TECHNICAL NOTE / NOTE TECHNIQUE

The physical activity counselling (PAC) randomized controlled trial: rationale, methods, and interventions

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Abstract: Primary care is a promising venue to build patient motivation and confidence to increase physical activity (PA). Physician PA counselling has demonstrated some success; however, maintenance of behaviour change appears to require more intensive interventions. In reality, most physicians do not have the necessary training nor the time for this type of counselling. The purpose of this paper is to outline the rationale, methods, and interventions for the ongoing physical activity counselling (PAC) randomized controlled trial (RCT), which aims to assess the impact of integrating a PA counsellor into a primary care practice. This RCT has 2 arms: (*i*) brief PA counselling (2–4 min) from a health care provider and (*ii*) brief PA counselling + intensive PA counselling from a PA counsellor (3 months). The impact of this intervention is being evaluated using the comprehensive RE-AIM framework. One hundred twenty insufficiently active adult patients, aged 18 to 69 y and recruited during regular primary care visits have been randomized. Dependent measures include psychological mediators, PA participation, quality of life, and physical and metabolic outcomes. The PAC project represents an innovative, theoretically-based approach to promoting PA in primary care, focusing on psychological mediators of change. We anticipate that key lessons from this study will be useful for shaping future public health interventions, theories, and research.

Key words: physical activity counselling, behavioural intervention, prevention, collaborative health care, motivational theories, fitness, clinical trial.

Résumé : Le contexte des soins primaires est prometteur pour optimiser la motivation et confiance des patients envers l'activité physique (AP). Le counseling en activité physique pratiqué par les médecins donne quelque résultat, mais des interventions plus soutenues semblent nécessaires afin de maintenir les changements comportementaux. En fait, la plupart des médecins ne possède ni de formation spécifique ni du temps nécessaire pour ce genre de counseling. Le but de cet article est de présenter les grandes lignes relatives à la théorie, à la méthodologie et aux interventions en cours dans l'essai clinique comparatif aléatoire (RCT) sur le counseling en activité physique (CAP) dont l'objet est d'évaluer l'impact de l'ajout d'un conseiller en PA dans les services des soins de santé primaires. Le devis de cette étude comporte deux axes : (*i*) une courte intervention de counseling en activité physique (2–4 minutes) faite par un médicin de famille et (*ii*) une

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courte intervention de counseling en activité physique + une intervention plus soutenue de counseling en activité physique faite par un conseiller en activité physique (3 mois). On analyse l'impact de cette intervention à l'aide du cadre RE-AIM. Cent-vingt patients adultes âgés de 18 à 69 ans et insuffisamment actifs ont été sollicités dans le contexte des services des soins de santé primaires puis ont été répartis aléatoirement dans les deux groupes expérimentaux. Les variables dépendantes sont : des médiateurs psychologiques, la pratique d'activité physique, la qualité de vie, les répercussions physiques et médicales et des variables physiques et métaboliques. Le projet CAP constitue une approche novatrice justifiée sur le plan théorique, conçue pour la promotion de l'activité physique dans un service des soins de santé primaires et se concentrant sur les médiateurs psychologiques du changement. Nous prévoyons que les informations tirés de cette étude seront utiles au développement des prochaines interventions en santé publique, des théories sous-jacentes et de la recherche dans ce domaine.

Mots-clés : counseling en activité physique, intervention sur le comportement, prévention, pratique clinique en collaboration, théorie de l'autodétermination, condition physique, essai clinique.

[Traduit par la Rédaction]

Introduction

Rationale and background

Physical inactivity is recognized as a leading modifiable risk factor for morbidity and mortality worldwide (Blair et al. 1996; World Health Organization 2002), following closely behind smoking as a principal cause of death (Mokdad et al. 2004). There is ample evidence of significant physiological and psychosocial benefits of regular physical activity (PA) (Bauman 2004; Blair, Cheng and Holde 2001; Blumenthal et al. 2005; Penedo and Dahn 2005; Roberts and Barnard 2005). In addition to individual health benefits, it is estimated that for every 1% increase in PA, Canada saves $15 million annually in direct health care expenses alone (Katzmarzyk et al. 2000).

Recently, Blair et al. (2004) reviewed the literature supporting public health recommendations for PA. They concluded that 30 min/d of moderate-intensity activity provides a broad range of health benefits for sedentary adults, and increasing those levels to 60 min/d is helpful for weight loss and improving physical fitness. Similar to these recommendations, the Canadian population is encouraged to engage in physical activity every day for 60 min at a light intensity, 30–60 min at a moderate intensity, or 20–30 min at a vigorous intensity (Health Canada 2003).

Despite the proven health benefits, rates of habitual PA around the world remain low (Cameron et al. 2002; Ni et al. 2003; World Health Organization 2002). PA levels in the US and Canada are similar, with approximately 26% of the population meeting guidelines, 46% engaging in some form of PA, and 28% categorized as inactive (Centers for Disease Control and Prevention 2003; Health Canada 1999). The past several decades have shown that without adequate intervention, most people are not sufficiently active to gain optimal health benefits (Marcus et al. 2000). The refractory nature of this widespread important problem calls for innovative interventions to stimulate long-term changes in these disturbing statistics.

Primary care should be part of the solution. Family physicians come into contact with a high percentage of the population (Canadian Institute for Health Information 2003; Lucas et al. 2004) and are viewed as very credible sources for health advice (Blair et al. 1998; Long et al. 1996). Many visits by patients are prompted by chronic disease conditions that can be partially or fully managed through regular PA. The ongoing personal relationship that characterizes family practice allows tailoring to the needs of patients, as highly recommended by the Task Force on Community Preventive Services (2001). Recently, Jacobson and colleagues (2005) issued a position statement recommending that primary care providers incorporate PA counselling into routine patient visits. Moreover, patients expect preventive health information from their primary health care provider (Whitlock et al. 2002).

Epidemiological calculations on preventable deaths by Woolf (1999) suggest PA counselling should be a priority health service, ranking second to smoking cessation, based on the number of patients needed to treat (NNT) to prevent one death. Based on Woolf's calculations, a physician would need to help sixteen 45-year-old women become sufficiently active to prevent one premature death (i.e., less than 75 years of age), compared with mammography screening for 205 women.

However, inadequate training in behavioural counselling and perpetual time constraints make it difficult for physicians to provide PA counselling (Kennedy and Meeuwisse 2003; Ritchie et al. 2002; Yarnall et al. 2003). Moreover, reviews have shown that when physicians do counsel, the effects on patients' PA are small to moderate and often short lived (Eakin et al. 2000; Petrella and Latanzio 2002; Smith et al. 2002). Consequently, several experts have recommended the use of a dedicated primary health team member with the time, enthusiasm, and skills needed to assist patients in making sustainable PA behaviour changes (Eakin et al. 2000; Glasgow et al. 2001; Stevens et al. 1998).

Theoretical frameworks

In a seminal paper, Baranowski et al. (1998) called for more theory-based PA interventions and highlighted the critical importance of understanding important theoretical mediating variables to determine "why" interventions work (or not). Several theoretical approaches have been used to develop interventions for PA (Lewis et al. 2002). Although these frameworks prioritize different psychological constructs, they all agree on the importance of motivational and confidence concepts.

We based the physical activity counselling (PAC) interventions primarily on self-determination theory (SDT; Deci

and Ryan 1985) and secondarily on social cognitive theory (SCT; Bandura 1986). We chose SDT because it is a broad theory that guides health care providers in the facilitation of patients' motivation for change and has been successfully used in the health care context (Sheldon et al. 2003; Williams 2002). The SDT approach has been recently combined with the highly recommended As model which proposes key behavioural counselling steps (i.e., assess, advise, agree, assist, arrange; Williams et al. 2002*a*; Williams et al. 2002*b*). Furthermore, SDT is being increasingly used for PA interventions (Levy and Cardinal 2004; Wilson et al. 2005). And finally, SDT advocates the use of a counselling style that is congruent with the currently recommended patient-centered approach, which has been associated with improved patient satisfaction, adherence, and health outcomes (McCracken et al. 1983; McWhinney 1989).

SDT focuses on helping people change their behaviour for internal reasons, such as alignment with life goals/values, personal commitment to improving well-being, or the satisfaction of changing. These reasons are considered to be autonomous and contrast with controlling motives, which in the case of PA might focus on pleasing others, improving appearance, or alleviating guilt. SDT posits that people have 3 innate psychological needs: relatedness, autonomy, and competence (see Ryan and Deci 2000 and Wilson et al. 2003 for definitions) and that social environments that nurture these basic needs facilitate autonomous motivation and subsequently behaviour change and maintenance. Support for these predictions has been revealed across an assortment of health behaviours (Williams 2002), including PA behaviour change (Fortier and Kowal 2007).

Williams' work using SDT has shown that perceived competence is a key construct in the health behaviour change process (Williams 2002). SCT (Bandura 1986) also posits the importance of a highly similar confidence construct, self-efficacy. Specifically, 2 types of self-efficacy are instrumental in predicting behaviour change: task efficacy (i.e., confidence in one's ability to perform the elemental aspects of a task such as walking for 30 min) and barrier efficacy (i.e., confidence in one's ability to walk for 30 min under challenging conditions such as when one lacks time) (Maddux 1995). Much research in the PA context has supported the importance of self-efficacy (McAuley and Mihalko 1998; Trost et al. 2002) and a recent review on mediators of change (Lewis et al. 2002) found that self-efficacy was one of the most common and influential predictors of PA behaviour change in adults. Indeed, many PA interventions (ACT, Blair et al. 1998; PACE, Calfas et al. 1996; PAL, Pinto et al. 1998) have been based on SCT.

According to SDT, environments that foster the 3 basic needs have been termed autonomy supportive. Specifically, autonomy support in the health care environment is characterized by a collaborative interpersonal climate where a health professional actively listens to, elicits, acknowledges, and considers patient perspectives, presents health-related information while minimizing pressure, and maximizes opportunities for personal decision making while supporting behaviour change (Sheldon et al. 2003).

Physicians using an autonomy-supportive style in practice have been shown to positively influence patients' autonomous motivation across numerous health-related behaviours, recently including lifestyle change incorporating PA (Williams et al. 2005). Moreover, in an RCT, Williams et al. (2002*a*) found that when physicians implemented an autonomy supportive counselling style with the As guidelines, patients were more autonomously motivated to quit smoking and autonomous motivation subsequently predicted quitting behaviour.

More clinical trial research is needed on autonomy support in the health care context, especially from providers that conduct intensive counselling and thus have the opportunity to apply the style over multiple sessions.

In the PA counselling area, a recent review (Tulloch et al. 2006) indicated that having an allied health professional work in conjunction with a physician produces better results in terms of patient PA behaviour change over time than the physician counselling alone. Specifically, 75% of studies using combined-provider approaches reported significant increases in patient PA, compared with 33% of trials using physician-only approaches.

Limitations of previous PA promotion primary care trials

Very few studies have examined a shared care approach with different providers working together in the same setting to promote PA, and even fewer have focused on a truly collaborative model. Moreover, previous trials have aimed to increase PA in either healthy or diseased populations, have tended not to include a comprehensive evaluation approach such as the RE-AIM framework (intervention reach effectiveness, adoption, implementation, and maintenance; Glasgow 2002; Glasgow et al. 1999; http://www.re-aim.org), including a qualitative perspective, and have mainly used self-report PA measures.

The PAC trial is therefore underway to address these gaps and, specifically, to assess the impact of a collaborative interdisciplinary shared care approach in the primary care setting. In particular, the effect of integrating a PA counsellor in the primary health care team to provide intensive PA counselling (IPAC) is being examined. The purpose of this paper is to present the rationale for the PAC trial and the methods used, including an overview of the interventions being evaluated. The measurement and interventions reflect the theories described above.

Materials and methods

Objectives

In accordance with Baranowski et al. (1998) suggestion and owing to the duration of the trial, the primary objective is to determine if patients receiving brief PA counselling (BPAC) plus IPAC (intensive counselling group, IC) will show greater improvements over the course of the intervention in two key mediators of change, task motivation and task self-efficacy to participate in PA, than patients receiving only BPAC (brief counselling group, BC).

The second objective is to determine if the intensive counselling group will self report higher levels of PA (confirmed by objective accelerometer data) over the course of the intervention than the brief counselling group.

These 2 objectives address effectiveness components. The tertiary objective is to respond to other key RE-AIM re-

search questions such as population reach, other effectiveness outcomes, adoption, implementation, and maintenance (see the project summary, available from www.health.uottawa.ca/pac/project). An additional exploratory objective of the study is to test the feasibility of measuring physical and metabolic outcomes in this type of trial.

Design and evaluation framework

This study incorporates a mixed-methods approach (i.e., combined quantitative and qualitative data gatherings) within a 2-arm randomized controlled design. The trial is following the revised CONSORT guidelines (Altman et al. 2001) and using the recommended RE-AIM evaluation framework (Glasgow et al. 1999). A program logic model was developed to direct evaluation (see the project summary, available from http://www.health.uottawa.ca/pac/project). This project has been approved by the University of Ottawa, Montfort Hospital, and Ottawa Hospital Research Institute ethics boards. All patients have now been recruited now and provided their informed consent.

Setting, recruitment, screening, and data collection

The patients recruited for this study attend a single, predominantly Francophone, community-based primary care practice in urban Ottawa. This practice is composed of 2 male and 2 female full-time family physicians and 1 female nurse practitioner, who have been practicing together for an average of 21.6 y (range = 12–24 y). The health care providers within the practice are paid by fee for service and offer comprehensive bilingual care, including hospital visits.

A schematic overview of the study steps and interventions, as well as patient flows to date, are presented in Fig. 1. The recruiting phase for this trial lasted 17 weeks. Patients were approached in the waiting room of the practice ahead of their scheduled visits. After being informed about the first phase of the study (level 1), all patients were asked to complete a set of questionnaires. Patients who were not interested, or did not have time to complete the first questionnaire (PA form in Fig. 1) before their appointment were not contacted further. The questionnaires answered prior to the patient's appointment were used for screening purposes to inform the health care providers about which patients were inactive and stable and should thus receive the BPAC. This phase of the study also provides an opportunity to compare the socio-demographics of interested versus non-interested patients and allowed us to obtain baseline data before beginning the intervention.

Patients were again approached after their appointment to assess health care provider intervention compliance and to inquire if they were interested in participating in the full study (level 2). Interested patients were then contacted and eligibility was determined. All eligible and interested patients were booked for a baseline assessment at the community hospital.

At the baseline assessment appointment (as well as at weeks 13 and 25) a questionnaire package containing primary psychological mediators, a Godin leisure-time questionnaire (GLTEQ; Godin and Shephard 1985), secondary psychological mediators, psychological health outcomes, and other health information scales were verbally administered to patients by a research assistant (see Table 1 for a complete list of patient measures). The data were instantaneously entered into an internet-based questionnaire (using a Web-based data-management service). In addition, a shorter version of the questionnaire package (including only primary psychological mediator measures and the GLTEQ) is being administered by phone at weeks 6 and 19. In addition to the questionnaires, patients were provided with instructions on how to use their accelerometer (Actical; Mini Mitter Co., Inc., Bend, Ore.) during their baseline assessment appointment, and were asked to wear it for all waking hours during the subsequent 2 weeks (i.e., baseline). Patients are also asked to wear their accelerometer at weeks 13 and 25 for periods of 2 weeks. A medical courier is being used for accelerometer returns.

Randomization into the brief counselling and intensive counselling groups took place at the community hospital once patients had completed their baseline assessment (see Randomization section below). Furthermore, one third of each group were randomly assigned to participate in physical and metabolic testing at baseline, at week 13, and at week 25. This testing session includes (*i*) drawing blood for metabolic measures, (*ii*) a breakfast, (*iii*) anthropometric measurements, and (*iv*) an aerobic fitness assessment (test of maximal aerobic power, $VO_{2\ max}$) on a treadmill.

Once the accelerometer is returned for the final time (week 25), patients in the brief counselling group will be offered 2 counselling sessions (one face to face and one by phone) with the PA counsellor. Debriefing sessions and information packets will also be provided to the patients who complete the study.

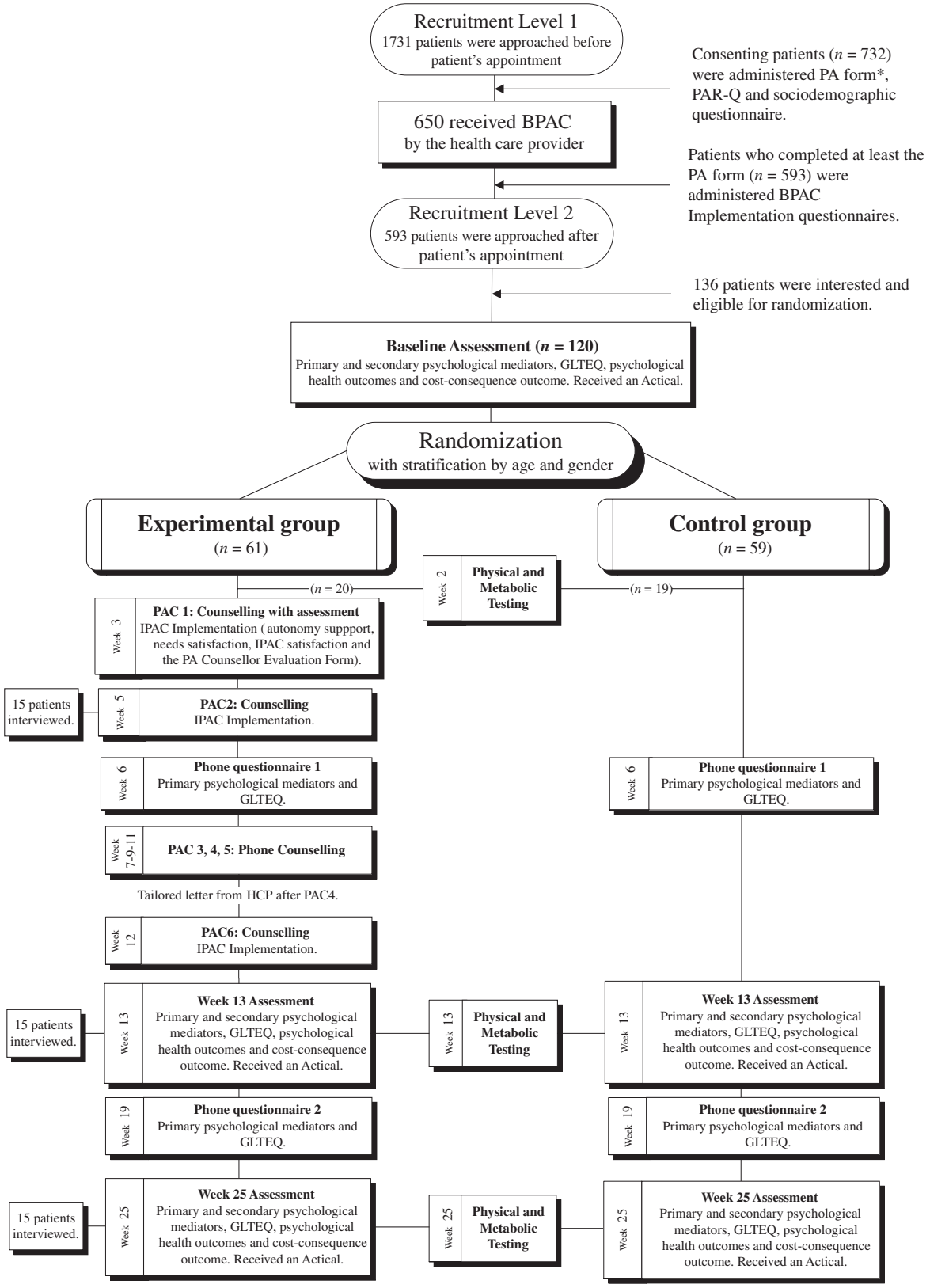
The health care providers have been asked to complete questionnaires at 4 time points (training phase and weeks 8, 16, and 22) and have been asked to participate in 2 focus groups (planning/preparation phase and week 38) and one individual interview (week 25). One health care provider also kept a journal during the recruitment phase. Exit interviews were conducted following the initial patient appointments to determine the health care providers' compliance to the BPAC protocol.

The PA counsellor participating in the research project is being interviewed twice (weeks 5 and 13; each interview is anticipated to last between 30 and 70 min). The PA counsellor is also keeping a journal of her reflections of the intervention and the collaboration with the health care providers. Pending patient consent, she is also randomly audio-taping 20 patients during all 6 PAC sessions for the purposes of supervision and process evaluation.

Study population

Patients 18 to 69 years of age who visited their health care provider during the recruitment period were eligible to participate in the study if they reported less than 150 min/week of PA and no uncontrolled medical conditions. Additional exclusionary criteria included pregnancy (funder's request), planned absence of >3 weeks during the first 3 months of the study period, if they live with someone who was already in the study, a medical condition where PA participation is inadvisable, not receiving a PA prescription from their health care provider during their BPAC, receiving BPAC from their health care provider more than once since the trial began, and if they did not want to be referred for

Fig. 1. Overview of study flow and interventions.



* PA form includes primary psychological mediators, GLTEQ, task motivation—increase PA and task efficacy—increase PA

Table 1. Patient effectiveness and implementation measures

			IPAC (weeks)			Maintenance (weeks)	
Effectiveness evaluation	Before BPAC	After BPAC	Baseline	6	13	19	25
Primary outcomes							
Primary psychological mediators							
Task motivation	X		X	X	X	X	X
Task self-efficacy	X		X	X	X	X	X
Secondary outcomes							
Physical activity							
GLTEQ	X		X	X	X	X	X
Accelerometer (Actical)			X		X		X
Tertiary outcomes							
Secondary psychological mediators							
Perceived competence			X	X	X	X	X
Autonomous and controlled motivation (TSRQ)			X	X	X	X	X
PA motivation (BREQ-2)			X	X	X	X	X
Enjoyment			X	X	X	X	X
Barriers self-efficacy			X	X	X	X	X
Task efficacy: goal			X	X	X	X	X
Task efficacy: increase PA	X	X	X	X	X	X	X
Psychological health outcomes							
SF-12 health survey			X		X		X
Subjective vitality scale			X		X		X
Cost–consequence outcome							
Medical visits			X		X		X
Exploratory outcomes							
Physical and metabolic outcomes*							
Aerobic capacity ($VO_{2\ max}$)			X		X		X
Blood pressure and heart rate			X		X		X
Anthropometric measurements							
Waist circumference (cm)			X		X		X
Percent body fat (BIA)			X		X		X
Total fat mass (kg)			X		X		X
Total lean mass (kg)			X		X		X
Metabolic measurements							
Lipids (total, HDL, and LDL cholesterol and triglycerids)			X		X		X
Glucose homeostasis and insulin resistance			X		X		X
Glycosylated hemoglobin			X		X		X
Qualitative interviews†				X	X		X

Implementation evaluation	After BPAC	PAC 1	PAC 2	PAC 3	PAC 4	PAC 5	PAC 6
BPAC implementation							
Health care providers' compliance to BPAC protocol	X						
BPAC satisfaction	X						
Autonomy support (HCCQ)	X						
Basic need satisfaction in relationships scale	X						
IPAC implementation							
Autonomy support (HCCQ)		X	X				X
Basic need satisfaction in relationships scale		X	X				X
IPAC satisfaction		X	X				X
The PAC evaluation form		X	X				X
PA counsellor's compliance to IPAC protocol‡		X	X	X	X	X	X

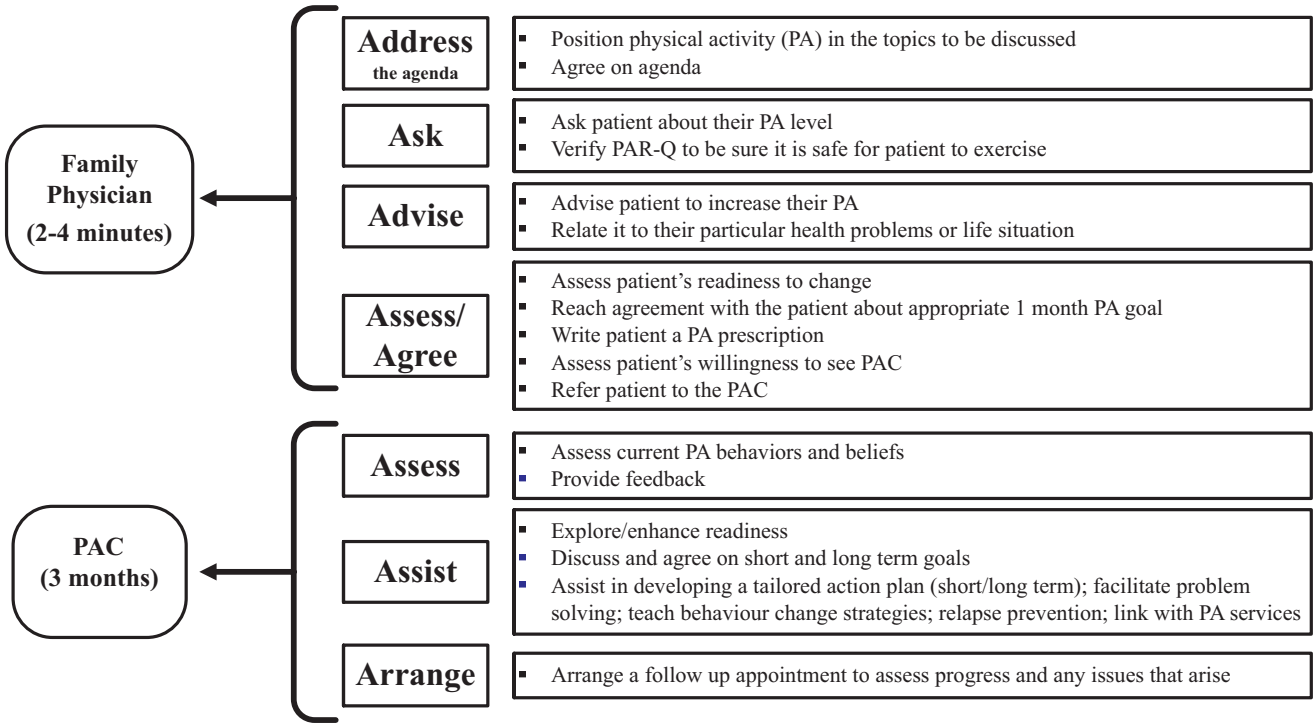
*One third of participants in each group.
†Fifteen patients from experimental group.
‡Every third patient was asked to consent to the recording of his or her counselling sessions.

PA counselling. A broad and diverse adult patient sample was targeted in this trial with some patients being healthy, some with risk factors (e.g., high body mass index (BMI), high blood pressure) and another group with known stable diseases (e.g., arthritis, diabetes).

Randomization

Patients have been randomized into 2 groups: brief counselling (BC) and intensive counselling (IC). From these 2 groups, 1/3 were randomly selected to participate in physical and metabolic testing. The randomization was stratified by

Fig. 2. The "7 As model" for interdisciplinary shared care PA counselling in primary care.



gender and age group (18–49 y or 50–69 y). A statistician created the randomization sequence using SAS 9.1 for Windows (SAS Institute Inc., Cary, N.C.) for input into a computer program. The allocation sequence was concealed by generating it with a central telephone randomization system operated by a data management company. At the end of each enrolment session, the research assistant confirmed eligibility and entered the gender and age of each participant to receive their allocated group. One hundred twenty patients (83 women, 37 men; mean age = 47.3 y) have been assigned to 1 of the 2 groups.

Interventions

The "7 As model" (Fig. 2) is being used as a guiding framework for this RCT. This clinical counselling approach was adapted as an interdisciplinary shared care model for PA counselling in primary care (Fortier et al. 2006). Central to the model is the integration of a PA counsellor into the primary health care team and the sharing of responsibilities (the As) between the health care provider and the PA counsellor. The basic premise to have the most appropriate care provided by the most appropriate provider is a common feature of efforts to reform primary care service delivery in Canada.

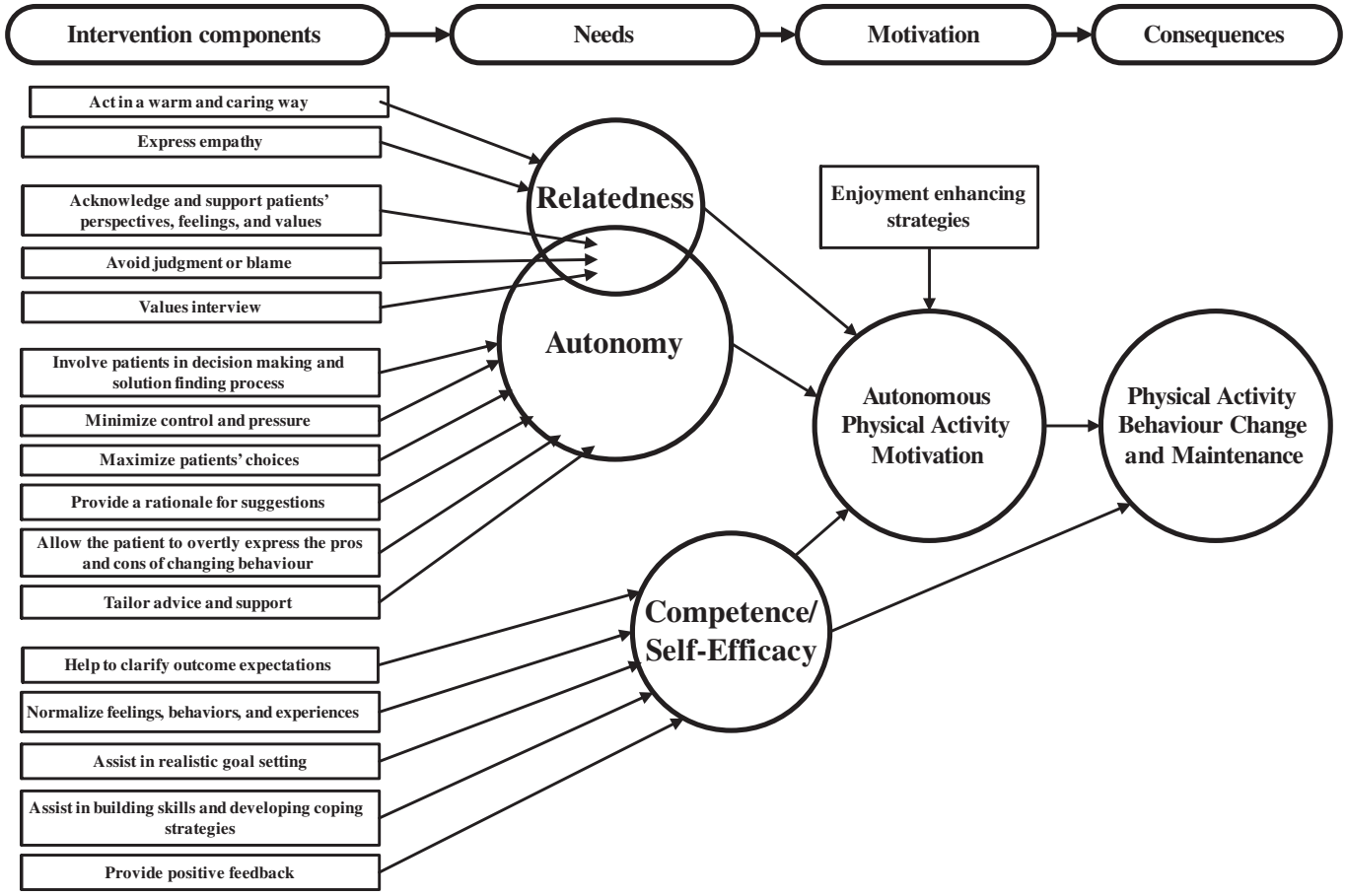
This new model incorporates several recommendations from key experts (Goldstein et al. 2004; Whitlock et al. 2002). It positions health care providers in a priming or motivation building role (Kreuter et al. 2000; Rippe 1999) and encourages the delivery of a written, tailored PA prescription (Duncan et al. 2005; Swinburn et al. 1998). It uses a specialized and less-costly allied health care provider, the PA counsellor, for an intensive multiple contact intervention to complement the health care provider's work, in an effort to foster sustainable patient behaviour change (Fiore et al. 2000).

The PA counsellor in our project has a university degree in exercise sciences with knowledge of exercise psychology, behaviour change counselling, and clinical exercise physiology, as well as certification from the Canadian Society for Exercise Physiology (CSEP). This specialized knowledge and skill set are precisely those that physicians feel they lack (Petrella and Wight 2000; Walsh et al. 1999) and put the PA counsellor in an optimal position to offer intensive counselling. The PA counsellor is situated in the primary care practice and works alongside the health care providers in a designated office.

The PAC project consists of 2 phases (see Fig. 2 and Fortier et al. 2006): phase one involved BPAC provided by the health care provider (family physician or nurse practitioner) during a regular primary care visit (first 4 As: 2–4 min). We optimized the role of the health care providers by designing a standard, evidence- and SDT-based BPAC intervention (see Fortier et al. 2006) and by providing 3 training seminars. Consequently, there was an emphasis on the provision of brief counselling using a patient-centered autonomy supportive approach, as described in the SDT section above. Both brief counselling and intensive counselling patients have received this intervention from their health care provider.

Subsequently (phase 2), intensive counselling patients are referred to a PA counsellor for intensive autonomy supportive PA counselling (IPAC: last 3 As) over a 3 month period. Prior to the beginning of the trial, the PA counsellor was provided with 2 months of training to develop an autonomy-supportive style and to learn and practice motivational interviewing (MI) techniques. Indeed, the practice of

Fig. 3. Combined SDT/MI process model of PA behaviour change.



MI (Miller and Rollnick 2002) appears "tailor-made" to facilitate the 3 basic needs that an autonomy-supportive style attempts to satisfy to promote autonomous motivation (Markland and Tobin 2004). The PA counsellor also learned and practiced behavioural counselling techniques and interdisciplinary collaboration strategies. Additionally, the PA counsellor is being provided with ongoing bi-weekly supervision sessions throughout the trial, with the first and third authors, which include tape recording patient counselling sessions and then reviewing them, as well as other issues related to the protocol or to patients' barriers and progress.

The IPAC intervention is based on a new combined SDT/MI process model of PA behaviour change (Fig. 3). Sequencing of the IPAC sessions is based on assumptions that relatedness and autonomy should be developed first, followed closely by competence and (or) self-efficacy building. Integral to the model is the goal of facilitating patients' autonomous PA motivation to foster greater and longer-term behaviour change, in addition to tailoring the intervention to each patient's needs (Task Force on Community Preventive Services 2001).

Based on experts' suggestions (Fiore et al. 2000; Nupponen 1998; Simons-Morton et al. 1998), the IPAC protocol includes multiple contacts with patients. Specifically, there are 6 patient counselling sessions, spread over a 3 month period at approximately every 2 weeks (3 conducted in person at the primary care clinic and 3 conducted by phone).

The purpose and format of each IPAC session are summarized in Table 2. Session one (the "assess" step) involves in-depth questioning and an exchange or dialogue to get to know patients, i.e., their life goals (via values interview), interests, medical history, past and current PA behaviours, motives (goal content) and further goal motives, competence and (or) self-efficacy for behaviour change, barriers, lifestyle, and social support networks. This step is designed to establish rapport and to individualize the intervention, as well as to explore the pros and cons of PA behaviour change.

The "assisting" step continues over all sessions. In essence, this step consists of providing encouragement and support and helping patients become more active. Several common evidence-based strategies used to assist PA adoption and maintenance have been incorporated (Kahn et al. 2002), several of which attempt to facilitate the development of patients' self-regulation skills. These strategies include helping patients set appropriate weekly goals and determine potential barriers, collaborative problem solving for potential strategies to overcome these barriers, teaching and encouraging self-monitoring, soliciting social support networks, relapse prevention, and linking patients with accessible PA services. These techniques have been used in previous primary care PA interventions and have been shown to facili-

Table 2. Purpose and format of IPAC sessions.

Session format and duration	Purpose	Tools
In person (60 min)	(*i*) Assessment (approximately 40 min); (*ii*) Discussed recommended PA rates; (*iii*) Goal-setting for next 48 h and next 2 weeks (FITT) and action plan (barriers, solutions, sources and mechanisms of social support, and self-reward (if needed and of interest to patient)	(*i*) Interview cue card session 1; (*ii*) Copy of health care provider's PA prescription; (*iii*) Goal, action plan, and log sheet; (*iv*) Tools if needed: activity preferences, environment questionnaire, self-talk log, time management grid, problem-solving sheet, barrier identification, decision balance sheet; (*v*) PA resources and (or) link with services
In person (40 min)	(*i*) Review how the previous weeks went; PA record; lessons learned; (*ii*) Summarize timeline (past, present, future and benefits of PA); short and long term goals; (*iii*) Action plan using the cones diagram to identify and prioritize barriers and solutions to address them; (*iv*) Ask what PAC can do to assist; (*v*) Goal-setting (FITT) and action plan for next 2 weeks	(*i*) Interview cue card session 2; (*ii*) Goal, action plan, and log sheet; (*iii*) Tools if needed: activity preferences, environment questionnaire, self-talk log, time management grid, problem-solving sheet, barrier identification, decision balance sheet; (*iv*) PA resources and (or) link with services.
Telephone (20 min)	(*i*) Review how the previous weeks went; PA record; lessons learned; (*ii*) Assess motivation and confidence; (*iii*) Discuss feelings when doing PA; how patient would like to feel; and strategies to enable feeling that way; (*iv*) Barriers, facilitators and behaviour strategies; (*v*) Ask what PAC can do to assist; (*vi*) Goal-setting (FITT) and action plan for next 2 weeks	(*i*) Interview cue card session 3; (*ii*) Goal, action plan, and log sheet; (*iii*) Tools if needed: activity preferences, environment questionnaire, self-talk log, time management grid, problem-solving sheet, barrier identification, decision balance sheet; (*iv*) PA resources and (or) link with services
Telephone (20 min)	(*i*) Review how the previous weeks went; PA record; lessons learned; (*ii*) Relapse prevention; (*iii*) Barriers, facilitators and behaviour strategies; (*iv*) Ask what can PAC do to assist; (*v*) Goal-setting (FITT) and action plan for next; 2 weeks	(*i*) Interview cue card session 4; (*ii*) Goal, action plan, and log sheet; (*iii*) Relapse prevention planner; (*iv*) Tools if needed: activity preferences, environment questionnaire, self-talk log, time management grid, problem-solving sheet, barrier identification, decision balance sheet; (*v*) PA resources and (or) link with services
Telephone (20 min)	(*i*) Review how the previous weeks went; PA record; lessons learned; (*ii*) Progression of physical activities; (*iii*) Motivation strategies; (*iv*) Follow up on relapse prevention if needed); (*v*) Barriers, facilitators and behaviour strategies; (*vi*) Ask what PAC can do to assist; (*vii*) Goal-setting (FITT) and action plan for next 2 weeks	(*i*) Interview cue card session 5; (*ii*) Goal, action plan, and log sheet; (*iii*) Tools if needed: activity preferences, environment questionnaire, self-talk log, time management grid, problem-solving sheet, barrier identification, decision balance sheet; (*iv*) PA resources and (or) link with services
In person (40 min)	(*i*) Review how the previous weeks went; PA record; lessons learned; (*ii*) Summary and evaluation of last 3 months; (*iii*) Evaluation of short term goals and review long term goals; (*iv*) Assess motivation and confidence for future; (*v*) Summary; (*vi*) Barriers and solutions; (*vii*) Behaviour strategies; (*viii*) Social support; (*ix*) Relapse prevention; (*x*) Motivation and progression strategies; (*xi*) Ask what PAC can do to assist; (*xii*) Wrap up unfinished items / details (paperwork, resources, etc)	(*i*) Interview cue card session 6; (*ii*) Summary sheet (long tem goals and action plan); (*iii*) Tools if needed: activity preferences, environment questionnaire, self-talk log, time management grid, problem-solving sheet, barrier identification, decision balance sheet; (*iv*) PA resources and (or) link with services

tate behaviour change (Elley et al. 2003; Kirk et al. 2003; Tulloch et al. 2006). Depending on the patient's needs or barriers, other strategies such as exploring ambivalence, using self-rewards, and challenging negative thoughts surrounding PA are also being used.

Following each in-person IPAC counselling session, all patients are provided with a standard one page written combined goal sheet or action plan and on the alternate side a self-monitoring tool for the subsequent 2 weeks. They are also provided with tailored tools (e.g., self-talk log) and materials upon their departure from in-person sessions. Suggestions of specific physical activities, classes, or programs based on the patients' needs and preferences are made and transitions facilitated by the PA counsellor.

The final step is to arrange for follow up to determine progress and address any issues arising (e.g., new PA barrier). This is done at the beginning of each session for sessions 2–6. This step has been incorporated to modify PA goals and (or) action plans and to ensure the patient is connected to the agreed upon external PA resource(s). Reframing and normalizing difficulties with goals is an important component to build competence and (or) self-efficacy.

Particular to this intervention (see Fig. 3) is the emphasis on creating an autonomy-supportive climate (similar to Williams 2002) and the teaching of enjoyment-enhancing strategies to optimize autonomous PA motivation. Although counselling is highly individualized, in all sessions, the PA counsellor attempts to foster a patient's feelings of relatedness, autonomy, and competence, and ensures that his or her PA experiences are as enjoyable and fun as possible.

To facilitate interdisciplinary collaboration, a 1-page progress report for each patient presenting his or her PA progress, main motives, and barriers are prepared by the PA counsellor and filed in the patient's chart half way through IPAC. At week 10, the PA counsellor prepares tailored letters for each intensive counselling patient. The letters are signed by the health care provider and provide encouragement to the patient to continue striving for his or her PA goals. Other evidence-based strategies to foster integration and collaboration (McDonough and Doucette 2001; Marcus et al. 1998) are being used throughout the trial (e.g., initial role clarification, weekly lunches, social activities).

Evaluation

As this is a clinical trial, the main focus of the evaluation is on patient-level effectiveness and implementation aspects of RE-AIM (Glasgow 2002). Consequently, this study includes a variety of quantitative effectiveness and implementation measures administered at different time-points (see Table 1 for study measures). Individual level maintenance in effectiveness indicators are assessed by following patients' post-IPAC for 3 months (2 time-points). In addition, 15 intensive counselling patients are participating in qualitative interviews at 3 different time-points: weeks 6, 13, and 25, to obtain in-depth perceptions on effectiveness and implementation aspects. Before commencement of data collection, socio-demographic information was obtained (e.g., age, gender, years of education).

Primary effectiveness outcomes

The primary psychological mediators of change being measured in this study are task motivation and task self-efficacy. The rationale for focusing on mediators of change as primary outcomes is based on recommendations by Baranowski et al. (1998) that behaviour change interventions should focus on the underlying mechanisms for change. Given the imposed time restrictions for this trial, this primary focus was determined by the investigative team as more apt to change, thereby allowing us to understand the reasons underlying change.

Both mediators (task motivation and task efficacy) are being assessed using the same graded approach recommended by Bandura (1986) and found to be reliable with other self-efficacy measures (McAuley and Mihalko 1998; McAuley 1993). Patients are asked "Over the next 6 weeks, how motivated are you to participate in PA for more than 20 minutes during your free time for at least … 1, 2, 3, etc. to 7 days per week." Task self-efficacy is being assessed by asking patients "Over the next 6 weeks, how confident are you to participate in PA for more than 20 minutes during your free time for at least 1, 2, 3 … 7 days per week". Patients are asked to rate their answers on a scale from 0% (not at all confident) to 100% (completely confident) for each of the 7 days and a mean percentage will be calculated for each outcome at each of the 6 time-points (before BPAC and every 6 weeks for the remaining 5 time-points).

Secondary effectiveness outcomes

Secondary outcomes include self-reported and objective measures of PA. The GLTEQ is being used to determine current self-reported PA by intensity of exercise (Godin and Shephard 1985). This instrument estimates frequency (no. of days per week) of PA by an individual in the past 7 days. The patients are asked to report the number of days per week they did PA for more than 20 min. The frequency in light (3 METs), moderate (5 METs), and strenuous (9 METs) activities for the past 7 days are multiplied by their MET values and then summed to produce the total weekly leisure activity score. This questionnaire has been validated and used extensively (see Kriska and Caspersen 1997 for a review). Godin has determined that a leisure activity score of 20 units is equivalent to meeting minimal Canadian recommendations (G. Godin, personal communication) of 150 min/week of moderate PA. In this study, the GLTEQ is being administered at the same time-points as the primary outcomes.

Levels of PA are also being measured using a portable accelerometer. Specifically, the Actical monitor was selected because of its small size and capacity to be worn underwater. This small accelerometer is considered to be "omnidirectional" (i.e., sensitive to movement in all directions and integrates both degree and speed of motion). These accelerometers have been calibrated by the manufacturer and their sensitivity to movement ranges from 0.5- to 3-Hz, allowing detection of sedentary to high-energy movements. The Actical was designed to record activity counts in epochs of 15, 30, or 60 s allowing collection for a period of up to 44 days. The Actical has been validated with adults (Heil 2006) reporting internal validity between $r = 0.81$ and $r = 0.998$ and validity to predict activity energy expenditure between $R^2 = 0.71$ and $R^2 = 0.85$ when the accelerometer is placed at the hip position. Intra-class reliability has been reported as $r = 0.62$ (Welk et al. 2004). In line with the recommendation of Trost et al. (2005), the devices have been set to capture short episodes of PA.

All patients are asked to wear their accelerometer on their predominant hip (or always the same hip) above the iliac crest under their clothes with a Velcro elastic belt during waking hours for 14 days at baseline, at week 13, and at week 25. A small poster with guidelines is supplied to patients at baseline to help them remember to wear the accelerometer. The accelerometer does not provide any information to the patient and is being used for data collection purposes only.

Tertiary outcomes

To thoroughly assess the impact of the interventions, additional valid and reliable effectiveness and implementation measures are being administered.

Tertiary effectiveness evaluation

Secondary psychological mediators of PA behaviour change based on the 2 theoretical frameworks, SDT (Deci and Ryan 1985) and SCT (Bandura 1986), are also being assessed. First, SDT measures include perceived competence (Williams and Deci 1996), autonomous and controlled motivation (Treatment Self-regulation Questionnaire; Williams et al. 1996), PA motivation (Behavioral Regulation Exercise Questionnaire - 2; Markland and Tobin 2004), and PA enjoyment (Motl et al. 2001). Second, additional SCT measures include barriers to self-efficacy (McAuley 1992) and task efficacy (increase PA and task efficacy — goal).

Psychological health outcomes are being assessed using the SF-12® health survey (Ware et al. 1993) and the subjective vitality scale (Bostic et al. 2000).

In addition, patients are asked to report the number of times they visited their health care provider, the emergency room, and (or) a specialist in the last 3 months at baseline, at week 13, and at week 25, for the purpose of the cost–consequence analysis. Costs in this study are defined as the direct health cost of the project, from the perspective of primary health care provider (excluding costs on the conduct of the research trial, data collection, and phone counselling for research purposes).

Tertiary implementation evaluation

The process evaluation involves an assessment of the quality and accuracy of the BPAC and IPAC delivery as planned. It includes tracking patient participation, measuring intervention fidelity, and patient satisfaction. See Table 1 for patient implementation assessment time-points. Satisfaction and collaboration of the health care providers and the PA counsellor is also included in this component.

With regards to the implementation evaluation of the BPAC, patients are asked to answer 4 questionnaires immediately after their BPAC. In the first questionnaire, there are 9 yes or no questions based on the Physical Activity Exit Interview (Sciamanna et al. 2004), to assess health care providers' compliance to the BPAC protocol. Additional questionnaires include a rating of their global satisfaction with the BPAC, on a scale out of 7, the Health Care Climate Questionnaire (HCCQ; Williams et al. 1998; Williams et al. 1996; Williams et al. 2004) to evaluate whether their health care provider was autonomy supportive during counselling, and the Basic Need Satisfaction in Relationships Scale (La Guardia et al. 2000) to evaluate whether they felt as though their 3 psychological needs were being satisfied during BPAC.

The implementation evaluation of the IPAC involves patient ratings of the PA counsellor on the aforementioned Health Care Climate Questionnaire and Basic Need Satisfaction in Relationship Scale. In addition to these scales, patients rate their satisfaction with the IPAC on a scale out of 7, as well as rating the PA counsellor on 11 characteristics (e.g., helpfulness; based on Partington and Orlick 1987). These questionnaires are administered to intensive counselling patients by phone after each in-person IPAC session. The PA counsellor's compliance to the IPAC protocol will also be assessed by evaluating the recordings of 3 intensive counselling patients, who will be randomly selected from the 20 recorded patients. The taped in-person IPAC sessions will be independently rated for compliance and quality by 2 trained bilingual researchers, using a coding scheme based on the IPAC intervention protocol (Table 2). IPAC tapes will also be coded for autonomy supportiveness and attempts to satisfy patients' basic psychological needs according to a coding scheme used by Williams (2002).

The assessment of satisfaction and collaboration of the health care providers and the PA counsellor involves 4 different methods: questionnaires, focus groups, interviews, and reflection journals. Health care providers were asked to complete a questionnaire on their PA, frequency of PA counselling, perceived effectiveness, motivation, and confidence for each BPAC step at baseline (i.e., training phase). These questions are repeated along with questions regarding the PA prescription, and reasons for following the BPAC protocol at weeks 13 and 18. Health care providers and the PA counsellor are also asked to complete an adapted version of the Physician/Pharmacist Collaboration Instrument (PPCI; Zillich et al. 2004) at 3 different time-points (weeks 8, 13 and 18). In addition, individual interviews are being conducted with the health care providers at week 18 and a focus group 3 months later, when the intervention is complete, to solicit their thoughts on the general intervention model, their experiences, their satisfaction, and the developmental process of collaborative practice and any suggestions on improving the intervention. The PA counsellor is being interviewed twice (weeks 5 and 13) with the same intention. The lead HCP and the PA counsellor are also asked to comment and reflect on the collaboration process and their interventions in a journal. Satisfaction with the overall interdisciplinary approach will be assessed in the final focus group for the health care providers (HCPs) and in the final interview for the PA counsellor. Furthermore, the impact of the integration of the PA counsellor on health care providers, team functioning, and service delivery will be explored during a focus group held at the end of the intervention phase with all members of the community-based primary care practice.

Exploratory outcomes

Aerobic capacity (cardiorespiratory fitness) is a powerful and independent predictor of mortality (Blair et al. 1995, 1996; Myers et al. 2002; Wei et al. 1999). Aerobic capacity ($VO_{2\ max}$) is being determined from an incremental treadmill exercise test using the Balke protocol (Pollock et al. 1982) using a Vmax 229 series metabolic cart (SensorMedics Corporation, Yorba Linda, Calif.). Blood pressure and heart rate are also being measured.

Anthropometric measurements include patients' waist circumference, percent body fat, total fat mass, and total lean mass. The last three are measured by dual energy X-ray absorptiometry (DEXA) using a GE-LUNAR Prodigy module (GE Medical Systems, Madison, Wis.). Furthermore, metabolic measures include lipid levels (fasting total cholesterol, high- and low-density lipoprotein (HDL and LDL) cholesterol, triglycerides (calculated using Friedewald's equation; Friedewald et al. 1972)), fasting plasma glucose, insulin lev-

els, and glycosylated hemoglobin levels. Insulin resistance is estimated using the HOMA formula (Matthews et al. 1985), which calculates insulin resistance based on the fasting plasma glucose and insulin. This method has been validated (Bonora et al. 1998). Owing to feasibility, these outcomes were assessed on 33% of the sample across both arms of the trial, at the 3 main time-points.

Data management

The patients, PA counsellor, and RAs were not blinded to group assignment after randomization, but the physical and metabolic testing are being conducted by a research assistant who is not aware of group assignment.

The PAC project is using a data management company that specializes in clinical trials. This secure software stores all of the quantitative data. Transcription errors are avoided, as most questionnaires are entered directly into the data management system by the research assistant administering the questionnaire. The system is designed to avoid missing data or data entry errors by providing logic and range checks. The only pen and paper questionnaires used were those conducted at the community-based primary care practice. These questionnaires were subsequently entered on a laptop computer, and then double checked by a different person before being synchronized with the main database. As for the physical and metabolic data, they are entered in a binder (one binder for each patient) by the research assistant assigned to administer all physical and metabolic testing. A second research assistant enters the relevant data into the database. This same research assistant will double check the entered data at the end of the trial.

Analytical procedures

Sample size

The number of patients needed to detect a clinically meaningful incremental effect in task motivation and task self-efficacy for patients receiving IPAC is 64 in the brief counselling group and 64 in the intensive counselling group. This sample size identifies a minimum clinically important difference of half of a standard deviation of the task motivation and task self-efficacy questionnaire results.

Analyses

Quantitative data from the trial will be analyzed using SPSS v. 14 statistical software package using the general linear model (GLM). The initial data analysis will include frequency tabulations and scatter plots to identify possible data problems. Analyses for primary and secondary objectives will be a mixed-model repeated-measures analysis of covariance (ANCOVA) comparing brief counselling and intensive counselling groups at weeks 6 and 13 while controlling for baseline levels. Intent to treat with last value carried forward will be used. PA confounders will be controlled for during the analyses. For the qualitative analyses, N*Vivo software (QSR 2002) will be used to code data into categories using both deductive and inductive approaches.

Regarding the measurement of PA using the accelerometer, we will consider the first 3 days as a habituation phase. The accelerometer will be considered removed when there are at least 60 min of continuous zero counts observed (allowing isolated 1 min of activity counts) and activity counts in this period will be considered missing. To calculate activity for a complete day, the technique of Catellier and colleagues (2005) will be used, in which a complete day is defined as the period during which at least 70% of the study population recorded activity counts, and 80% of that observed period constitutes a minimal day for inclusion in data analysis (80% of 10.48 h = 8.39 h). Only patients with at least 4 completed days (with at least 1 weekend day) will be included in the statistical analysis. Missing or invalid days will be treated with intent to treat carrying the last valid day forward. Cut-points for light (0–349 activity counts), moderate (349–1199 activity counts), and vigorous (1200 + activity counts) PA will be used to categorize patients level of PA (Heil 2006). To see if patients met the PA guidelines, as suggested by Mâsse and colleagues (2005), bouts of at least 10 min (allowing 1 min of interruption) of moderate–vigorous PA (349 + activity counts) will be calculated.

Methodological limitations

Several methodological limitations of this study should be acknowledged. First, the time period for the trial was limited by the project funder, therefore it was not possible to extend the timeframe of the intervention or follow-up intervals. The interviews could act as an intervention for the 15 intensive counselling patients. The experiment is not blinded.

Comments

This project represents an approach to promoting PA in primary care. It is anticipated that the lessons from this trial will build on the knowledge in several different areas, including, but not limited to, PA counselling interventions, application of psychological theory, self-determination theory, preventative health care, interdisciplinary collaboration, and evaluation of public health interventions using the RE-AIM framework.

The focus of this trial addresses the previously expressed need for RCTs to focus on psychological mediators (Baranowski et al. 1998). Integrating a PA counsellor within the primary care team and promoting a truly collaborative approach is a novel model that focuses on health promotion and disease prevention and expands the literature on interdisciplinary collaboration in family practice. Moreover, few other trials have incorporated a comprehensive and mixed-methods assessment approach, including an objective measure of PA and such a broad and diverse adult patient sample.

The importance of PA promotion has been reiterated time and again as a critical strategy to enhance population health. This project will demonstrate the feasibility of providing comprehensive support for PA behaviour change within a community-based primary care practice. Patients need significant help to make and especially maintain PA behaviour changes that are essential for optimal health benefits.

If encouraging results are found, a follow up study should be long enough to address the issues of sustainability and health improvement in the population and should include thorough economic analyses. This RCT lays the foundation for this type of research.

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