A Multicenter Randomized Controlled Trial of Motivational Interviewing in Teenagers With Diabetes

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OBJECTIVE — We sought to examine the efficacy of motivational interviewing with teenagers aged 14–17 years with type 1 diabetes.

RESEARCH DESIGN AND METHODS — In a randomized controlled trial analyzed by intention to treat, 66 teenagers with type 1 diabetes attending diabetes clinics in South Wales, U.K., were randomly assigned to the intervention group (38) and control group (28). Teenagers in the intervention group received motivational interviewing, and the control group received support visits. All participants received individual sessions over 12 months. The main outcome measures assessed at baseline, 6, 12, and 24 months were serum A1C and psychosocial self-report questionnaires including quality of life and well-being measures.

RESULTS — At 12 months, 60 patients had complete data. At the end of the intervention (12 months), the mean A1C in the motivational interviewing group was significantly lower than in the control group ($P = 0.04$), after adjusting for baseline values. At 24 months (when $n = 47$), this difference in A1C was maintained ($P = 0.003$). There were differences in psychosocial variables at 12 months, with the motivational interviewing group indicating more positive well-being, improved quality of life, and differences in their personal models of illness (all $P < 0.01$). Some of these differences were maintained at 24 months.

CONCLUSIONS — Motivational interviewing can be an effective method of facilitating behavioral changes in teenagers with type 1 diabetes with subsequent improvement in their glycemic control.

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Type 1 diabetes is the third most common chronic illness in teenagers (1). It imposes physical and emotional burdens on young people and their families (1) and can have a profound effect on quality of life (2). The beneficial effects of favorable glycemic control in the prevention of long-term complications are well documented (3). However, recognition of the impact of psychosocial factors on self-care during adolescence has led to a focus on psychosocial interventions to improve outcomes.

A review of educational and psychosocial interventions for adolescents with type 1 diabetes (4) concluded that there was a need for more well-designed trials of such interventions, particularly in the U.K. health care context. Motivational interviewing, a counseling approach to facilitate behavioral change (5), has been demonstrated as effective in adults in some health care settings (6,7), and there is preliminary evidence of its effectiveness in improving glycemic control and psychological well-being in teenagers with type 1 diabetes in short-term, uncontrolled trials (8,9). The multicenter randomized controlled trial reported here was developed to replicate and extend the findings of the pilot study (8), employing a fully powered design and an evaluation of longer-term outcomes.

RESEARCH DESIGN AND METHODS

Aims and hypotheses

The aim of this study was to examine the impact of motivational interviewing, compared with the control intervention of support visits, on serum A1C concentrations and psychosocial functioning in adolescents with type 1 diabetes. We hypothesized that, compared with the control group, motivational interviewing would improve psychosocial functioning and reduce A1C concentrations.

Design and participants

This study was designed as a multicenter trial of a complex intervention, providing a phase II level of evidence of efficacy (10). Each intervention was delivered by one person for all participants in their arm of the study. Following randomization, participants received either motivational interviewing or support visits for 1 year with a 12-month follow-up. The interventionists worked independently from the diabetes clinics. Clinic staff were unaware of which children were participating in the study, and participants were unaware to which arm of the trial they had been randomized. The study received ethical approval from the local research ethics committees.

Participants were recruited from five diabetes services between January and September 2002. The centers with diabe-

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A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

tes clinics ranging between 49 and 220 patients were all in the industrially developed region of South Wales. All individuals aged between 14 and 17 years with type 1 diabetes, regardless of glycemic control, attending diabetes clinics in the participating centers were eligible, with the following exceptions: those with <1 year since diagnosis, learning disabilities, other medical conditions affecting diabetes management, medical care predominantly managed elsewhere, or accommodation by social services.

The diabetes nurse specialists for each center sent information about the study to all eligible patients and to their parent/guardian. Following consent to contact, the patients were seen by the researcher and given further information about the study. Informed consent was obtained both from the patients and their parent/guardian before randomization.

In order to detect a difference of 1% in mean A1C (SD = 1.2%) at a 5% significance level with 90% power, 30 patients per group would be required. To allow for a loss to follow-up rate of 25%, we aimed to recruit 80 patients.

Randomization

Participants for each center were all recruited and completed the baseline assessments before being randomized into one of two groups using randomly permuted blocks of four. One group received motivational interviewing, and, to control for the effect of additional contact, the control group received support visits. Randomization was completed independently and remotely stratified by sex and clinic.

Interventions

There were two female interventionists, both with a nursing background. The motivational interviewing interventionist was in training as a health psychologist. The motivational interviewing intervention (described in Channon et al. [11]) used the "menu of strategies" approach (12,13), eliciting patient views and then exploring discrepancies between beliefs and behavior. While no two motivational interviewing sessions will be the same, as they are patient driven, they are likely to include the following aspects.

Awareness building. The clinician's role is to help the patients articulate their simultaneously held but conflicting beliefs about behavioral change. In making decisions about changing behavior, individuals weigh up the benefits of making the change against the personal costs, which may be social, emotional, or financial. Their ambivalence about making that change reflects the balance of those benefits and costs; the clinician's role is to elicit them and increase the patient's awareness of them.

Alternatives. Once the patients are more aware of the costs and benefits of their behavior, alternatives to the current behaviors are considered.

Problem solving. Having identified alternative behaviors, the costs and benefits of the different options are discussed.

Making choices. The selection of an alternative behavior to implement rests with the patient.

Goal setting. Once the alternative behavior has been chosen, the clinician and patient set a goal that is realistic and achievable in the time between appointments.

Avoidance of confrontation. One of the central tenets of motivational interviewing is avoidance of confrontation, to reduce resistance and argumentation. Instead the style is one of eliciting, using open-ended questions to encourage participants to articulate their concerns and goals.

The control intervention was nondirective psychological support with the aim of providing support, information, and education in a patient-centered style. Both interventionists received fortnightly supervision to ensure quality control and, where possible, interviews were recorded via audiotape. A sample of the motivational interviewing tapes was also reviewed by external motivational interviewing trainers to ensure fidelity of the method to the tenets of motivational interviewing. In neither group was advice given regarding changes in insulin regimen; all these issues were directed to the participant's diabetes team.

For participants in the motivational interviewing group, the frequency and location of appointments was determined by the participants to fit with the patient-driven principles of motivational interviewing. In the control group, the pattern of visits was more structured, with appointments arranged every 6–8 weeks, a frequency based on contact data from the pilot study, to control for anticipated level of contact in the motivational interviewing group.

Intervention delivery took place between July 2002 and September 2003, mostly in participants' homes, with some interviews conducted in cafes or parks, etc., and lasting between 20 and 60 min. Interviews finished after a maximum of 12 months' contact for each individual. The mean number of visits was six for the control group participants and four within the motivational interviewing group.

Primary and secondary outcome measures

The primary outcome measure was mean serum A1C concentration, measured at baseline, 6, 12, and 24 months. The secondary outcome measures were psychosocial questionnaires completed independently by the participants. The measures used (and domains they measured) were as follows: *1*) The Diabetes Quality of Life Measure for Youths (14) measured life satisfaction, disease impact, and disease-related worries. *2*) The Child Health Locus of Control (15) studied the locus of control in relation to health issues. *3*) The Modified Health Care Climate Questionnaire (16) assessed perceptions of the degree of autonomy support from health care providers. *4*) The Diabetes Knowledge Scale (17) measured knowledge about diabetes. *5*) The Self-Efficacy for Diabetes Scale (18) assessed self-efficacy beliefs. *6*) The Well-being Questionnaire (19) assessed depressed mood, anxiety, and positive well-being. *7*) The Diabetes Family Behavior Scale (20) studied diabetes-specific family support. *8*) The Personal Models of Diabetes Scale (21) looked at personal beliefs and models of illness. All the questionnaires were completed at baseline and 12 months, with the Diabetes Quality of Life Measure for Youths and Well-Being Questionnaire also completed at 24 months.

Data collection and collation

The baseline A1C and psychosocial data collection was completed before the start of the intervention. All capillary blood samples for A1C measurement were mailed to a single independent clinical biochemistry department and analyzed by high-pressure chromatography. The coefficients of variation (CVs) within and between the A1C assays were <1.15 and <1.75%, respectively. Questionnaire data were collated and coded onto SPSS Software, version 11. Follow-up data were collected between June and September 2004.

Statistical analysis

To compare the two groups, a repeated-measures ANCOVA was performed with

A1C concentrations at 6, 12, and 24 months and the baseline measurement treated as the covariate. Analysis is presented for the effect of the intervention immediately postintervention, as well as the overall analysis across all time points.

For each of the psychological scales, participants with ≤20% of scale items missing were imputed by using the mean values of the remaining items. ANCOVA was used to compare the groups with respect to their individual psychosocial measurements at 12 and 24 months, again using baseline as the covariate. To allow for multiple comparisons, a Bonferroni correction was used.

Exploratory analysis of the associations between changes in key psychosocial outcomes during treatment (0–12 months) with subsequent changes in A1C (12–24 months) was conducted within groups using Pearson's correlation coefficients. All analyses were carried out on an intention-to-treat basis.

RESULTS — The flow diagram (Fig. 1) shows the trial profile. Of the original 169 eligible patients, 80 agreed to participate and were randomly allocated to either motivational interviewing (n = 43) or support visits (n = 37). One participant randomized to the control group was ineligible. A total of 13 patients (5 in the motivational interviewing group and 8 in the control group) declined to participate after randomization but before the first visit. Analyses were based on the remaining 66 participants, of whom 60 had complete A1C data at 12 months.

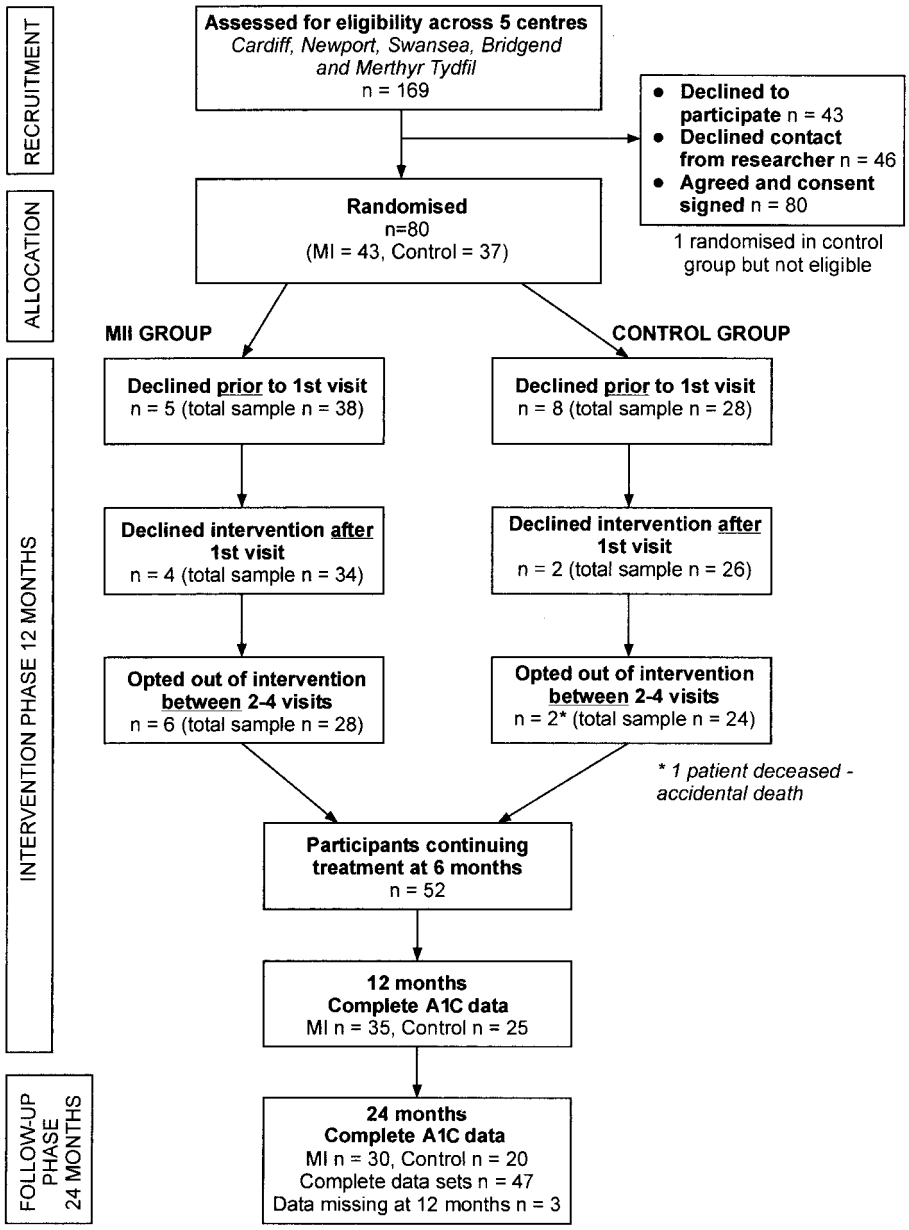

Figure 1—*Flow chart of participants through each stage of the trial*

Demographic characteristics

Participants in the motivational interviewing and control groups were well matched for age (15.3 ± 0.97 and 15.4 ± 1.19 years, respectively), duration of diabetes (9.2 ± 1.96 and 9.1 ± 1.47 years), ethnicity (all Caucasian), sex (47 and 50% male) and socioeconomic status (median group 4 and 3). There were no significant differences between the two groups with respect to the baseline characteristics of age, duaration of diabetes, sex, and A1C. The mean A1C for the five participating centers ranged from 8.4 to 10.0%, and for the participants the range was 8.8 to 10.3%. There were a variety of insulin regimens across both groups, with participants all injecting insulin 2–4 times daily.

Attrition

More participants withdrew from the motivational interviewing intervention in the first 6 months (n = 10) than from the control group (n = 4), but this was not statistically significant (P = 0.24). There were no significant differences between these participants and those who continued with respect to baseline characteristics, A1C, or psychological outcomes.

Primary outcome measure: serum A1C concentration

At the end of the year-long interventions, the mean A1C concentrations between the two groups were significantly different (F = 4.276, P = 0.04) (Table 1) after adjusting for baseline. This effect was maintained 1 year after completion of the intervention, 24 months after starting the study (F = 9.707, P = 0.003).

Although every effort was made to ensure a complete A1C dataset for each participant, this was not achieved because of lost or insufficient samples or participants discontinuing the study or being unavailable for sampling. The analysis of the mean A1C concentrations in the 47 participants with a complete dataset (i.e., four measurements) is shown in Table 1. The patterns of change were similar to those seen when all participants' data, including those with incomplete data, were analyzed.

Table 1—*A1C levels at baseline, 6, 12, and 24 months for participants with complete data*

Time point	MI group (n = 27)	Control group (n = 20)	Difference between groups
Baseline	9.3 ± 2.11	9.0 ± 1.56	0.3 ± 1.90 (−0.80 to 1.40)
6 months	9.0 ± 1.63	9.5 ± 1.93	−0.5 ± 1.76 (−1.52 to 0.52)
12 months	8.7 ± 1.84	9.2 ± 1.78	−0.5 ± 1.81 (−1.55 to 0.55)
24 months	8.7 ± 1.88	9.1 ± 1.51	−0.4 ± 1.73 (−1.40 to 0.60)

Data are means ± SD (95% CI). MI, motivational interviewing.

Secondary outcome measures: psychosocial questionnaires

There were no baseline differences between groups in any of the psychosocial measures. Differences were found between groups in well-being, quality of life, and personal models of illness after 12 months (all $P < 0.001$) (Table 2). Compared with the control group, the motivational interviewing group had higher life satisfaction, lower life worry, experienced less anxiety, and had more positive well-being. The motivational interviewing group also perceived their diabetes to be more serious and placed greater importance on controlling it. They had stronger beliefs that certain actions were more likely to help prevent future complications of diabetes and perceived it to have a smaller degree of impact on their lives.

At 24 months, although fewer questionnaires were completed (n = 34), significant differences were still found between the two groups with respect to life worry and anxiety (F = 17.795, P = 0.001 and F = 18.908, respectively; $P <$ 0.001). Differences in satisfaction and impact were also significant at 24 months (F = 7.007, P = 0.012 and F = 8.129, respectively; P = 0.008).

Exploratory analysis of the associations between changes on key psychosocial measures during the intervention phase and subsequent levels of glycemic control showed that increasing worry and reduction in satisfaction from 0 to 12 months in the motivational interviewing group were significantly associated with improvements in A1C from 12 to 24 months (r = −0.40, P = 0.03 and r = −0.61, $P <$ 0.001, respectively). There were no significant associations between these measures and subsequent control in the support group (r = 0.31 and r = 0.22, respectively), and the directions of association were the opposite of those found in the motivational interviewing group.

CONCLUSIONS — The results of this study show that motivational interviewing can be an effective method of working with teenagers with diabetes, producing long-term improvements in glycemic control, psychological well-being, and quality of life. Their personal models of illness indicated a stronger belief that self-care could make a difference to diabetes outcomes.

The study reported here is the first randomized controlled trial of motivational interviewing in childhood diabetes. It extends the evidence and confirms the beneficial impact of psychosocial interventions based on the principles of motivational interviewing that have been previously reported in smaller-scale stud-

Table 2—*Psychosocial measures at 12 months*

Measure	Intervention group	Control group	F	P
DQoLY				
Satisfaction*	33.28 ± 9.88	45.55 ± 10.79	31.769	<0.001
Impact*	50.49 ± 12.05	61.05 ± 18.48	9.553	0.003
Worries*	17.71 ± 7.15	30.23 ± 11.59	22.209	<0.001
CHLC	15.88 ± 2.59	16.40 ± 1.95	0.034	NS
HCCQ	78.06 ± 20.34	84.25 ± 13.30	0.010	NS
DKN	11.16 ± 1.86	11.75 ± 1.77	1.406	NS
SEDS	175.92 ± 22.73	169.85 ± 27.45	0.733	NS
WBQ				
Depression	10.08 ± 2.25	11.85 ± 1.81	4.326	0.044
Anxiety	6.03 ± 2.23	11.55 ± 3.69	41.267	0.001
Energy	6.19 ± 1.86	7.20 ± 2.31	2.086	0.156
Positive well-being	14.48 ± 3.20	10.24 ± 3.27	22.923	<0.001
Total well-being	40.56 ± 4.51	30.31 ± 5.90	39.419	<0.001
DFBS	145.56 ± 20.64	155.57 ± 16.45	1.162	NS
PMDQ				
Importance	32.58 ± 5.06	22.84 ± 4.02	64.776	<0.001
Likely	41.46 ± 6.25	29.52 ± 5.54	59.056	<0.001
Worry	33.19 ± 8.76	24.78 ± 5.98	13.605	<0.001
Agree/disagree	28.32 ± 5.66	34.52 ± 6.23	13.845	<0.001
Total	135.55 ± 15.30	111.66 ± 10.97	44.642	<0.001

Data are means ± SD unless otherwise indicated. *Lower score indicates higher quality of life. CHLC, Child Health Locus of Control; DFBS, Diabetes Family Behavior Scale; DKN, Diabetes Knowledge Scale; DQoLY, Diabetes Quality of Life Measure for Youths; HCCQ, Modified Health Care Climate Questionnaire; PMDQ, Personal Models of Diabetes Scale; SEDS, Self-Efficacy for Diabetes Scale; WBQ, Well-Being Questionnaire.

ies (8,9). Furthermore, this study is one of very few that demonstrate, using a randomized control study design, the potential of a psychosocial intervention to improve glycemic control in children with diabetes over a time period as long as two years (4). Given the potential benefit of improved glycemic control on the future risks of developing microvascular complications of diabetes (3), our results suggest that psychosocial interventions such as motivational interviewing may be of value in addition to pharmacological developments in reducing the longer-term adverse consequences of diabetes.

This was a robust study across centers representing a variety of demographic and clinical contexts with high-quality intervention delivery, closely monitored to ensure adherence to the documented approaches. However, there were also some recognized weaknesses. By using two interventionists, the outcome could be interpreted as therapist effect rather than resulting from motivational interviewing. However, both interventionists were closely supervised to ensure fidelity to the method of their respective interventions, and this design was selected as the best possible for this phase of intervention development. The next phase would be a multicenter trial with multiple interventionists.

Another possible explanation for the improvement in glycemic control in those receiving motivational interviewing may relate to changes in insulin regimen. Unfortunately, these data were not collected during the trial, but a retrospective analysis of a subsample of participants shows no evidence of a difference in frequency of change in insulin regimen between groups (data not shown). This would be a measure that would need to be incorporated into any larger-scale trial.

Some attrition was inevitable in a multicenter clinical trial with a 2-year period of data collection. The volume of questionnaires was overwhelming for participants, leading to the decision at 24 months to collect psychosocial data only on well being and quality of life to avoid the risk of losing all the follow-up data. There were few exclusion criteria, and as a result we recruited some participants who already experienced good glycemic control in whom behavior change may have been unrealistic. Within a service setting, it might be more appropriate to focus this intervention on young people with A1C >8%, in whom there was a degree of readiness to change—a group who realistically would be the target for the clinical teams.

The results show a rise, albeit statistically nonsignificant, in A1C concentrations in the control group during the first six months with a return to baseline levels after one year. This phenomenon persists whether data for all participants or only those with complete data sets are analyzed and was not seen in those receiving motivational interviewing. A possible explanation for this rise is a seasonal effect as this data period coincided with winter, when glycemic control is known to deteriorate in children, presumably because of decreased levels of physical activity (22).

The results of our study demonstrate an association between changes in certain psychological variables and changes in A1C, the latter increasing in significance with time. Although cause and effect cannot be assumed, if psychological factors were to impact A1C, it might be anticipated that such psychological changes would precede changes in self-care, which consequently led to changes in A1C concentrations. Our analyses suggest that motivational interviewing might highlight concerns (with the reduction in satisfaction between baseline and 12 months) but also facilitate the patients' perception that they had the capacity to make changes that in turn would lead to reduction in A1C. One possible theoretical explanation for these results could be taken from the work by Draycott and Dabbs (23,24), who mapped the principles of cognitive dissonance onto the principles and method of motivational interviewing. The method of motivational interviewing incorporates the principle of "deploying discrepancy" in which the patients' core values and personal aspirations are contrasted, through empathic listening, with the behavioral problem under discussion. It is hypothesized that this experience of discrepancy could trigger the motivation to change behavior.

A systematic review of the literature of psychosocial interventions in childhood diabetes concluded that well-designed studies of such interventions are required (4), and our study meets many of their criteria. It has demonstrated that a psychosocial intervention can have a significant impact on psychosocial variables and A1C concentrations in a representative group of teenagers. Further work is required to determine whether motivational interviewing is more suitable for certain subgroups of children and whether the independence of the intervention from the clinic, both in terms of venue and practitioners, is essential to its success. Furthermore, to maximize the value of this intervention, it would be important for the intervention to be part of routine care. Given the shortage of skilled child psychologists and psychiatrists available to support pediatric diabetes services, the next research priority is to identify the key components of motivational interviewing that successfully result in behavioral changes in teenagers, with a view to developing training of clinicians working in pediatric diabetes services to use these skills as part of everyday clinical care.

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