

# Original Research Paper

## Lessons learned from a green prescription evaluation too many layers, too many players

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### ABSTRACT

This paper describes an evaluation of the effectiveness of the Green Prescription to increase the physical activity of New Zealand adults who lead sedentary lifestyles. The study was terminated because of inadequate recruitment and protocol departures. The project is reported to illustrate pitfalls and offers positive suggestions for general practice research. "Too many layers and too many players" resulted in a complicated study design and created convoluted relationships between all parties. Valuable lessons were learned, however, for implementing the green prescription nationwide. The primary message is "keep it simple".

### INTRODUCTION

This paper describes a research project that failed to meet its objectives: a quantitative and qualitative evaluation of the effectiveness of the green prescription. It illustrates potential pitfalls in conducting general practice research,

### Key points

- A study of green prescription effectiveness was not completed because of inadequate recruitment and protocol departures
- Practitioners should be proficient in an intervention before being recruited to evaluate its effectiveness
- GP research with simple study designs is most likely to succeed
- Researchers should work directly with GPs, not through administrative intermediaries
- Valuable lessons were learned for future implementation of green prescription nationwide

especially when multiple collaborations are involved, and offers positive suggestions for conducting this type of research.

Green prescription (GRx) is a written, goal-orientated exercise prescription given by GPs to sedentary patients – a tangible reminder of an exercise plan negotiated between patient and doctor. A GRx specifies the duration and frequency that the patient should go for a brisk walk or engage in some other moderate physical activity. The expectation is that a GRx is more effective in increasing patients' level of exercise than verbal advice.

GRx was introduced to New Zealand GPs in 1997 by the Hillary Commission – a public funding agency supporting physical activity and sport to promote health. The commission distributed doctor and patient kits and offered to train GPs to use them. The research aim was to measure its effectiveness in the Northland and Auckland areas.

GRx is an intervention that recognises that a sedentary lifestyle is a major risk factor for a number of conditions, particularly obesity,<sup>1</sup> non insulin dependent diabetes,<sup>2,3</sup> coronary artery disease,<sup>4-8</sup> stroke<sup>9</sup> and fall-related bone fractures.<sup>10</sup> This was demonstrated by the 1996 US Surgeon General's Report: *Physical Activity and Health*.<sup>11</sup>

While the capacity of regular, moderate-intensity physical activity to improve health is now well recognised, a large percentage of adults do not exercise sufficiently to accrue the benefits.<sup>12</sup>

The Hillary Commission's 1997 "Sport and physical activity survey" classified 34 per cent of adults as physically inactive (spending less than 2.5 hours a week being active), including 10 per cent who are sedentary (had not taken part in any sports or recreational physical activities for four weeks prior to interview).<sup>13</sup>

GPs are well placed in the community to promote increased physical activity to at-risk patients. In 1995 a randomised control trial (RCT) in New Zealand found that patients given a GRx increased their physical activity levels at six weeks' follow-up significantly more than those just given verbal advice.<sup>14</sup> A qualitative study of GPs' attitudes found that they viewed GRx as beneficial for patients and achievable within general practice.<sup>15</sup>

## **METHOD**

### **The research project**

A 12-month comparison of an intervention group prescribed GRx with a control group was planned to evaluate the effectiveness of GRx. Participating GP practices were randomly assigned to either intervention or control groups. The intervention had two arms: both included GRx plus verbal advice about physical activity, but the second involved referring patients to the local regional sports trust (RST) for activity advice and support. Intervention and control patients were to be followed up at three, six and 12 months.

Focus groups, conducted by the RNZCGP Research Unit, aimed to describe the attitudes and experience of all those involved in GRx – patients, practice nurses, GPs and RST staff.

The study was jointly funded by the Hillary Commission and a regional health funding agency (North Health); designed by the Research Unit in conjunction with the Hillary Commission; and administered by two Independent Practitioner Associations (IPAs).

Both IPAs had approximately 70 members. All 70 were expected to participate and be paid by their IPA for each recruited patient. After several weeks familiarising themselves with GRx, GPs were to invite five suitable patients to participate, using the selection process.

"Intervention" GPs randomly assigned suitable patients to one of the two arms. Inclusion criteria specified physically inactive patients believed by GPs to be at "high risk" but clinically stable, and so most likely to benefit from increased physical activity. The practice nurse or receptionist referred patients assigned to the second arm to their RST.

"Control" GPs were asked to recruit five suitable inactive, "at risk" but medically stable patients and give them routine exercise advice but no GRx.

Baseline data (repeated at each follow-up) to be collected from intervention and control patients included demographics; weight; blood pressure; duration and form of current physical activity and quality of life measures.

IPA managers administered the project. This involved: writing letters to recruit GPs; meeting GPs to explain the project; supplying GPs with the Hillary Commission GRx kits and data collection forms from the Research Unit; collecting completed forms and sending them to the Research Unit for analysis; and maintaining a database.

Unfortunately, after six months the study was terminated because of inadequate subject recruitment and serious protocol violations which precluded valid data analysis. From an anticipated 500 patients in the intervention group and 100 controls, only 38 had been randomised to the intervention (from 10 GPs) and nine recruited as controls (from three GPs).

## **RESULTS**

### **What went wrong**

Hindsight shows the study attempted too much. Furthermore, there was no pilot study to determine GPs' proficiency in using GRx before the assessment began. Four main factors contributed to the project's failure.

First, training was inadequate. GPs were not briefed separately about GRx and the research project. Although the protocol required GPs to be familiar with prescribing GRx before the evaluation began, GPs were issued with the GRx kits and evaluation forms in the same package. There also was a time lag between the initial IPA briefings for GPs and the arrival of the resources in their practices. The result was a large volume of information that was confusing and daunting; some GPs had not even opened their packages when the evaluation began.

Inadequate training resulted in GPs and nurses being insufficiently motivated, not adhering to research protocols and not understanding the randomisation process. Some unsuitable patients were recruited (eg, one very fit marathon-runner) and no data were received from one IPA. Some practitioners offered GRx only to patients they felt were likely to comply, introducing selection bias into the sample.

GPs' and nurses' confusion and uncertainty were reflected in the focus groups (note: because the study terminated prematurely, the focus groups provide impressions of GPs' and nurses' responses rather than a formal qualitative analysis).

GPs and practice nurses generally expressed enthusiasm for the concept but relatively few prescriptions were issued. Some GPs found that it took five to 10 minutes to discuss and initiate a GRx, which for some practices effectively doubled

consultation time. This estimate may have included the time to complete evaluation forms, potentially distorting their perception.

Other barriers identified by GPs who had not used GRx included: a perception that few patients would be motivated; too much paperwork; or that they were already writing an informal version of "GRx". GPs using GRx found these concerns diminished once they were familiar with the routine, and implementation was particularly effective in practices where nurses took the initiative to identify suitable patients. GPs said that very few patients refuse a GRx offered enthusiastically by a doctor.

GPs face increasing demands on their time and resources and, while generally supportive of academic research that might aid patient care, they may be reluctant to participate if they feel the study burdens them unduly.

Second, introducing the arm to measure the effect of RST support made the intervention too complicated. It blurred the roles of GPs, nurses and RST staff, and involving "non-health professionals" caused concerns about patient confidentiality. For their part, RST staff thought some GPs prescribed inappropriate activities for beginners, preferring to determine the level of activity themselves. One RST staff member independently recruited patients and then instructed them to get GRx from their GP, further undermining the integrity of the study.

Third, the administration of the study was far too complex, resulting in complicated communication and relationships. Three-way communication was required between the two funders and the Research Unit. The evaluation was administered by the IPA managers, thus limiting supervision, explanation and encouragement to participating general practices by the Research Unit coordinator. IPA managers are not trained to administer research projects in general practice and expectations that they could organise and coordinate the evaluation proved unrealistic.

Fourth, the two IPAs had very different populations; one based in an ethnically diverse part of Auckland city and one more rural, based in a smaller city. This added to the complexity of the study and made implementing standardised protocols at arm's length even more difficult for the Research Unit.

## **OUTCOME**

This account of a failed study is reported so that others will be wary of the pitfalls. It is in no way a criticism of those involved. Indeed, IPA administrators, RST staff, GPs, nurses and patients all contributed their time and effort generously to the project.

Despite the failure of the evaluation, valuable lessons were learned and used by the Hillary Commission to improve the delivery of GRx, which is now nationwide and part-funded by the Ministry of Health.

To provide the training and support that GPs and nurses lacked in the trial, seven regional coordinators now liaise between the commission, GPs, practice nurses, IPAs, other health professionals and RSTs. Training is offered to GPs in motivational interviewing and also on the benefits of physical activity for specific conditions: focusing on the benefits for arthritis and osteoporosis in 1999 and diabetes and obesity in 2000.

Independent research is carried out three times a year to establish GP uptake of GRx, awareness of the initiative and barriers to use. Data collected in February 2000 indicate that half the nation's GPs now use GRx and suggest that it is becoming an established part of patient care, with almost 60 per cent following up

their patients' progress. Strengthening patient support in each region is the Hillary Commission's emphasis in the future.

### **How to do it better**

The following lessons may aid those planning future general practice research:

- delay evaluating an intervention's effectiveness until its use is established
- keep implementation of an intervention independent from its assessment
- avoid protocols that impose upon or burden GPs
- keep the design as simple as possible
- introduce checks to ensure protocols are understood and adhered to
- keep the layers of participants (funders, administrators, researchers, practitioners, patients) to a minimum
- establish and maintain efficient communication between all players
- consider a pilot study before embarking on a full-scale project.

In summary, avoid too many layers and too many players: research studies in general practice are most likely to succeed when they are kept simple.

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