

Can behavioural intervention help at-risk people increase their physical activity?

In this section, a panel of multidisciplinary team members give their opinions on a recently published diabetes paper. In this issue, the focus is on the results of a randomised trial investigating which type of behavioural intervention (personal or distance) will help an at-risk group increase their physical activity.



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There have been calls for healthcare professionals to promote physical activity in overweight and obese individuals in response to the obesity epidemic. The results of the ProActive UK trial are therefore timely. This trial differs from many previous trials because the researchers used rigorous methods for measurement of physical activity and energy expenditure. The participants included sedentary adults who had a family history of type 2 diabetes. Unfortunately, the results from the home-based or the telephone-based intervention were no different to the posted advice leaflet. This is surprising because the research team used a well designed theory based behavioural intervention. The intervention was acceptable by the majority of the participants and there was a high rate of completeness for the intervention. There were also no changes in biomedical or anthropometric measurements at the end of the one-year intervention. The study was well conducted, however, as the authors point out, there were limitations. The trial participants

were mainly Caucasian and from a non-deprived population with 98% having a car and the majority owning their own homes. Furthermore, two-thirds of the participants were female and three-quarters of them lived with their children.

So what are the implications of the ProActive UK trial to my clinical care? Previous prevention trials have shown that lifestyle interventions lead to an approximate 50% reduction in development of type 2 diabetes in high risk individuals. However, as seen in previous prevention trials, sustained efforts are needed to change behaviour. Even if the intervention was effective, my primary care trust would not have the resources to provide the level of intervention given in the two more intensive arms of the trial. Furthermore, although a well designed trial, the results cannot be generalisable to all populations including the deprived populations and the non-Caucasian populations. With the trial showing no benefit of an intensive intervention, I will tend to continue my routine practice and also advise my practice nurses and nurse assistants to continue using brief verbal advice supplemented with leaflets for promoting physical activity.



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In our daily work in caring for people living with diabetes, many of whom are overweight and physically inactive, we spend quite a bit of time trying to encourage and motivate them to become more active. We may feel that if only we had more resources we could do a better job. This paper from Professor Ann-Louise Kinmonth and her colleagues gives an interesting insight into this.

It is a very well conducted and very clearly described study. It is an excellent example of good science. The participants were well motivated to improve physical activity due to a family history of diabetes. The 3 interventions being compared were delivered as per protocol and virtually all subjects were eligible for analysis at one year. The main outcome measure was energy expenditure on daytime physical activity, expressed as a ratio to measured resting energy expenditure. Many papers on increasing physical activity use self reported exercise as their outcome so these authors are to be commended for using an

objective measure, even though I guess the majority of us don't understand the measurement or have a grasp of their validity and reproducibility.

The fascinating thing is that giving a leaflet was as effective as a detailed one year behaviour change programme delivered by trained people either in the subjects homes or by telephone. We might say "Thank goodness"! The nation could never afford the resources it would require to deliver such a programme to every sedentary adult in the UK, but perhaps we could afford to give everyone a leaflet!

The suggestion that simple interventions are as effective as more expensive complex ones is reassuring for all of us in our daily one to one discussions with people with diabetes who are physically inactive. Advice on physical activity, encouragement to increase and a leaflet are fairly low cost interventions that we can all do.

The study illustrates how difficult it is to design interventions to get people more physically active at the level of the individual. There is clearly a need for public health and environmental strategies at the population level to increase physical activity.

Efficacy of a theory-based behavioural intervention to increase physical activity in an at-risk group in primary care (ProActive UK): a randomised trial

Kinmonth A-L, Wareham NJ, Hardeman W et al; (2008) *Lancet* **371**: 41-8

THE LANCET

Behavioural intervention has no effect on physical activity

- 1** This study aimed to assess whether behavioural intervention based on theory and evidence would increase physical activity.
- 2** Recruitment occurred between March 2001 and October 2003. Inclusion criteria: must have a parent with type 2 diabetes and must not already have diabetes. Participants were identified because their parents were on diabetes registers at one of 20 general practice clinics in the UK, or from family history records at 7 of the 20 clinics.
- 3** A total of 1521 eligible people were identified, aged 30–50 years, from which 365 sedentary adults with a parental history of type 2 diabetes were enrolled.

4 Participants were assigned to one of three groups (two intervention - IT and IP, and one comparison - CG) all were sent an advice leaflet: the first (intervention by telephone, IT) group followed a behavioural change programme delivered by a facilitator over the telephone; the second (intervention in person, IP) group followed the same programme but it was delivered in the home; the third (comparison group, CG) were sent only the advice leaflet.

5 The behavioural change programme delivered by facilitators focused on eight self-regulatory strategies: goal-setting; action-planning, self-monitoring; using rewards; goal-review; using prompts; support from family and friends; prevention of relapses.

6 The programme lasted one year. Both methods were introduced by a session in the home. The IT group received four 45-minute calls and two 15-minute support calls during the 5-month intensive phase, followed by monthly postal contact for the following 7 months. The IP group received four 1-hour home visits and two 15-minute telephone calls during the 5-month intensive phase, followed by monthly phone calls for 7 months.

7 Data were analysed for 321 (88%) participants for whom the data was available. The proportions analysed in different trial groups remained the same ($P=0.29$).

8 The study showed that IT and IP combined did not have a higher energy expenditure than the CG. IT was no more effective than IP. The physical activity ratio increased in all participants by an average of 0.11 (95% CI 0.05–0.18) which is equivalent to 20-minutes of brisk walking every day.

9 Therefore, less intensive support might be as effective as more costly interventions. Study participation may have had more effect on physical activity than the intervention.

10 The authors conclude by suggesting that approaches based on personal education and individual behaviour change alone are unlikely to increase physical activity in a sedentary culture.



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In the wake of publication of major diabetes prevention trials (Pan et al, 1997; Tuomilehto et al, 2001; Knowler et al, 2002) that have employed various combinations of increased physical activity and dietary interventions, there is a need to understand how such results might be translated into routine clinical practice in a cost-effective manner.

Therefore, this paper by Kinmonth and colleagues is of considerable interest. The authors conclude that healthcare providers should remain cautious about commissioning behavioural change programmes for health prevention. Is this conclusion valid?

This was a carefully designed study. Clearly, there are a variety of contentious issues in the methodology, not least the acknowledged difficulties in measuring free living energy expenditure in humans. However, it is likely that the observed results are true, since there were no significant differences between groups after the intervention in terms of body weight or metabolic variables. This raises the question (acknowledged by the authors) whether the advice leaflet had a significant placebo effect. How does this negative result measure up in view of the apparently positive effects of behavioural interventions on diabetes and its prevention in other

large studies? Several suggestions may be made; the intervention may have been deficient in some way that was unintentional, such as lacking direct contact, direct supervision or a peer-pressure element. Alternatively, the selection of volunteers from real-world primary care, and the specific selection criteria employed here, may have identified a somewhat differently motivated population from the ones identified in other trials – although one would expect a family history of diabetes to be a powerful motivator for behavioural change!

Previous data on diabetes prevention (Pan et al, 1997; Tuomilehto et al, 2001; Knowler et al, 2002) and, more recently, management of established diabetes (Pi-Sunyer X et al, 2007) through behavioural change are convincing in different populations. Increased physical activity appears to be a key component of this. Therefore, this study does not cast doubt on those data, but it certainly does strike a note of caution as we seek to replicate these results in clinical practice. This particular model didn't appear to work. Others may well do so, but further research will be required to identify how diabetes prevention might work in the UK.

Knowler WC, Barrett-Connor E, Fowler SE, et al (2002) *New England Journal of Medicine* **346**: 393–403.
Pan XR, Li GW, Hu YH et al (1997) *Diabetes Care* **20**:537–44
Pi-Sunyer X, Blackburn G, Brancati FL et al, Look AHEAD Research Group (2007) *Diabetes Care* **30**:1374–83.
Tuomilehto J, Lindström J, Eriksson JG et al (2001) *New England Journal of Medicine* **344**: 1343–50.



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The ProActive UK trial reported on by Kinmonth and colleagues in *The Lancet*, on the face of it, generates rather disappointing results. Given what is presented in the article it would be reasonable to conclude that there is little point talking to patients to increase their exercise: just send

them a motivational leaflet! However, I think this trial illustrates two fundamental problems.

Firstly, the trial set out to get people to be more active. In a very sophisticated way, the facilitator set about getting the participants to do what they, the facilitators, deemed was the best thing for the patients. I would argue, that there is good evidence that this kind of approach, done well, can be very effective in the addiction field – including smoking cessation – and good evidence that it is not very effective in lifestyle change. Furthermore, the 'telling' approach is at odds with the notion of informed choice. In contrast, there is evidence that supporting people in making informed decisions about their risk factors and behaviour change options, facilitates more autonomous motivation, a strong predictor of subsequent behaviour change, as increasing physical activity is not the only way to improve health risks.

Instead they chose alternative methods to address their risks. For instance a recent cardiac lifestyle intervention study showed that increases in stress management behaviours were more closely related to changes in metabolic and obesity measures than changes in dietary or exercise behaviours (Daubenmier, et al, 2007).

Secondly, I was surprised that Kinmonth and colleagues do not discuss problems of fidelity. In a separate report (Hardeman, 2008), the ProActive UK team report on the fidelity of the delivery of the intervention. Their analysis on the delivery of the programme, by a sample of their facilitators, indicates that 'observed adherence to techniques across participants was modest (median 44% IQR 35 – 62%).'

Further adherence decreased across intervention sessions. This is a perennial problem in this field of research, and one wonders why researchers continue to evaluate interventions, without first confirming the programme will be delivered as it is intended to be. This raises the question as to how much we attribute the null result to the failure of the intervention, or the failure of the implementation of the intervention.

Daubenmier JJ (2007) *Annals of Behavioural Medicine* **33**:57–68.
Hardeman W (2008) *Psychology and Health*, **23**: 11–24