

Accurately measuring physical activity is a challenging area, with advantages and disadvantages of the many different techniques reported in the literature. There are a number of different patient questionnaires in use for assessing levels of physical activity, and this study focuses primarily on two that are in use within the UK, the International Physical Activity Questionnaire (IPAQ) and the General Practice Physical Activity Questionnaire (GPPAQ). With more than 130 peer-reviewed publications, the IPAQ has been well validated for use across a wide range of settings, cultures and languages.[46-51] It has been developed for the surveillance of populations, is an open access

questionnaire, and is free to use. The GPPAQ was commissioned within the UK by the Department of Health, and developed originally to assist primary health care services to identify patients' levels of physical activity to be able to offer advice and services to reduce their modifiable health risk factors for heart disease.[52] The IPAQ and GPPAQ can both be used to stratify subjects based on their results, although these groups are not necessarily directly comparable. This stratification is displayed in Table 1.

(INSERT TABLE 1 NEAR HERE)

A very simple way of measuring physical activity in the context of a medical consultation was introduced in Kaiser Permanente which listed physical activity as a "vital sign".[53] This endeavoured to routinely assess physical activity in consultations, in the same way that weight and blood pressure are, by bringing this in as the 5th vital sign. In this process patients are asked two questions:

- *"on average, how many days/week do you engage in moderate or greater physical activity (like a brisk walk)?"*
- *"on those days, how many minutes do you engage in activity at this level?"*

These two figures are then multiplied to give an approximate value of the average number of minutes per week of moderate or greater physical activity undertaken. This very rapid tool can identify patients with low levels of physical activity, triggering further analysis and support.

Studies in primary care have found that physical activity promotion has a significant increase on physical activity levels at 12months in adults[54] although with less of an effect in children.[55] Tailored interventions can increase walking by up to one hour per week,[56] and simple "point of decision interventions" can increase activity within various settings.[57-61] However no published research was found using this strategy to influence active transport to hospital appointments. This study tries to

encourage the first steps of behaviour change with the provision of simple written material to change a variety of aspects of physical activity patterns.

This randomised controlled trial investigated whether simple written material is able to increase either the regular physical activity, or the use of active transport modalities, of patients attending a hospital musculoskeletal-focussed outpatient clinic. This population may be an ideal target group for exercise promotion as many patients attending the clinic have a range of health problems including osteoarthritis, tendinopathies, chronic pain conditions, and osteoporosis all of which may specifically benefit from activity.[20, 62-65]

Material and Methods

- **Study methodology**

Patients referred to a single National Health Service (NHS) Sport & Exercise Medicine clinic at a large teaching hospital in the UK, were potentially eligible for inclusion to this study. All patients referred during the six-month study period were sent a written letter informing them in general terms of the study investigating physical activity patterns, and that on arrival in the Department for their appointment they would be asked to complete a questionnaire to examine this area. This letter gave the subjects a chance to opt out of the study by telephoning the clinic or advising on arrival.

Subjects were randomised to either the intervention group or the control group on receipt of their referral letter in the clinic, using a random number table drawn up prior to the study commencing. This randomisation process was coordinated by a single member of the clinic administrative staff, managed separately from the clinical staff in the department. The control group had their outpatient appointment booked in the normal manner and aside from the introductory letter received no further contact until they attended for their appointment. The members of the intervention group

also had posted to them written information material to read before their appointment, promoting increased physical activity as part of a daily programme. This information utilised publicly available information about the benefits from the patient.co.uk website. In addition, this included further positive health messages about activity, links to other local resources such as the local council and public health department material on physical activity and resources promoting the use of active transport to attend the hospital appointment such as walking, cycling and local bus routes. There was an average of 6-weeks between the information being posted to the patients in the intervention group and them attending their first hospital appointment.

When the subjects attended the clinic for their first appointment, consent was confirmed to continue within the study and patients completed a bespoke study questionnaire, including a range of questions about physical activity. Subjects also had their physical observations (height, weight, blood pressure, etc.) recorded by the clinic nurse. After this was completed the subjects were seen in clinic as per normal practice. Once the questionnaire was completed, members of the control group were also provided with a copy of the same written information that the intervention group had received.

Inclusion criteria were all patients referred and seen in a single hospital Sport & Exercise Medicine clinic that were seen from November 2011 to end of May 2012 inclusive. Data was included only for patients that attended their first booked appointment. Subjects failing to attend their initial hospital appointments were recorded and were excluded from this study. Patients had been referred to the hospital clinic for a range of musculoskeletal problems. Common conditions treated include osteoarthritis, various tendinopathies or other soft-tissue musculoskeletal problems including rotator cuff pathology, tennis elbow, plantar fasciitis and Achilles tendinopathy, as well as mechanical low back pain. There are low numbers of patients with inflammatory joint disease or connective tissue disorders also referred.

- **Patient / Study blinding**

Subjects gave explicit consent for inclusion in the study and knew in general terms about the aims of the study, but were not aware of the group allocation until after the questionnaire had been completed, thus ensuring their blinding. The data was analysed by subject number by the Principal Investigator with group un-blinding occurring only after the analysis was complete ensuring investigator blinding.

- **Ethical approvals**

This study received a favourable opinion from a local independent Research Ethics Committee, (NRES Committee East Midlands - Northampton, study REC number: 11/EM/0208) and received all necessary site permissions from the host NHS Trust before commencing recruitment.

- **Data collection form & statistical analysis**

A bespoke data collection form was created for the purposes of this study and was completed by the patient. This questionnaire included the short-form / 7-day recall version of the IPAQ, the GPPAQ, the “Vital Signs” questions, and several specific questions from SF-36, and in addition had a range of bespoke questions written for this study. The questionnaire was informally piloted before use within clinic patients seen in routine practice, with feedback used to shape the final study tool. Whilst the questionnaire was thought by some to be lengthy it was not found to be overly burdensome by the pilot group.

Data was obtained from the patient questionnaires and entered into a bespoke Microsoft excel spreadsheet for simple descriptive data, and statistical analysis was conducted with the SPSS analytical package (SPSS Inc, Chicago, IL). Data that had been entered into the spreadsheet was re-checked for accuracy against the paper questionnaire.

Comparisons were made between groups for the range of data collected, including the primary outcome measurements of activity rates, and also the secondary markers. Where appropriate, data was tested using the Shapiro-Wilk test for normality in SPSS. Data that was normally distributed, which included subjects' heights, weights, waist circumference, and diastolic blood pressure, was analysed with two-independent samples T-test to identify the significance of any differences between allocated groups. Ordinal data, and data which was not normally distributed, were analysed with non-parametric testing, predominantly the Mann-Whitney U test. All analysis was conducted on an intention to treat basis, in that all patients in the intervention group, whether recognising that they were sent the information and whether they read it or not, were compared as a single group with the members of the control group. Statistical significance was set a $p<0.05$

An *a priori* power calculation was performed with available data using GPower (v3.1.2), which suggested a minimum sample size was 262, although this was hampered by limited published data on activity rates in this population.

Results

Results were obtained from a total of 546 patients (342 male), over a six-month period from November 2011 to May 2012. During this study period no patients referred during the study period chose to opt out of completing the study questionnaire. 43% (235/546) (43%) were randomised to the "intervention group" and were posted the Physical Activity information prior to their appointment, and the remaining 311 to the "control group." Of the Intervention Group, 63% (147/235) believed that they had received the information, and of these 95% (139/147) declared that they had read the material, conversely 9% (27/311) of the Control Group mistakenly believed that they had received the information about physical activity. It is possible that the control group may have mistaken the information about booking their hospital appointment with the Sports

Medicine Department or answered falsely believing that they had received information and did not want to admit to having not read something they thought they had been posted. This data is displayed in Fig 1 (CONSORT 2010 Flow diagram)

(INSERT FIG 1 NEAR HERE)

There were no significant differences between the two groups for the physical and demographic data, except for the patient weight, BMI and waist circumference. Any impact of these differences on activity rates remains unclear. Table 2 displays the physical parameters for the patients in each group. Values shown are mean ±SD (and range)

(INSERT TABLE 2 NEAR HERE)

There were no significant differences in the ethnic origins of the subjects in the intervention and the control groups. Overall the respondents' ethnic origins were reported as 75% "White", 18% "Asian / Asian British", 3% "Black / African / Caribbean / Black British", 2% "Mixed/multiple ethnicities", and 1% from "Other ethnic group", these groups reflect the diversity of population of the catchment areas of the clinic.

There were found to be no significant differences between the intervention and the control groups in employment status, with a mean household income of £29,766 and 11.9% overall reported themselves to have a disability, none of these factors differed significantly between the two groups. There were no significant differences in the location or number of musculoskeletal problems between the intervention and control groups. In addition, two general health questions were asked, including a question about self-reported perceived health rating (question 1 of the SF-36), and the

perception of the subjects' health compared to one year previously (question 2 of the SF-36), and there was no significant difference between the two groups for the answers to either of these questions.

- **Journeys and transportation types**

The intervention group travelled an average of 9.44 miles (range 0.25-195) to their appointment, the control group an average of 10.33 miles (range 0.5-200) and this difference was not statistically significant. The written material that the intervention group received discussed ways of increasing activity through walking or cycling for at least a part of the journey to appointments rather than driving, however there were no significant differences in transport types used to reach the hospital appointment with 91% attending by car/motorbike (including taxi), 6% by bus, 2% walking and 1% cycling.

- **Measurements of Physical Activity**

Physical activity was measured in a range of difference methods in this study design.

- "Vital Signs"

Using the "vital signs" questions as discussed above, there was no significant difference between the intervention and control groups with any of the variables studied. Table 3 displays the mean values ±standard deviation of the two groups.

(INSERT TABLE 3 NEAR HERE)

- IPAQ

There were found to be no significant differences between physical activity levels in the intervention and control groups as recorded by the short-form IPAQ. Table 4 displays the proportion of the

intervention and the control groups in each of the categories of physical activity as determined by the IPAQ. Although in the intervention group there appeared to be fewer patients recorded at "Category 1: Low" and more at "Category 2: Moderate" compared to the control group, the differences were not of statistical significance.

(INSERT TABLE 4 NEAR HERE)

- GPPAQ

The answers for GPPAQ stratifies subjects into one of four activity groups: "inactive", "moderately inactive", "moderately active" and "active." There were no significant differences in the responses to individual questions within or group allocations based on answers to the GPPAQ for members of the intervention and control groups. Table 5 displays the proportion of subjects in the intervention and control groups in each activity category as assessed by GPPAQ.

(INSERT TABLE 5 NEAR HERE)

- Other measures

In case the medical problems that had led to the referral of the subjects to the department had a significant impact on their regular physical activity, subjects were asked to self-report using a categorical system of the minutes of moderate and vigorous activity they undertook in a "typical week" before their current problem, however it is understood that these figures are likely to be affected by recall bias. Subjects were asked about the number of days in a typical week before their problems that they reached either 30 minutes of moderate activity or 20 minutes of vigorous activity (and gave examples of each.) For this question the mean values for the subjects in the intervention group for this question was 3.5 ±2.2) and for the control group this was 3.1 ±2.2, this difference was not found to be statistically significant.

Discussion

This study was not able to show any significant difference in the primary end points studied; that of self-reported physical activity rates through a range of different measures. This study used a number of validated physical activity questionnaires, including the 7-day recall version of the IPAQ, and the GPPAQ. It is possible that the tools used were not sensitive enough to detect small changes, as the study was potentially powered only for a clinically significant change in physical activity for an increase of 30minutes per week and instead the long-form of the IPAQ may have been more sensitive to smaller changes.[46]

This study confirmed a general low level of physical activity across the study population, with only one-third currently meeting a target of 150 minutes moderate activity over a week. In addition, high levels of physical inactivity were recorded, with about one in every five people undertaking no activity in their regular week regardless of which questionnaire was used. These figures are broadly comparable to the results from other published sources,[38-42] and the real scope of the physical inactivity problem may be higher than is reported here as people are believed to over-report levels of physical activity with written questionnaires.[51] The results recorded of no activity undertaken for the seven days immediately prior to the appointment were higher than the "typical week" figure of no activity. This difference may represent the effect a current musculoskeletal injury can have on a subject's physical activity rates, a less reliable question format for one of the questions, or an over-reporting of physical activity in the "typical week" questions.

A weakness of this type of study design is that it relies on patient's being prepared to read the material that they were given and to have sufficient motivation to act upon this, and it was not necessarily clear that all patients received and read the written information that they had been provided with. One way to assess this would be to ask specific questions whose answers would be

known if the material had been read, although this lay beyond the scope of this study as it was conducted and would have added increased complexity to this study questionnaire which was already relatively lengthy as it asked a range of measures. Due to of this uncertainty the data was analysed on an intention to treat basis, which may had reduced a treatment effect seen from the intervention.

This study did indicate the possibility of an increase in the walking done by members of the intervention group across a range of the questions asked, although these did not reach statistical significance with the size of this study population. The measures most of interest included the frequency and duration of walking done in the last seven days, the number undertaking no walking in the previous week, and the journey chosen to attend the hospital appointment, and some of these measures nearly reached statistical significance, unlike in more intensive intervention studies.[56] However the study may have been underpowered to detect small changes in these areas and further research into this area is suggested, possibly using other patient groups with other medical problems.

There were statistically significant differences noted in in the weight (and hence BMI) of the subjects in the intervention and control groups. It was not clear of the reasons behind this, or any implications that this could have had on the results of the physical activity intervention. An argument could be made that the intervention group, who were slightly leaner, could have been expected to have better physical activity rates than the control group, based on their body composition alone, however this was not shown. It is theoretically possible that the intervention itself which promoted activity and healthy lifestyles could have had an impact on the body composition of the intervention group, although this is an optimistic conclusion to reach given the other limited findings of this study.

One further limitation of this study was the choice of tools that were available to assess physical activity. Due to the study design chosen and the additional funding requirements that would have been needed for accelerometers, the outcome measures of written questionnaires were used. These written questionnaires are valid measures of physical activity, although different numbers of respondents chose to answer different questions, which raises issues of patient compliance with the long survey questionnaire used as a tool in this study. Issues remain over the choices of written questionnaires, with simplicity over length being an important factor. For the sake of brevity the short-form of the IPAQ was used in this study, along with other study tools, however the longer-form of the IPAQ may be able to give more detailed analysis [46] and may have been more useful in identifying smaller changes to physical activity patterns. These limitations may have been a factor in the limited results that were found. Further research in a similar design which utilises a more robust tool, and one sensitive to small changes in activity rates, is worth considering for population health benefits.

In conclusion, this study has not shown any significant change in physical activity levels of clinical importance following the use of simple written material, and a more individually tailored response may be required for meaningful population benefit. However, like many habits, physical activity patterns are difficult to change. This study shows that physical activity levels remain low and the majority of subjects in this study do not meet current UK guidance for optimal regular physical activity in their week.

Acknowledgements

The author would like to thank the patients that took part in this study, and the clinic administrative staff for the posting out of the letters and the written material vital for the running of this study.

Declaration of interest statement

428 The author states that there are no declarations of interest regarding this study to disclose.

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Tables

Table 1: IPAQ and GPPAQ Activity categories

IPAQ activity categories	GPPAQ activity categories
• "Low" - This is the lowest level of physical activity. Those individuals who not meet criteria for categories 2 or 3 are considered low/inactive. • "Moderate" - Any one of the following 3 criteria: 3 or more days of vigorous activity of at least 20 minutes per day OR 5 or more days of moderate-intensity activity or walking of at least 30 minutes per day OR 5 or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum of at least 600 MET-min/week. • "High" - Any one of the following 2 criteria: Vigorous-intensity activity on at least 3 days and accumulating at least 1500 MET-minutes/week OR 7 or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum of at least 3000 MET-minutes/week	• "Inactive" - Sedentary job and no physical exercise or cycling • "Moderately inactive" - Sedentary job and some but < 1 hour physical exercise and / or cycling per week OR Standing job and no physical exercise or cycling • "Moderately active" - Sedentary job and 1-2.9 hours physical exercise and / or cycling per week OR Standing job and some but < 1 hour physical exercise and / or cycling per week OR Physical job and no physical exercise or cycling • "Active" - Sedentary job and ≥ 3 hours physical exercise and / or cycling per week OR Standing job and 1-2.9 hours physical exercise and / or cycling per week OR Physical job and some but < 1 hour physical exercise and / or cycling per week OR Heavy manual job

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436 **Table 2: Demographic details of the intervention and control groups**

	Intervention Group (n = 235)	**Control Group** (n = 311)	*p-value*
Gender (% males)	63%	63%	*0.972*
Mean age (range)	40.9 ±16.9 (16-80)	41.0 ±15.7 (16-80)	*0.874*
Mean height in meters (range)	1.72 ±0.10 (1.50-2.00)	1.71 ±0.10 (1.48-2.04)	*0.856*
Mean weight in kg (range)	79.9 ±15.7 (43.6-121.0)	83.0 ±16.3 (45.4-142.9)	* *0.027*
Mean BMI (range)	27.1 ±5.0 (18.6-45.2)	28.3 ±5.1 (18.2-46.2)	* *0.006*
Mean waist circumference in cm (range)	91.1 ±13.6 (56.5-130)	93.6 ±12.9 (59-138)	* *0.028*
Mean systolic BP in mmHg (range)	133.3 ±17.5 (101-187)	134.5 ±15.4 (100-187)	*0.153*
Mean diastolic BP in mmHg (range)	80.2 ±11.6 (52-115)	82.5 ±11.3 (52-120)	* *0.022*
Mean heart rate in beats per minute (bpm) (range)	73.1 ±13.7 (44-125)	74.4 ±14.6 (43-128)	*0.458*

437 ** = statistically significant difference (p<0.05) –found for weight, BMI, waist circumference and*
438 *diastolic BP*

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442 **Table 3: Physical activity rates as assessed by "Vital Signs" questions**

"Vital Signs" questions	**Intervention Group** (n = 192)	**Control Group** (n = 206)
Q. On average, how many days per week do you engage in moderate or greater physical activity?	3.06 ±2.14	3.20 ±2.22
Q. On these days, how many minutes do you engage in activity at this level?	31.71 ±25.9	35.15 ±25.8
(calculated) minutes / week of at least moderate activity	191.59 ±204.2	174.58 ±173.3

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446 **Table 4: Physical activity rates as assessed by short-form IPAQ**

IPAQ Categories	Intervention Group (n = 235)	Control Group (n = 310)
Category 1: Low	18%	27%
Category 2: Moderate	33%	27%
Category 3: High	32%	32%
Subjects with insufficient information for calculation	17%	14%

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450 **Table 5: Physical activity categories as assessed by GPPAQ**

GPPAQ Categories	Intervention Group (n = 235)	Control Group (n = 311)
Inactive	22%	22%
Moderately inactive	11%	13%
Moderately active	16%	19%
Active	37%	32%
Subjects with insufficient information for calculation	14%	15%

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