Management of type 1 diabetes

Glycaemic control and trial participation

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Nearly 2 decades ago, I heard the late Tony Mitchell (Professor of Medicine at the University Hospital in Nottingham) say that every patient should be in a study. Tony was a wise and astute clinician, and the paper by J Hans De Vries et al reviews what is known about the 'study effect' in type 1 diabetes. There is little published, but that which exists suggests that the study effect may have a significant impact on, for example, glycaemic control – with temporary improvements in HbA_{1c} by 1% for up to 16 weeks. This has important implications for both study design and the interpretation of uncontrolled studies.

The De Vries study consisted of a 14 week run-in period before randomisation to either pump therapy or optimised multiple injection therapy. Improvements were seen in glycaemic control, treatment satisfaction and coping scores following a 30 minute education session during week two. It is not clear if patients were seen again before the end of the run-in.

The study by Viner et al used motivational and solution focused techniques in a group setting, weekly for six sessions for teenagers with poor glycaemic control. This was a controlled but non-randomised study and there was no mention of either knowledge testing, insulin regimen or skills training. The 1.5% fall in HbA_{1c} over the next 3 months was impressive and was partly sustained 7–12 months later.

The reasons are not clear but as metabolic control was so poor initially, it is likely that a reduction in the omission of insulin will have been partly responsible. The important message from these two papers is the need for robust study designs before adopting new treatment approaches, and the benefits patients gain from being studied.

DIABETES METABOLISM RESEARCH AND REVIEWS

Improved glycaemic control after participation in trial

Readability	✓✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! factor	✓✓✓✓

1 Various randomised controlled trials have shown an improvement in glycaemic control in the standard treatment group as well as the intervention group. Glycaemic control has also been shown to improve in the run-in phase before randomisation in some trials. This 'study effect' has received little attention in the literature.

2 This article reviews the effects of glycaemic and psychological outcomes in patients with long-term poorly controlled type 1 diabetes who are participating in a qualification phase of a good clinical practice trial.

3 The authors describe a study in which they incorporated a 14-week qualification phase before randomisation to uncover any 'study effects'.

4 There was a substantial improvement in glycaemic control during the phase before randomisation in a sample of patients with previously poor control.

5 This improvement could be due to the education given in the run-in phase or the increased frequency of self monitoring of blood glucose observed during the study.

6 Therefore, benefits seen in uncontrolled trials should be interpreted with caution.

7 A run-in phase of adequate duration should precede randomisation in order to stablise glycaemic control before the study.

DeVries JH, Snoek FJ, Kostense PJ, Heine RJ (2003) Improved glycaemic control in type 1 diabetes patients following participation per se in a clincal trial – mechanisms and implications. Diabetes Metabolism Research and Reviews **19**: 357–62

DIABETIC MEDICINE

Motivational intervention improved HbA_{1c}

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! factor	✓✓✓

1 There is evidence to suggest that young people with diabetes are often the most difficult to engage.

2 This non-randomised pilot study examined the effects of motivational therapy on the glycaemic control of young people with poorly controlled type 1 diabetes (HbA_{1c} >8.5%).

3 A total of 21 young people received six weekly sessions of motivational and solution focused therapy. This group were matched with 20 controls in terms of age, HbA_{1c}, duration of diabetes and socioeconomic status.

4 There was a 1.5% improvement in HbA_{1c} at 4–6 months postintervention in the intervention group compared with no change in the control group ($p<0.05$). This improvement was maintained at 7–12 months postintervention.

5 However, there was no association between motivational stage and HbA_{1c} level.

6 Self selection of participants to the intervention group and the inclusion of some patients with very poor metabolic control could have inflated the effects of the intervention.

7 Motivational therapy is useful for the improvement of HbA_{1c} in young people but this needs to be investigated further in a randomised controlled trial.

Viner RM, Christie D, Taylor V, Hey S (2002) Motivational/solution-focused intervention improves HbA_{1c} in adolescents with type 1 diabetes: a pilot study. Diabetic Medicine **20**: 793–42