Research Article

Perceptions of a Physical Activity Promotion Programme for inactive people using a mixed methods model: a randomised controlled trial

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ABSTRACT

Given the paucity of qualitative research into the perceptions of inactive people, we sought to identify the issues associated with the benefits of a Physical Activity Promotion Programme (PAPP) and the perceptions of risks in 100 inactive people in primary healthcare centres in Torremolinos, Spain. Method: this randomised controlled clinical trial with concealed allocation and assessor blinding was supplemented by in-depth interviews with inactive people. Participants received either a PAPP which lasted 60 minutes, twice per week for three months which had been developed for progressive intensity in the Sports Centre in Torremolinos (n=50), or health education in primary healthcare centres (n=50). The primary outcome was quality of life, which was measured with the EuroQoL-5D self-report (EQ-5D). Secondary outcomes included general health status, as measured by the SF-12 self-report in inactive people. Detailed

BACKGROUND

Physical inactivity is an independent risk factor for chronic diseases.¹ A recent retrospective observational Spanish study suggested that inactive individuals have a greater risk of having multiple chronic diseases.² It has been shown that adults who are physically active are at a decreased risk of mortality and have increased longevity.³ The regular practice of physical activity has a positive effect on reducing obesity, preventing cardiovascular pathologies.⁴ The effectiveness of a primary care based physical activity programme has also been assessed on the health-related quality of life of patients and on reducing the total number of consultations at the healthcare centre.⁵ Despite the well-documented benefits to the population of the adoption of healthier lifestyles, such changes are extremely challenging.⁶ There is scarce evidence about whether recommendations to exercise referral schemes over advice or counselling interventions are effective in improving exercise participation by sedentary adults.⁷ The available evidence does not show exercise referral schemes to be significantly more effective at increasing physical activity than other, potentially lower cost, approaches.7

From the perspective of a quantitative methodology, there are studies that have shown associations between different risk factors and the promotion of physical activity and quality of life.⁸ The use of a qualitative methodology in a randomized controlled trial allows us to implement a deep and comprehensive analysis of data.^{9,10} Qualitative and quantitative methods are seen as different, potentially complementary, ways of gathering data, whose usefulness depends upon appropriateness for a given research task.¹¹ There are few randomised controlled trials that

field notes were analysed using interpretive phenomenological analysis. Results: The men in the experimental group improved their EQ-5D score to 0.73 (p=0.05). The quantitative data showed statistically significant improvements in the generic health status of men after the intervention. A total of 10 semi-structured in-depth interviews were conducted with inactive people. Conclusions: There were no differences in the impact on the quality of life between the groups. In contrast, a total of 10 semi-structured in-depth interviews suggested important changes in beliefs about quality of life and risk factors for health. This study provides evidence for a PAPP as a mode of exercise training in inactive people.

Keywords: Physical inactivity; patient views; quality of life; qualitative research.

analyse the quality of life related to health in combination with qualitative studies.^{12,13} Recent findings suggest the importance of creating health promotion efforts which are more tailored to older adults' motivations and confidence in their ability to make behaviour changes.⁶

The main aim of this study was to look in depth at the opinions of inactive subjects in primary healthcare centres after participating in a PAPP in order to describe changes in the perceived quality of life and the risk perception of these subjects. The generic health status and the health-related quality of life were also analysed after participating in the PAPP.

METHOD

Design

This is a randomised controlled clinical trial, while we also carried out a phenomenological descriptive study.

Triangulation was carried out by complementary methodologies from three different instruments to understand the multidimensional nature of the phenomenon under observation. The instruments used were the following: a) a general health questionnaire (SF-12), b) a quality of life questionnaire (EQ-5D), c) in-depth interviews to analyse participants' perceptions of the effects of the PAPP. The two phases, randomised controlled clinical trial and phenomenological descriptive study, were performed at the same time.

Participants and setting

One hundred people from primary healthcare centres in Malaga started participating in the study and 75 subjects completed the study (Figure 1). The participants were of both 268

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genders and ages ranged between 57 and 69.

Inclusion and exclusion criteria

A General Practitioner selected the study participants.¹ The main inclusion criterion was inactive persons not engaged in moderate physical activity for 30 minutes at least five times a week. Participants also had to have three or more of the following cardiovascular risk factors: have high blood pressure (140/90); be a smoker; have cholesterol above 230 mg/dl; have a family member who suffered a heart attack before the age of 55 if male or before 65 if female; be an insulin-dependent diabetic, and/or be obese, or overweight by more than eight kilograms.¹⁴

Exclusion criteria were as following: contagious symptoms; malignancy; metastasis; osteoporosis; inflammatory arthritis; fractures, and/or cognitive impairment.¹⁵

Ethical considerations

Written informed consent was obtained from all the subjects of this study. Ethical approval was obtained from an appropriate Research Ethics Committee prior to this research, according to The Declaration of Helsinki. All subjects participated freely, respecting those who did not want to be part of the study, or wished to leave once they had started participating in the study. It has fulfilled the principles of privacy and confidentiality, assuring the anonymity of the participants in the study. Before conducting the interviews, we explained the purpose of the study and ensured the confidentiality of the data.

Randomisation

The subjects were separated into the Intervention Group (IG) or the Control Group (CG), choosing random closed envelopes. All the subjects who met the inclusion criteria signed a consent form. An initial evaluation was carried out.

Control group

Participants assigned to the control group were asked to continue their routine daily activities, received health education in primary healthcare centres and their usual care from their primary care practice whenever it was needed. They were



Figure 1: Study flowchart.

invited to the first and the last session (three months later) of the programme, in which the different parameters were evaluated. The SF-12 and EQ-5D questionnaires were carried out before and after the intervention phase, together with an evaluation of body composition.

Intervention

The Physical Activity Promotion Programme

When a subject agreed to participate, an assigned professional health worker sent a registration form to the investigation team and to the specialist who led the exercise group. The subject was contacted by telephone to carry out the evaluation and to start the intervention. The experimental group participated in the PAPP in the Sports Centre in Torremolinos twice a week for 12 weeks (24 sessions), at no cost to themselves, following the criteria of the American College of Sports Medicine.¹ Each session lasted 60 minutes, and all protocols were developed for progressive intensity.

All sessions included 20 to 30 minutes of an aerobic activity, such as walking at a fast pace. Each session also included upper and lower body strength-based exercises, such as knee bends, floor transfers, lunges, leg squats, leg extensions, leg flexions, abdominal curls, throwing and catching a ball, and push-ups against the wall.⁵ An eight repetition maximum was established at the first training session and was repeated at the second training session. The participants initially performed one to two sets of six to eight repetitions of each exercise; the number of repetitions was increased when a participant was able to complete eight repetitions at lower perceived exertion intensity; the maximum number of repetitions was 15. This protocol was developed in a pilot training study.⁴

Blinding

The evaluator was 'blind', being unaware of the allocation of participants to the group. Baseline measures were taken prior to the allocation of randomisation. An independent investigator assessed participants at the end of the three months programme.

Outcome measures

Health-related quality of life and general health questionnaire

The evaluation of quality of life related to health was assessed through two questionnaires, SF-12 and EQ-5D. We also took into account the gender differences in quality of life measured with both questionnaires. The SF-12 questionnaire is a shortened version of the SF-36, with a reliability coefficient of 0.97.¹⁶

We report the results of eight dimensions of general health: physical functioning; physical role; body pain; general health; vitality; social functioning; emotional role, and mental health.¹⁷ These eight dimensions can also be used to generate physical and mental health summary scores.¹⁶ The SF-12 proved to be a practical alternative to the SF-36 for measuring the overall health of the population because of the high degree of correspondence between physical summary and mental health measures estimated using the SF-12 and SF-36.¹⁸

The EQ-5D has five dimensions: mobility; self-care; usual activities; pain, and anxiety/depression .¹⁹ Each dimensions has three possible levels indicating no problems, moderate problems

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or severe problems.²⁰ Total scores range from 1 to $-1.^{21}$ The EQ-5D valuation questionnaire comprises a visual analogue scale which was not included in this research. It has been shown to be a valid tool, with an average estimate of $0.87.^{21}$

Complementary qualitative study: In-depth interview

To gain an insight into people's experiences of PAPP, indepth interviews, following a semi-structured script (Figure 2), were conducted before and after with the control and intervention groups. The selection of participants was based on those who passed the selection criteria of randomised clinical trials. Every in-depth interview lasted approximately one hour. We performed the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist for reporting important aspects of this qualitative study.²² The COREQ checklist consists of 32 items to help researchers report important aspects of the research team, study methods, context of the study, findings, analysis, and interpretations (Figure 3).

Type of analysis used, including power calculation

A multi-method or 'mixed methods' approach is being adopted in this research. In this eidetic phenomenological study, qualitative data is thematically analysed. Thematic analysis is a method for "identifying analysing and reporting patterns (themes) within data".²³ Essentially, it involves coding participants' talk into categories that summarise and systemise the content of the data. All interviews were audio-recorded, transcribed verbatim and anonymised. The categories used were lifestyle changes from performing physical activity or

1. Carrying out physical activity			
PE1: How do you feel before you perform physical activity?			
PE2: How do you feel after you perform physical activity?			
PE3: Why do you perform physical activity? And/or what kind of benefits does the physical activity give you?			
No physical activity			
NPE1: What do you think of physical activity?			
NPE2: Why do you not perform physical activity?			
NPE3: How would you feel if you did?			
2. Quality of life			
QL1: What do you mean by quality of life?			
QL2: How do you feel when you think about your physical health?			
QL3: How do you feel when you think your social health (job, friends)?			
QL4: How do you feel when you think about your emotional health (personal, family)?			
QL5: Do you have to look after someone?			
QL6: How long do you have to take care of them every day?			
3. Risk perception			
RP1: What kind of behaviours could cause you to become ill?			
RP2: Which ones?			

RP3: Why?

Figure 2: Interview schedule.

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Item	Guide question/description
Domain 1: Pesearch team and reflevivity	Guide question/description
Parsonal Characteristics	
1 Interviewer/facilitator	Researcher
2 Credentials	PhD
3 Occupation	Researcher from university
4 Gender	Famala
5 Experience and training	Two years of training
Palationship with participants	Two years of training
6. Relationship established	There was no relationship prior to the start of the study
7. Participant knowledge of the interviewer	Reasons for doing the research
8. Interviewer characteristics	Reasons for doing the research
Domain 2: Study design	
Theoretical framework	
9 Methodological orientation and theory	Phenomenology
Participant selection	
10 Sampling	Snowball
11 Method of approach	Face-to-face
12 Sample size	10
13 Non-participation	No
Setting	10
14 Setting of data collection	Sports centre
15 Presence of non-participants	External researcher
16 Description of sample	Demographic data
Data collection	
17. Interview guide	There was a pilot test
18 Repeat interviews	Interviews were repeated
19 Audio/visual recording	Audio recording carried out to collect the data
20 Field notes	Field notes made during the interviews
21 Duration	One hour
22 Data saturation	Yes between researchers
23. Transcripts returned	Yes, verbatim transcripts were returned
Domain 3: Analysis and findings	
Data analysis	
24. Number of data coders	385
25. Description of the coding tree	No
26. Derivation of themes	Yes
27. Software	Yes
28. Participant checking	Yes
Reporting	
29. Quotations presented	Yes, participant number was presented
30. Data and findings consistent	Yes
31. Clarity of major themes	Yes, there are four major themes
32. Clarity of minor themes	No

Figure 3: Consolidated criteria for reporting qualitative research (COREQ): 32-item checklist.

not, perceptions about quality of life, and perception about risk behaviours. After 10 in-depth interviews, participant answers were classified into categories that made up each dimension. The number of interviews was limited by the criterion of saturation; the degree of information provided by each case, and the quality and sufficiency of the data obtained.¹¹ Furthermore, answers were decomposed, systematised and analytical quality was improved in order to be qualitatively analysed.

ATLAS.ti software was used to analyse the interviews. To maintain the scientific rigour of the research we have taken into account the reliability of Denzin and Lincoln's criteria (1994): credibility, transferability, dependency or stability, and impartiality.²⁴ We took the following procedures into account: feedback from informants; alternating stages of collection; transcription; interpretation and systematisation of the data; applying the criterion of saturation and, finally, comparing the conclusions of the researcher about the participants.

Data analysis

Data were analysed with SPSS 17.0 for Windows. The Kolmogorov-Smirnov tests for normal distribution were completed on the baseline values representing parametric data. We performed Student's T test for independent samples to get the effect of inter-group intervention (Table 2). The calculation and analysis of the size of the effect between groups was performed using the following formula: [(mean post-test outcomes of intervention)].²⁵ In all cases, P values <0.05 were taken as significant.

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Sample size

G-Power analysis set for the sample size. It was calculated with an alpha error of 0.05, a power of 0.80 and a beta risk of 0.20 in a bilateral contrast. To detect less than 0.15 differences between the two groups, there must be a minimum sample of 424 people 212 individuals in the IG and 212 in the CG compared to 100 in this research.²⁶ A dropout rate of 20% is estimated in this study.

Evaluation of clinical relevance

Analysis of the effect size (ES) values was based on Cohen's criteria, which determined a small or large effect on treatment. Values below 0.2 were considered to have no effect, values between 0.2 and 0.5 have a small effect, values between 0.5 and 0.8 have a medium effect and values above 0.8 have a large effect.²⁵

FINDINGS

Effect of intervention: Evidence from self-reported questionnaires

Descriptive statistics for the outcome measures at baseline are shown in Table 1, taking into account the gender difference. Table 1 shows the initial characteristic outcomes of the SF-12 and EQ-5D of the participants. Table 2 shows the demographic characteristics of participants of the in-depth interviews.

The mean differences of the SF-12 and EQ-5D measures between the baseline and the 12 week follow-up scores are shown in Table 3. Significance was found for the EQ-5D of men (p<0.05), compared with women who did not show statistically significant changes. No significant differences in the SF-12 questionnaire were found when comparing pre- and post-intervention measures. Intervention did not result in an improvement in body mass index comparing pre- and postintervention measures.

Changes between the control and intervention groups were obtained in the outcomes of the SF-12 and EQ-5D.

Effect of intervention: The findings of in-depth interviews

Triangulation of methodologies allowed us to achieve a more in-depth and varied knowledge of the phenomenon under investigation. Although the benefits of exercise are commonly known, it was important to understand participant perceptions of these benefits (Table 4). Participants were asked firstly to share their opinions on the best things about exercise. Both males and females recognised the importance and perceived benefits of undertaking physical activity to improve their health and wellbeing.

In order to understand the perceived barriers to carrying out physical activity, participants were asked to identify the barriers they experience and believe others experience (Table 4). Participants cited "lack of time", "lack of money", "caring for family" and "bad weather conditions".

According to their general state of health and quality of life, differences are shown between males and females. There are influences on quality of life and general health state with regard to interpersonal relationships with family (Table 4).

The perceived risks to health of participants in this study were "sedentary lifestyle", "pain", "obesity", and "anxiety and depression" (Table 4).

DISCUSSION

The use of a qualitative methodology in this randomised controlled trial has allowed us to implement a deep and comprehensive analysis with our informants, the same as in some articles to which we have referred.^{9,10} The qualitative interview will also be crucial in helping us to understand the most likely effective aspects of the intervention in our research. Data triangulation involves using different sources of information in order to increase the validity and viability of a study. The purpose of data triangulation is to arrive at consistency across data sources or approaches; both quantitative and qualitative methodologies used together overcome any weaknesses and build on the strengths of the other.

The PAPP showed statistically significant changes (p=0.05) in the quality of life of men from the self-reported questionnaire EQ-5D, compared with women, who did not show statistically significant changes (Table 2). However, the ES in men compared to women is of small value (0.05 vs -0.13). In other studies, the EQ-5D tool also detected changes in the population but, in the analysis of the results, we took gender difference into account.^{9,27} Based on the findings of the analysis of in-depth interviews of this study, we see a better quality of life among people living with others than people living alone. Tajvar's study (2008) also states that people who are married enjoy a better quality of life than those who are unmarried, widowed or divorced.²⁸

The general state of health, as measured with the SF-12 questionnaire, did not show statistically significant changes in our research. In contrast, in the in-depth interviews, we observed changes related to self-esteem, motivation, and feeling more

Table 1: Initial characteristics, according to gender difference.

	Contro	l Group	Intervention Group		
	Men (n=12) Women (n=22)		Men (n=18)	Women (n=23)	
	Mean (CI)	Mean (CI)	Mean (CI)	Mean (CI)	
Age (years)	64.25 (59-69)	62.82 (60-65)	60.50 (57-63)	63.6 (60–66)	
Weight (kg)	93.29 (79–106)	78.50 (71–85)	87.44 (77–97)	78.21 (71-85)	
Height (m)	1.68 (1.64–1.72)	1.58 (1.5-1.60)	1.67 (1.62–1.74)	1.56 (1.54–1.59)	
BMI (kg/m^2)	32.64 (28–37)	31.56 (28-34)	29.34 (24–34)	31.80 (29–34)	
EQ-5D (0-1)	0.57 (0.38-0.75)	0.59 (0.48-0.72)	0.58 (0.36-0.76)	0.53 (0.40-0.67)	
Physical SF-12	52.8 (46-60)	49 (43–55)	46.1 (40-52)	51 (44–57)	
Mental SF-12	34.06 (26-42)	36.43 (30-42)	37.5 (30-44)	39 (33–45)	

Table 2: Demographic characteristics of simple.					
Demographic characteristics	I=10				
<u>Gender</u> Male Female	5 5				
Age, years 52–54 55–57 58–59 60–62 63–64 65–66	1 3 3 1 1 1				
<u>Marital Status</u> Single Married Divorced Widowed	2 5 2 1				

Table 3: Changes in both control and intervention groups obtained in the outcomes: SF-12 and EQ-5D.

	Control Group						Intervention	Group
	MEN		Women		Men		Women	
	PRE Mean (CI)	POST Mean (CI)(ES)						
EQ-5D (0-1)	0.6(0.38-0.75)	0.8(0.83-0.94)(-0.3)	0.59 (0.48-0.72)	0.6(0.52-0.78)(0.01)	0.58 (0.36-0.76)	0.7(0.58-0.88)(0.12)*	0.53 (0.40-0.67)	0.66(0.53-0.80)(0.13)
Physical SF-12	45.12(40-51)	45.42(39-52)(0.3)	49 (43–55)	34.47(22-46)(14.53)	46.1 (40–52)	45.72(39–52)(-0.38)	51 (44–57)	39.7(34.19-45.3)(-11.3)
Mental SF-12	34.06(26-42)	36(31-40)(1.94)	36.43 (30-42)	41.20(15-67)(4.77)	37.5 (30–44)	37(28-46)(-0.5)	39 (33–45)	36.09(30-42)(-2.91)

able to improve their general state of health. Similarly, Fox et al.'s findings (2007) showed more changes in the in-depth interviews than in the results of self-reported questionnaires; another study in which no significant differences in the SF-12 questionnaire were found when comparing pre- and post-intervention measures.²⁹ However, focus groups suggested that a pedometer-based walking programme, in combination with physical activity consultations in adults aged 65 and over were helpful and feasible.¹⁰

In our research the main barrier for not doing physical activity was "lack of time". Other studies agree that "lack of time" is a barrier to being physically active.³⁰ After analysing the answers of the people interviewed, we see that people with economic difficulties have limited ability to improve their quality of life. Also, studies in Iran noted that people in poor economic situations had a worse quality of life.²⁸ Another study describes the development of a social marketing campaign for increasing walking by those on a low income.³¹ The meteorological conditions also influenced the amount of physical activity already undertaken by the participants in our research. Aoyagi's (2010) research agreed with our study; the people interviewed explained that bad weather influenced their willingness to complete the PAPP.³²

In spite of participating in the PAPP, the answers of the participants continue to indicate concern because they perceived risk to their health. The main health risk perceived by men in this study is "sedentary behaviour". Other research also shows people who are overweight and obese perceived prolonged sitting time as having negative consequences on health.¹² Similarly, women perceive obesity as a major health risk, as women did in another triangulation.³³ Parker and Keim's findings (2004) found a link between overweight women and low incomes.³³

Based on the findings of these interviews, all the people in this study agree that carrying out physical activity, maintained over a period of time, reduces the risk of illness. Previous studies also took into account how physical activity contributes to have physical and mental health benefits.³¹ Anxiety and depression appeared in the answers of the participants as a perceived risk to health. There is a study that found an association between depressive symptoms of anxiety and poorer quality of life in people with hypertension.³⁴ In our research, we did not find this association.

The Type II error should take into account the outcomes which did not show effects due to lack of subjects. Conclusions from this research are tentative, and it must be acknowledged that this research study reflects only the experiences of the 10 participants. Further research could focus on differences in demographic characteristics and reported outcomes of other provinces in Spain.

We conclude that the PAPP is effective in the quality of life of men measured with EQ-5D, whereas in women no significant changes were observed. Individuals realise that physical activity is important for improving their health and illness. The quality of life perceived is different between men and women. Men Perceptions of a Physical Activity Promotion Programme for inactive people using a mixed methods model: a randomised controlled trial 272

iew results.	
Males	Females
"because I am hypertensive. I think that physical activity has helped me regulate my blood pressure" [M, 57 years].	"I feel better after physical activity, I even feel healthy while performing physical activity. If I did not perform physical activity for seven or 10 days, I feel worse" [F, 58 years].
 "Yes, I would like to improve my health, but the employment situation is terrible. I am very worried latelyI'm stressed about some situations in my life" [M, 59 years]. "I have to take care of my parents who are oldermy circle of friends is greatly reduced" [M, 58 years]. 	 "Due to lack of time, because at the end the day, I have things to do at home" [F, 59 years]. "At Christmas, I stopped physical activity because the weather was rainy, but now I'm going" [F, 66 years].
"A little of physical and mental wellbeing, what one does at work, in life, with people around him. Get that balanced wellbeing" [M, 62 years].	"The quality of life could be your friends, having enough money, enjoying good health, the wellbeing of the family. We must add everything up" [F, 64 years].
"I am a widower, my father died, then I cared for my mother, who has Alzheimer's disease. My general health state is normal" [M, 52 years].	"a good state of health is being well off, yourself, your friends, your family, all of them are quality of life" [F, 58 years].
 "I worry far too much about sitting down all day" [M, 57 years]. "I cannot afford to get sickI have a lot of pain in my legs and waist" [M, 59 years]. 	 "obesity is my main concern, which hurts meIf I could lose my tummy, I would feel better emotionally and physically" [F, 58 years]. "Sometimes I am depressed I would like to reduce the constant anxiety. I run to and from" [F, 58 years].
	 Males "because I am hypertensive. I think that physical activity has helped me regulate my blood pressure" [M, 57 years]. "Yes, I would like to improve my health, but the employment situation is terrible. I am very worried latelyI'm stressed about some situations in my life" [M, 59 years]. "I have to take care of my parents who are oldermy circle of friends is greatly reduced" [M, 58 years]. "A little of physical and mental wellbeing, what one does at work, in life, with people around him. Get that balanced wellbeing" [M, 62 years]. "I am a widower, my father died, then I cared for my mother, who has Alzheimer's disease. My general health state is normal" [M, 52 years]. "I worry far too much about sitting down all day" [M, 57 years]. "I cannot afford to get sickI have a lot of pain in my legs and waist" [M, 59 years].

perceived sedentary behaviour and pain as health risks, while women perceived obesity as a health risk.

To ensure the quality of this randomised clinical trial, the guide developed by the Consolidated Standards of Reporting Trials (CONSORT) statement has been followed.^{35,36}

CONFLICT OF INTERESTS

The authors declare that they have no conflicts of interest.

AUTHORS' CONTRIBUTIONS

All authors contributed to the study design and development of the trial protocol. All authors read and approved the final manuscript.

SOURCES OF FUNDING

This research was made possible by a grant received as a research fellow from the Junta de Andalucía and the University of Malaga.

ACKNOWLEDGEMENTS

We would like to thank the subjects who participated in this research, the Primary Care Team and the Sports Centre in Torremolinos.

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