



RESEARCH ARTICLE

REVIEW OF RANDOMIZED PRIMARY CARE PHYSICAL ACTIVITY COUNSELLING INTERVENTIONS

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ABSTRACT

The results show that most interventions took place in primary care, included health professionals in delivery, and involved advice or counselling given face to face or by phone (or both) on multiple occasions. From the review, promotion of physical activity and exercise to sedentary adults recruited in primary care significantly increases physical activity levels, as measured by self-report. There was insufficient evidence to recommend exercise referral schemes over advice or counselling interventions. The two objectives were to determine whether such trials showed sustained effects on physical activity or fitness in sedentary adults, and whether exercise referral interventions were more effective than other interventions

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INTRODUCTION

Research suggests that the majority of adults expect advice from the healthcare system regarding diet and exercise (Tulloch *et al.*, 2006; Whitlock, Orleans, Pender and Allan, 2002). Some research suggests that primary care practitioners (PCPS) are interested in providing physical activity (PA) advice, writing exercise prescriptions and recognize the importance of primary care PA promotion (Garry, Diamond, and Whitley, 2002; Jacobson, Strohecker, Compton, and Katz, 2005). Further, there is evidence of an association between clinician advice with and increased satisfaction with medical care (Whitlock *et al.*, 2002). Research suggests that the impact PA counseling in primary care could have at a population level is tremendous. Pinto, Goldstein, and Marcus (1998) describe the interaction between the high prevalence of sedentary behavior and the frequency of physician visits, coupled with primary care PA promotion as having the potential to significantly impact the incidence of hypokinetic diseases such as heart disease, stroke, hypertension. In 2005, the American College of Preventive Medicine issued a position statement

“that primary care providers should incorporate PA counseling into routine patient visits” (Jacobson *et al.*, 2005). Several other professional organizations echo this sentiment including the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Obstetrics and Gynecology, the American Heart Association, National Institutes of Health, and the Surgeon General (Garry *et al.*, 2002; Jacobson *et al.*, 2005). The ACSM is yet another organization that recognizes and endorses the importance of primary care PA counseling through its initiative, “Exercise is Medicine” (Sallis, 2009). This initiative seeks to create awareness that “exercise is medicine” and should be prescribed accordingly (Sallis, 2009).

MATERIALS AND METHODS

A comprehensive literature search was carried out for in the Pubmed, Crossref, Genamics Journal Seek, Global impact factor.com, Google Scholar, Academic keys, Open Academic Journals Index, Sherpa/RoMEO (University of Nottingham), Chemical Abstracts (CAS), Open-j-Gate, Cochrane Library and MEDLINE databases (search descriptors: exercise therapy, training, physical fitness, physical activity, rehabilitation, exercise is medicine; Chronic disease; Primary prevention; Secondary prevention). In addition, we sought literature by

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examining reference lists in original articles and reviews. We have primarily identified systematic reviews and thereafter identified additional controlled trials. Non-controlled trials and controlled trials in which the randomization was uncertain have been included in cases where the other literature was sparse, or where these studies contained important information.

Randomized Primary Care Interventions

A cluster-randomized controlled trial was conducted with Australian GPs (GrahamClarkeand Oldenburg, 1994). The Fresh Start program is a multiple risk factor intervention that is based on the Transtheoretical Model comprised of three subprograms (smoking cessation program, healthy eating, and PA) that can be used alone or in combination depending upon a patients' risk profile. Eighty GPs were randomly allocated to one of three conditions, routine care (control), lifestyle counseling using video, and lifestyle counseling using video plus self-instructional materials. GPs randomized to one of the intervention groups were asked to conduct a risk factor assessment on all patients and to offer the Fresh Start program to those eligible (n=758; 18-69 y old, one or two modifiable risk factors for cardiovascular disease [CVD], and no chronic, debilitating disease). The program consisted of stage of change (preparation, action, and maintenance) specific strategies, but no clear information was provided regarding details of the intervention. Data (self-reported PA and stage of change) measured at 4-6 months and 12-18 months revealed no significant differences between groups and no clear effect of intentions to change. It is important to note that clustering did not appear to be taken into account in the analysis. The authors also cite several methodological considerations including the possibility that the intervention was not delivered as intended and limitations (including limited measures and inappropriate time frame for measurement) in this study that may account for the interventions' lack of success.

Several successful randomized PA promotions in primary care studies have been conducted as well. The Green Prescription Study, a written exercise advice intervention by GPs was evaluated using a randomized controlled trial (Swinburn, Walter, Arroll, Tilyard, and Russell, 1998). Participants (n=491) were patients of and chosen by 37 GPs in New Zealand who were considered likely to benefit from and able to increase their exercise for a period of 6 weeks. Physicians "underwent a training session on assessing and prescribing physical activity" (Swinburn *et al.*, 1998). Physicians assessed current PA and provided verbal PA advice (79% was to increase walking) and an agreed upon PA goal. The physician would then open an envelope revealing randomization to verbal advice only (n= 252) or a written green prescription (n=239). The green prescription consisted of receipt of written PA advice and a goal from the physician. The length of time spent assessing and advising PA levels ranged from 2 to 15 minutes, with an average length of 5.1 minutes. Analyses found that after 6-weeks, PA (as measured by 2-week PAR) increased more in the green prescription group (p=0.004). An 11-month follow up survey of a random selection of participants (n=100) found that 59% (47/80) of those in the green prescription group self-reported maintenance of increased PA suggesting the first long term evidence of success through this type of intervention. However, an important limitation to this study is the lack of a no advice control group.

A replication of the Green Prescription intervention was conducted by Pfeiffer, Clay, and Conatser (2001) utilizing geriatricians (n=3). The intervention was completed in the same manner as the previous study (Swinburn *et al.* 1998). Analyses revealed that there was an average increase in PA duration of 149 minutes per week, when combining the verbal advice only group (n=25) and the green prescription group (n=24). In contrast, to Swinburn *et al.*'s findings, there was not a significant difference in the number of participants that reported more PA after 6 weeks. Similarly, there was no significant difference in the increased duration of PA between groups (verbal advice =+180 minutes; green prescription=+116 minutes). Another noted difference was that the geriatricians reported an average of 14-minutes (range=9-25 minutes) to assess and advise PA compared to the 5-minute average reported by Swinburn *et al.* (1998). Elley, Kerse, Arroll, and Robinson (2003) conducted a long-term clusterrandomized intervention utilizing the Green Prescription approach. Participating practices were stratified by size and randomized to intervention (n=23) or control (n=19). Unlike Swinburn *et al.* (1998) participants included all willing and eligible (sedentary, healthy enough for PA, aged 40-80) participants who had a regularly scheduled appointment during a 5-day period. Screening occurred in the waiting room and participants received a prompt card (that included individualized stage of change information) to give to their GP or NP during the consultation. The GP would then provide verbal and written information on increasing PA and a goal would be set for and with the patient. Following the appointment, the written information was then provided to a local sports foundation, where over the course of three months, exercise specialists would make three 10-20-minute phone calls to patients providing encouragement and support.

Quarterly newsletters were also sent to the participants. Control GPs provided usual care and control patients were offered the intervention at the end of the trial. At 12-months follow-up, approximately 95% of intervention participants (370/389) recalled receiving a green prescription during the previous year. At one year follow-up, mean total energy expenditure increased by 9.4 kcal/kg/wk (p=0.001) and leisure exercise increased by 34 min/wk (p=0.02) in intervention participants. The proportion of intervention participants who achieved a minimum of 2.5 hours of moderate and/or vigorous PA per week increased by 14.6% compared to just 4.9% in control participants (n=361). Regarding the intervention delivery of 451 intervention participants, 385 received intervention from a GP, while 66 received intervention from a NP. Subsamples of 31 GPs found a 7-minute mean intervention delivery time, while a subsample of 19 NPs spent an average of 13-minutes on intervention delivery. Results based upon intervention delivery provider (GP or NP) are not reported. This was one of the first studies to identify the use of GPs or NPs for intervention delivery and to provide evidence of long-term success of PA counseling in this setting. A post-hoc analysis of participants aged 65 and older in Elley and colleagues (2003) study was conducted by Kerse, Elley, Robinson, and Arroll (2005). Participants were middle aged and older adults (n=878; mean age=71.6±4.4) in 42 primary care doctors' offices in New Zealand. Twelve months following the green prescription intervention, leisure time moderate activity increased more in the intervention group participants (+40 min/week) than in the control group but did not reach statistical significance. General health on the 36-item Short Form Quality of Life was significantly improved in the

intervention group ($p=0.005$). There was also a significant reduction in hospitalizations among intervention participants (-7%) following the intervention compared to control participants (+6%, $p=0.03$). This study provides additional long-term evidence of the success of this type of intervention specifically for older adults. A randomized controlled trial conducted by Jimmy and Martin (2005) compared the effects of physician feedback regarding stage of change for PA to a more comprehensive approach involving stage based hand outs and the opportunity to attend a counseling session with a PA specialist. Five physicians in Zurich, Switzerland were trained to deliver a PA intervention using the Transtheoretical Model and based on patient stage of change. All patients (>15 yrs old) visiting were asked to complete a stage of change questionnaire and PAR-Q. Approximately 10% of patients did not wish to participate in the project. Willing participants currently in precontemplation, contemplation or preparation stages of change were randomized to either the Feedback ($n=92$) or Advice Plus ($n=69$) groups. Feedback only participants received general advice about their current stage of change and general PA recommendations.

Advice Plus participants were also provided with a stage specific handout, physician recommendations to increase PA and were offered the opportunity to participant in a 45-minute counseling session with a PA specialist. At 7-wk telephone follow-up, approximately 1/3 of participants in both groups could be considered active ($p=0.69$) as measured through 7-day PAR. Of the Advice Plus participants, over half (60%) could be considered active. By 14-mo follow-up approximately half of all participants were considered active. Over 70% of participants in this group who had chosen to attend counseling were classified as active. Follow-up interviews with physicians found that the intervention was easy to implement. Physicians reported needing 2-10 minutes to discuss PA with patients. Ten interviews were completed with Advice Plus participants (five who chose to attend counseling and five who did not). These participants reported that the project had been useful. Of those attending counseling, the physicians' recommendation to do so was the primary incentive, suggesting the benefits of physician based PA interventions. Barriers to attend the counseling session included lack of time and pain (e.g. back pain, rheumatism). These findings indicate that both brief feedback and additional advice with the possibility to attend a counseling session increased PA participation in patients. The Physically Active for Life (PAL) project was conducted to assess the efficacy and feasibility of another stage of change, physician-based PA intervention aimed at older adults (≥ 50 y) (Pinto, Goldstein, DePue, *et al.*, 1998; Goldstein *et al.*, 1999). Matched randomization (solo vs. group practice) was conducted allocating 17 physicians each to a control and an intervention group. Physicians and office staff provided a list of eligible patients (ambulatory with a scheduled routine appointment) to the researchers, attended a 1-hour training session (intervention only) and a thirty-minute training session for office staff (intervention and control), and received financial compensation (\$400 reimbursement to practices, \$100 reimbursement for training, \$40 reimbursement per patient follow-up).

All participating patients (control $n=174$; intervention $n=181$) were asked to provide information including stage of change for PA, exercise history and barriers to becoming active prior to their initial office visit. This information was provided to intervention physicians to be used during counseling.

Additionally, physicians followed a patient-centered approach utilizing the "5 As" (address the agenda, assess, advise, assist, and arrange followup), which has been found successful in smoking cessation interventions in primary care (Pinto, Goldstein, and Marcus, 1998). During the office visit, intervention physicians were asked to counsel the patient for approximately five minutes, provide a written PA prescription, and a manual with instructions for patient to read the section appropriate to his or her stage of readiness. Follow-up appointments held within four weeks of initial appointment at which time, the physician would provide additional PA counseling and a new PA prescription (Goldstein *et al.*, 1999). Four monthly follow-up mailings were also sent to intervention participants. The PASE and stage of motivational readiness were obtained at baseline, six weeks and eight months over the telephone by trained research staff. At baseline, there was no significant difference between intervention ($n=181$) and control participants ($n=174$). At 6-weeks there were significantly more ($p<0.001$, $OR=3.56$, 95% CI 1.79-7.08) intervention patients (89%) in advanced stages of readiness (preparation or action) than control patients (74%), but this was not maintained at 8-months follow-up (Goldstein, *et al.*, 1999). There were no significant differences in meeting CDC/ACSM PA recommendations between groups at any of the assessments (Goldstein *et al.*, 1999).

At 8-months follow-up, Pinto, Goldstein, DePue, *et al.* (1998) found that confidence in counseling was significantly improved in intervention physicians yet there were no significant changes in physician reports of exercise counseling provided to all patients. Interestingly, of the intervention participants ($n=151$) who provided data at six-weeks, 93% reported receiving PA counseling from their physician during the initial visit. When asked about receipt of exercise prescription, 67% of intervention participants reported they had, of which, they rated as moderately useful (3.4 on a scale of 1-5, where 5=extremely useful). These results indicate that the PAL program was effective in some regards, but insufficient in terms of inducing physicians to offer exercise counseling to all of their patients. Pinto Goldstein, DePue, *et al.* (1998) suggest, "more intensive training is needed to promote physician skill development in this area and generalization of exercise counseling to other patients." Larger PCP PA promotion studies added the use of fitness measures to examine intervention success. Petrella, Koval, Cunninham, and Paterson (2003) conducted the Step Test Exercise Prescription to evaluate fitness and exercise self-efficacy among elderly community-dwelling patients following a primary care intervention. Patients randomized to intervention ($n=131$) completed a step test (20 times up and down on a 9.5cm step) to estimate VO_{2max} , received exercise counseling, and received information on how to determine heart rate as a method of identifying exercise intensity. Control patients ($n=110$) received usual care in addition to exercise counseling including ACSM guidelines and benefits of exercise. At 12-months follow-up, VO_{2max} was significantly increased in the intervention group (14%; from 21.3 to 24.9 ml/kg/min) compared to control (3%; from 22.1 to 22.8 ml/kg/min; $p=0.001$). Exercise self-efficacy also increased significantly more in the intervention group (32%) compared to a 22% increase in the control group ($p=0.001$). These results suggest the beneficial impact of a fitness measure used in office. One of the more complex PCP interventions was conducted by Grandes *et al.* (2009) in Spain to examine the effectiveness of the Experimental Program for Physical Activity Promotion.

Family physicians were randomized to intervention (n=29) or standard care (n=27). Similar to Bull and Jamrozik (1999), Grandes and colleagues (2009) utilized technology to individualize intervention for participants.

Web-based software managed the intervention delivery by prompting questions for assessment, individualizing a PA plan for each patient (4-page pamphlet based upon individual readiness and other behavioral factors), and ensuring quality of the intervention (Grandes *et al.*, 2009). At 6-month follow up, intervention participants (n=2248) had significantly increased weekly PA by a mean of 18 minutes (95% CI: 6-31 minutes) compared to standard care patients (n=2069). This study also utilized VO₂ max as estimated by the YMCA cycle ergometer submaximal test as an outcome measure. However, both groups showed a dose response relationship between change in PA and VO₂max. There were no significant differences in VO₂max (p=0.45). Subgroup analyses found that older adults in the intervention group had increased PA by a mean of 35 minutes per week. This is another example of the effectiveness of PA promotion in primary care increasing patient PA levels.

One of the largest physician-based PA promotion interventions was the Activity Counseling Trial (ACT) (King *et al.*, 1998). This intervention was the first to evaluate the effectiveness of increasing and maintaining PA and cardiorespiratory fitness in sedentary participants utilizing two exercise intensities (moderate and vigorous). This was a multi-site intervention utilizing several theoretical constructs from the social cognitive theory (self-regulation, social support, and self-efficacy) and stages of readiness for change from the Transtheoretical model. There were three arms of the study, a standard care/advice care group (n=292), an assistance group (n=293), and a counseling group (n=289) (Writing Group for the Activity Counseling Trial Research Group, 2001).

The standard care group (advice group/comparison group) received physician assessment of current PA, PA goal-setting, and referral to onsite ACT health educator. The assistance group consisted of the standard care treatment provided to the group plus additional staff assistance that included a 17-minute video on the importance of PA, possible PA goals, and role modeling for PA. A health educator would then review and reiterate the PA goals presented by the physician, provide a community resource guide for PA and a pedometer for self-monitoring. Participants in the assistance group also received 24 newsletters each with a mail-back card for participants to provide minutes and types of PA over the past week. The counseling group received the most intensive intervention approach that consisted of each of the methods in the first two conditions, in addition to on-going telephone counseling (once weekly for initial 2-weeks, biweekly for 6-weeks and once a month for the rest of the first year), in-person counseling (monthly for the duration of the second year was recommended), and behavior change classes. At two years follow-up, women in the assistance groups and the counseling groups had a significantly higher average VO₂max (+80.7 mL/min; +73.9 mL/min, respectively) than women in the advice group (Writing Group for the Activity Counseling Trial Research Group, 2001).

There were no significant differences in average total physical activity for women or men in any of the three groups, or men in any of the groups for cardiorespiratory fitness. Further analyses revealed that the cost of the assistance intervention compared to advice was approximately \$500 per participant,

and the cost of the counseling intervention was approximately \$1100 per participant over the two-year intervention. Due to the multiple extensive components of this study and likely prohibitive costs, future research is needed to determine feasibility of PA counseling using providers' existing resources. Several PA promotion studies have been conducted to varying degrees of success in primary care and this is by no means an exhaustive list. The majority of PA counseling primary care interventions have produced short-term success (4-weeks, 6-weeks, and 12-weeks (Calfas *et al.*, 1996; Harland *et al.*, 1999; Kelly, 1988; Lewis and Lynch, 1993; Smith *et al.*, 2000). A few have demonstrated longterm success when patients are followed up at 6-months and 1-year (Elley *et al.*, 2003; Grandes *et al.*, 2009; Kerse *et al.*, 2005; Logsdon *et al.*, 1989). Characteristics of previous successful primary care interventions include a focus primarily on PA as opposed to several behaviors at once, provision of interactive training for the healthcare providers, and use of a theoretical foundation (Jacobson *et al.*, 2005). The Transtheoretical Model's stages of change were used in a majority of successful studies (Calfas *et al.*, 1996; Elley *et al.*, 2003; Smith *et al.*, 2000).

Additionally, successful primary care interventions often provided more than brief counseling, but multiple intervention components (e.g. written prescription, newsletters, etc) (Calfas *et al.*, 1996; Elley *et al.*, 2003; Grandes *et al.*, 2009; Harland *et al.*, 1999; Kerse *et al.*, 2005; Smith *et al.*, 2000). However, this type of approach may be considered too intensive for physicians seeing patients regularly (Tulloch *et al.*, 2006). Additionally, some PCP studies featured advice delivered by the physician, yet had PA assessed and other data collected by a nurse or other office staff (Eden, Orleans, Mulrow, Pender, and Teutsch, 2002; Goldstein *et al.*, 1998; Grandes *et al.*, 2009; Norris, Grothaus, Bucner, and Pratt, 2000; Smith *et al.*, 2000). Therefore, PA assessment and counseling delivered by other health providers, such as NPs and physician assistants, is worth consideration as they may be able to provide this type of attention to patients on a regular basis. Tulloch and colleagues (2006) suggest that this population may be better suited for providing PA promotion in primary care due to an increased ability to spend more time and provide a more intensive intervention.

Conclusion

In summary, there is a need for PA promotion interventions in primary care and evidence that providers want to provide PA information to their patients. Several randomized trials have been conducted evaluating the efficacy and effectiveness of primary care PA promotion interventions. Typical protocol for these interventions have included screening of patients within the waiting room, followed by brief PA counseling (verbal and sometimes written materials) by physicians (primarily) and non-physician clinicians such as NPs. Patient follow-up varied from 4-weeks to 12-months and included additional physician visits, telephone calls, and/or mailings. While not all primary care PA promotion interventions were successful, the majority of studies support this approach to increasing PA. It is the position of several organizations that primary care providers should incorporate PA counseling into patient visits (Jacobson *et al.*, 2005). Surveys of primary care providers suggest that the primary barriers to PA counseling include lack of time, needing to address more important issues and insufficient educational materials (Buchholz and Purath, 2007; Bull *et al.*, 1995; Burns *et al.*, 2000; Lawlor *et al.*, 1999; Rogers *et al.*,

2002; Sherman and Hershman, 1993). Such evidence reinforces the potential usefulness of non-physician clinicians, such as NPs and physician assistants, as PA promoters in primary care. Tulloch and colleagues (2006) suggest that this population may be better suited for providing PA promotion in primary care due to an increased ability to spend more time and provide a more intensive intervention. Although the current limited body of literature provides some information regarding the attitudes and confidence of NPs to promote PA is positive, there is no information regarding physician assistants in primary care PA counseling.

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