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Link to published version (if available):
10.1002/pdi.1866

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Self-care and misplaced confidence: a randomised controlled trial of provision of VibraTip for patients with diabetes at high risk of complications

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Received: 3 April 2014
Accepted in revised form: 25 April 2014

Abstract
The aims of this study were to assess the feasibility of a randomised controlled trial of foot care using patients recruited from the retinal imaging clinic, and to determine whether in addition to standard care and advice, giving patients with diabetes a VibraTip would enhance confidence in foot self-care.

Sixty subjects recruited in retinal imaging clinics were randomised to receive a standard foot care leaflet, or leaflet plus VibraTip with a demonstration of its use. VibraTip recipients were encouraged to take it home but given no further instructions. Participants were asked to complete a ‘confidence in self-care’ questionnaire at enrolment and follow up, six months later.

Recruitment was completed in three, all-day clinics. Follow-up rates were also high with only one subject lost from each group. Confidence in the ability to check feet for sores or blisters rose in the control group from 90.4% to 96.6% and fell from 90% to 88.6% in the VibraTip group.

The feasibility results indicate that large randomised controlled trials in this patient group would be achievable for short educational interventions. Although only a feasibility trial, the study suggested that, if anything, providing VibraTip might actually cast doubt in the minds of patients with diabetes who had been very confident that they could look after their feet. Self-confidence may be more likely to foster complacency than behaviours likely to minimise risk of harm. Copyright © 2014 John Wiley & Sons.

Practical Diabetes 2014; 31(5): xxx–xxx

Key words
neuropathy; vibration perception; education

Introduction
More than half of the 2.8 million patients with diabetes in the UK are destined to develop diabetic neuropathy and, with it, increased risk of tissue damage and loss. Current educational and psychosocial interventions have at best relatively small and transient beneficial effects on diabetic outcomes.1–3 There is good evidence that complications are minimised by optimising diabetic control,4 but in the real world lifestyle modifications to achieve this are almost impossible to sustain.

The problem is how to conduct large scale trials of different educational interventions cheaply enough to make small gains in health status cost effective. Persuading patients with diabetes to take extra care of their feet when they are not experiencing any discomfort could take many forms but each could have a small effect size and be cost effective due to the great numbers of people with this condition. The emphasis on methodology to establish the presence of diabetic neuropathy seems misplaced as those without neuropathy remain at risk of developing it, and may be no less receptive to education and advice at a time when rehearsing appropriate behaviours might be advantageous in the long term.

The present study was designed to exploit an alternative and more tangential approach akin to those used ubiquitously by the advertising industry and, in so doing, evaluate methodology for trialling a short educational intervention.

VibraTip (Figure 1) is a key fob-sized device that provides a constant source of gentle vibration when squeezed firmly between finger and thumb. It is as effective as other sources of vibration for detecting the presence of impaired vibration sensation.5,6 As well as being highly functional, however, VibraTip is novel, inexpensive, clean, safe and like manual toothbrushes and wet
razors that house vibrating motors, has particular consumer appeal and aesthetic utility.

The principal aim of the study was to see whether, in addition to standard care and advice, giving patients with diabetes presenting for retinal imaging a VibraTip to take home – not necessarily to use but certainly to ‘engage with’ – would enhance confidence in foot self-care and potentially improve foot safety. We hypothesised that a VibraTip left on the bedside table, for example, had the potential to remind patients with diabetes to put their hands in their shoes before putting their feet in them, first thing in the morning.

Further, we anticipated that VibraTip might evoke the ‘pester power’ of grandchildren, who might ask what the device is, play with it, and indirectly raise the profile of diabetic foot problems by asking their grandparents what the device is for, how it works and whether they could try it out.

Patients and methods

Patients with diabetes were recruited from the retinal imaging clinics in the Bristol Eye Hospital. They consisted almost entirely of patients with fairly long-standing diabetes and constituted a large, captive population, already attending hospital at set intervals, who were at increased risk of complications and in possession of a relatively compelling reason to modify risk-taking behaviour.

Subjects attending the retinal imaging clinics were alerted to the study by a letter sent home. Those who opted for further consideration were approached by a trained member of staff while waiting in the retinal imaging clinic for their follow-up appointment to take place. This included patients who had been screened in the community and needed further review. Almost all had some degree of diabetic retinopathy. Recruitment for the study of 60 patients was completed in three weeks (three clinics).

Subjects were consented for the study and given the patient information sheet. They were randomised using the sealed envelope system (www.sealedenvelope.com/protocols.php) to either an educational package consisting of the trust’s standard foot care leaflet alone, or an enhanced package containing the above but followed by a demonstration of how to test for sensory loss using VibraTip on their foot or lower leg, or, if it was inconvenient to expose the lower limb, on their hand.

The technique demonstrated entailed holding VibraTip between thumb and forefinger firmly, and applying its rounded tip as gently as possible to the subject’s skin twice, each time for about half a second. VibraTip was randomly activated on either the first or second touch and the patient asked which of the two touches vibrated. By explaining during the test that ‘this is touch one and this is touch two’, any slight noise from the device was obscured, making the test highly specific for vibration sensation. People given VibraTip were encouraged to take it home but were given no further instructions about its use or storage.

Participants were asked to complete a validated 21-question ‘confidence in self-care’ questionnaire and were helped if required.

The questionnaire was repeated on follow up six months later (or at the nearest routine follow-up appointment to six months) to see whether the perception of ability to self-care had changed. In the event that the subject was unable to attend for follow up, the questionnaire was completed by phone.

Statistical methods. Means and standard deviations were reported for the groups at baseline and six months. Follow-up rate percentages were reported with 95% confidence intervals calculated using the exact binomial method. The outcome scores of health-related quality of life, confidence in care, and the foot care item of the confidence in care questionnaire were analysed using an analysis of covariance (ANCOVA) to control for baseline when examining the difference between the two randomised groups. P-values for the difference between the groups have not been calculated; however, to aid the planning of a future trial, effect sizes with 95% confidence intervals are reported with the standard deviation coming from the ANCOVA results.

Results

Table 1 shows the means ± SD for the three variables of interest at baseline and six months in the information pack only group and the VibraTip + information pack groups – one patient from each group was lost to follow-up (1/29; 3.4%). High scores for the EQ-5D represent increased health-related quality of life, and higher scores for the confidence in care questionnaires represent more confidence. It should be noted that this population reported confidence in care scores that were higher than expected, with seven patients recording absolute confidence on all items at baseline in spite of their referral with suspected retinopathy.

Patients with diabetes were recruited from three, all-day clinics (averaging 20 patients per clinic) at an average rate of one subject every 24 minutes and 20 recruited patients for every 24 patients booked (a recruitment rate of >80%). Follow-up rates were 96.7% (58/60) with 95% confidence interval (88.5%, 99.6%) calculated using the exact binomial method.

Effect sizes were calculated with 95% confidence intervals to aid in the planning of further studies. Health-related quality of life worsened by 0.02 standard deviations representing a very slight worsening of health for the intervention group compared with the control group (95% CI -0.51, 0.55). Confidence in care and the foot care items showed a decrease in confidence for the intervention group of 0.27 and 0.52 standard deviations respectively, a small and a medium effect size (95% CIs -0.27, 0.80 and -0.02, 1.07 respectively).
Discussion and conclusions
The study confirmed that it is feasible to recruit subjects in the retinal imaging clinic but showed, if anything, that confidence in self-care was adversely affected by giving patients with diabetes a VibraTip to take home in addition to standard foot care guidance. This led us to question the hypothesis that confidence in self-care is desirable in itself and, although not directly addressed in the present study, that confidence would correlate with competence in self-care and in the longer term, with a reduction in complications. Although insufficiently powered to provide a clear outcome in terms of confidence in self-care and in general health perception as assessed by the EQ-5D instrument, the study suggested that providing VibraTip might actually cast doubt in the minds of patients with diabetes who until that point had been completely confident that they could look after their feet.

On reflection, complete confidence in the ability to self-care or that, for example, the absence of symptoms implies impeccable diabetic control, might not be optimal positioning to foster behaviours that minimise risk. Indeed, self-assurance may be more likely to foster complacency than behaviours expected to minimise risk of harm. The uncertainty is the point at which a strategy that reduces self-confidence becomes counter-productive, causing disempowerment and fatalism, instead of encouraging self-help and self-care.

To quote Darwin: ‘Ignorance more frequently begets confidence than does knowledge: it is those who know little, and not those who know much, who so positively assert that this or that problem will never be solved by science.’

Declaration of interests
Funding: NIHR Research Capacity Funding linked to NIHR Senior Investigator Award.

A Levy designed and was involved in the development of VibraTip as an honorary employee of University Hospitals Bristol NHS Foundation Trust, who in turn own the intellectual property.

Key points
● Retinal imaging clinics attract an ideal population for diabetic complication trials. Very rapid recruitment of 60 people with longstanding diabetes was achieved from only three such clinics
● Self-awareness rather than self-confidence might be the key to reducing diabetic complications

References

Table 1. Self-reported health-related quality of life, confidence in self-care and confidence specifically in foot self-care in patients with diabetes attending retinal imaging clinic at baseline and 6 months after being given either a standard foot care leaflet alone, or a leaflet with a VibraTip to take home (intervention group). In response to the statement ‘I believe I can check my feet for sores or blisters every day’, patients with diabetes rated their ability from ‘1 – No, I am sure I cannot’, to ‘5 – Yes, I am sure I can’, with ‘4’ being ‘Yes, I think I can’.