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The Effects of a Family-Based Intervention on Regimen Adherence and Metabolic Control of Adolescents with IDDM: A Randomized Controlled Outcome Study

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ABSTRACT

Patients with insulin-dependent diabetes mellitus (IDDM) must adhere to a complex treatment regimen. Adherence is often poor during adolescence, when the regimen behaviours may interact negatively with many of the developmental tasks. In a randomized controlled outcome study, 15 adolescents and their families participated in a family-based intervention for improving adherence to the diabetic regimen. Fourteen comparison group adolescents with IDDM spent a comparable amount of time learning stress management techniques. Adolescents in both groups attended a diabetes management review session with the clinic nurse. Inclusion criteria included mean glycosylated hemoglobin (HbA1c) levels > 9.0% over the previous nine months. At a 6-month follow-up, adolescents in the family intervention group were testing blood glucose levels more regularly ($p < .001$). Both groups demonstrated significant improvements in mean HbA1c levels over the period of the study ($p < .0005$). One third of the adolescents in the family intervention group, with pretreatment HbA1c levels of 10.0%-13.0%, had levels < 8.0% at follow-up. No adolescent in the comparison group achieved values in this range ($\chi^2 = 5.62$, $p = .05$). When mean HbA1c levels 9 months before treatment were compared to mean levels after treatment, more adolescents in the comparison group showed deterioration in glycemic control of > 1% (0% vs.29%, $\chi^2 = 6.32$, $p = .05$). Methodological issues were discussed.

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INTRODUCTION

It is estimated that 10% of all children will have experienced a chronic physical disorder by age 18 (Pless, Roghmann and Haggerty, 1972). Chronic illnesses such as diabetes and cystic fibrosis are treatable, but they are not curable. This means that the illness must be "managed" in some manner for the rest of the patient's life. Although the physician remains involved in the patient's medical care, much of the treatment depends on the daily self-care behaviours as well as the family's ability to motivate and offer support to the patient. Patients on long-term regimens are at risk for compliance problems (Haynes, Tayler and Sackett, 1976). This is particularly true during the period of adolescence (Dunbar, 1983; Friedman and Litt, 1987), when families often have difficulty striking the right balance between involvement in the regimen tasks and allowing adolescents increasingly more responsibility for their self-care. The medical consequences of poor adherence to medical regimens can be costly from a therapeutic and health-delivery perspective, and can add to the stresses and demands that are already placed on a family with a chronically ill child. This has prompted investigations of psychosocial factors such as characteristics of the family environment that are associated with regimen adherence and/or health status. The reasoning behind this research is that if causal factors can be delineated, interventions to improve adherence to the medical regimen can be developed.

There is a great deal of evidence in support of the contention that "the family constitutes perhaps the most important social context within which illness occurs and is resolved" (Litman, 1974, p.495). Families play an important role in many aspects of compliance to medical regimens (Becker and Green, 1978; Baranowski and Nader, 1985)). What is lacking is empirical evidence that

intervening with families makes a difference with respect to the management of the illness and the health of the patient (Doherty, 1985; Pless, 1984). Baranowski and Nader (1985) write, "We found no literature in which an intervention for promoting regimen compliance by involving families was evaluated with a pediatric population" (p.98).

There is a major contribution of self-care behaviours in the treatment of diabetes (Surwit, Feinglos and Scovern, 1983). This makes it a "model disease" for exploring contextual factors such as family interactions that either promote or interfere with the regimen behaviours and for applying this knowledge to the design of a pragmatic family-based intervention for improving adherence in diabetic adolescents.

The following review of the research literature will look at: (1) the extent and nature of adherence problems in adolescents with insulin-dependent diabetes; (2) factors other than regimen adherence that may influence metabolic control; (3) family determinants of adherence to the diabetic regimen; and (4) interventions for improving adherence and/or metabolic control. But first an overview of diabetes and diabetes management will be provided.

1. Overview of Diabetes and Diabetes Management

Insulin-dependent diabetes mellitus (IDDM), or Type I diabetes, is the most common endocrine disease found in children. A Canadian study conducted between 1976-79 in the Montreal area showed an overall juvenile diabetes incidence of 9.05 per 100,000 children under the age of 17 (Belmonte, 1983). It results from the body's insufficient production of insulin due to the destruction of the beta cells of the pancreas. Insulin is responsible for maintaining appropriate levels of blood sugar. When secretion is deficient, the body loses its ability to utilize and store sources of energy (fats, carbohydrates, sugars), and, in particular, to transport glucose to the cells.

Although some controversy exists, the weight of evidence from clinical studies suggest that maintaining near normal blood glucose levels may lessen the severity of long-term complications of diabetes such as retinopathy, neuropathy and microvascular diseases (Skyler, 1987). However, even the short-term consequences of low (hypoglycemia) or high (hyperglycemia) blood glucose levels are undesirable and can be life-threatening. Hypoglycemia interferes with cognitive and motor functioning and can produce symptoms such as irritability, headaches, dizziness, sweating, anxiety, extreme weakness and shakiness. If left untreated, unconsciousness and even death can occur. Hyperglycemia can produce symptoms such as sleepiness, headache, nausea, drymouth and increased thirst and urination. If left untreated, it can lead to a condition known as ketoacidosis, a profound metabolic disturbance that produces acute and severe illness. In light of these difficulties, the attainment of good glycemic control is a primary goal among health care professionals treating patients with IDDM.

Maintaining the blood glucose at normal or near normal levels presents a formidable challenge to diabetic children and their families. At the time of

diagnosis the child is most often hospitalized for a period of time until the diabetes is stabilized. During this period the patient and the family must complete a step-by-step educational program that teaches them the skills and knowledge necessary for the management of diabetes. Once the child leaves the hospital and returns home, most of the medical treatment is transferred to the patient and family under the guidance of the physician. The effectiveness of the treatment becomes primarily a function of the child's and family's adherence to the medical regimen.

The diabetic regimen can best be understood as a series of self-care behaviours that enable patients to externally control their blood glucose levels. The basic components of the self-care regimen are: administration of insulin, regulation of food intake by diet, physical exercise, and frequent monitoring of blood and/or urine to assess glucose levels. The following is a brief overview of each component.

Insulin Therapy. As type I diabetics produce little or no insulin of their own, they must rely on exogenous insulin to survive. Most frequently this involves one or more injections of insulin per day. Insulin is drawn out of a vial into a syringe and is injected into the fatty tissue between the skin and the muscle. In the nondiabetic person insulin enters the system in two ways: there is a basal rate, that is, a constant supply of small amounts of insulin, and, there is an insulin response, that is a larger amount of insulin that goes into the system in response to eating. Insulin injections are timed to duplicate the body's normal insulin delivery system. A combination of intermediate and short-acting insulins is most often used to duplicate the basal rate and insulin response. Successful insulin therapy necessitates a careful balance of caloric intake, activity and insulin dose. Meals must be timed to coincide with the action of insulin.

Furthermore, the amount of insulin injected is dependent on the amount of carbohydrates consumed at meals. If insulin dose, meal timing and amount of carbohydrates are not well coordinated, high or low blood glucose results.

Diet. The main role of diet in the management of diabetes is to ensure equal food intake from day to day. This is the easiest way to keep blood glucose levels within the normal range. Patients are usually placed on an exchange system diet. The exchange system divides foods into six basic food groups and patients are told how many "exchanges" from each list to eat for their meals and snacks. In general, the daily eating pattern is arranged so that most children are to get less than 30% of their calories as fat, 12-20% as protein and 50-65% as carbohydrates (Brink, 1988).

Exercise. Regular exercise is also important in the management of diabetes. It can improve the effectiveness of insulin action and may also reduce the amount of insulin needed to maintain satisfactory blood glucose levels (Stratton, Wilson, Endres and Goldstein, 1987). In anticipation of vigorous exercise, it is necessary for the child with diabetes to either increase his/her caloric intake or decrease the insulin dose to avoid hypoglycemic reactions during or after exercise.

Glucose Monitoring. Traditionally urine testing was the only means available for diabetics to assess control of their diabetes. Urine normally contains no glucose. When glucose is above a certain level in the blood the extra glucose will spill over into the urine. This level is referred to as the renal "threshold". Urine testing does have limitations. The results only indicate whether blood glucose levels are above or below the renal threshold. They do not indicate whether the blood glucose level is excellent, acceptable, too high or too low.

Two recent advances in the area of diabetes management are the

development of techniques for accurate home blood glucose monitoring and the laboratory assessment of long-term blood glucose control by measurement of the glycosylated hemoglobins (HbA1 and HbA1c) (Danemen, 1985). Home blood glucose monitoring allows patients themselves to measure capillary blood glucose concentrations and to monitor their control on a daily basis. When used correctly, this method is more accurate than urine glucose monitoring. Blood is drawn by pricking the finger with a lancet. A drop is placed on a reagent strip and "read" by the patient or put into a monitoring meter. For maximum effectiveness patients should check their blood 2 to 4 times daily to determine glucose levels and if adjustments are needed in either insulin dose or food intake.

The measurement of HbA1c provides an objective means for monitoring control over a 2 to 3-month period. Glycosylated hemoglobin is formed by the interaction between glucose and the substance hemoglobin that transports oxygen into the red blood cells. While daily fluctuations in blood glucose levels do not significantly influence HbA1c values, longer term elevations are reflected.

2. Adherence to the Diabetic Regimen: Problems with Compliance and Glycemic Control During Adolescence

When compared to most other chronic illnesses, the diabetic treatment regimen is notable for its complexity and for the degree of responsibility and lifestyle changes it imposes on the patient and his/her family. One of the best predictors of compliance problems is a complicated regimen persisting over a long period of time and requiring substantial behavioural change (Haynes, Taylor and Sackett, 1979). Not surprisingly, adherence to the diabetic regimen is difficult for many patients to achieve (Wing, Epstein, Nowalk and Lamparski, 1986; Watts, 1980). The most comprehensive survey of diabetes self-care demonstrated that

80% of 60 patients studied administered insulin in an unacceptable manner; 58% administered the wrong dose of insulin; 77% tested urine incorrectly or misread results; 73% did not adhere to the prescribed diet and 75% did not have a regular eating schedule (Watkins, Roberts, Williams, Martin and Coyle, 1967; Williams, Anderson, Watkins and Coyne, 1967).

More recent studies have documented similar insulin and metabolic monitoring errors and compliance problems in children and adolescents with IDDM. Johnson and her colleagues (1982) observed 146 children with IDDM, ages 6-18, in skills demonstration of urine testing and self-injection. She found more than 80% of the youngsters made significant errors in urine testing and almost 40% made significant errors in giving insulin injections. Another survey of blood glucose monitoring by Wing, Lamparski, Zaslow, Betschart, Siminero and Becker (1985) indicated that of the 209 children over 8 years of age who were taught self-monitoring, 12% reported that they were not testing their blood glucose levels at all, 25% reported testing less than once a day, 37% reported testing 1-2 time a day and 26% were monitoring three or more times daily. Furthermore, out of a random sample of 100 children who were asked to check their blood sugars with a Chemstrip and have them compared to laboratory values, only 36% estimated their blood glucose within +10% of their actual blood glucose level and 57% estimated within +20%. Thus, more than one third of the patients did not achieve sufficient levels of accuracy.

Problems in detecting true blood glucose values are due to more than just performance errors. A study reported by Wilson and Endres (1986) evaluated compliance to blood glucose monitoring in adolescents, ages 12-18, using blood glucose reflectance meters specially equipped with memory capabilities. They found that 40% fabricated test results and 18% failed to record test results. The

omission and intentional alteration of test results is not unique to adolescents. Mazze, Shamoon and Pasmantier (1984) reported similar results with adults. The high occurrence of technical and reporting errors has lead most clinicians to use the glycosylated hemoglobin measurement as the "gold standard" of diabetic control (Ahern, Bates, and Tamborlane, 1988).

Substantial dietary skill deficits and dietary adherence problems have also been reported in the research literature (Delamater, Smith, Kurtz and White, 1988; Lorenz, Christensen and Pichert, 1985). Mothers and children have been found to have difficulty determining food portions and their exchange equivalents (average score was 50%), as well as simply remembering their dietary prescriptions (average recall rates ranged from 21% to 53%). Together with the noted glucose monitoring problems, these findings suggest that diabetic children and their families should receive periodic reassessment of their skills and knowledge in order to reinforce good treatment practices and counteract changes in perspective and priorities.

It has frequently been noted in the clinical literature that adolescents with IDDM have particular difficulty cooperating with the regimen tasks (Tattersall, 1987). Many of the personal-social tasks of adolescence related to independence, sexuality, identity, greater responsibilities, and self-esteem interact negatively with the daily demands of managing diabetes (Cerreto and Travis, 1984). Moreover, parental supervision and involvement has often diminished by the time the adolescent is 15, but this is not necessarily accompanied by adolescents assuming responsibility for some of the important aspects of their self-care (Ingersoll, Orr, Herrold and Golden, 1986).

Two recent studies have included developmental comparisons in their analysis of compliance behaviours giving empirical support to what has been the common clinical experience. Johnson, Silverstein, Rosenbloom, Carter and

Cunningham (1986) used 24-hour interviews with 168 children, ages 6-19, and their parents in order to gather information on 13 daily diabetes management behaviours. Interviews took place with each participant on 3 occasions over a two-week period. They found adherence behaviours to be strongly influenced by age. Compared to their younger counterparts, adolescents monitored their blood glucose less often, exercised less, had more variable injection times, and deviated more often from the ideal interval between injections, as well as from the dietary recommendations. Jacobson, Hauser, Wolfsdorf, Houlihan, Milley and Herskowitz (1987) documented deterioration in compliance during the first 18 months after the onset of diabetes. Using health provider assessments of diet behaviours, insulin usage and blood monitoring, they found early adolescents, ages 13-15, to be less compliant than preadolescents, ages 9-12. Together these studies support the clinical view that adolescents are indeed at risk for compliance problems. Methodological issues related to the measurement of adherence will be discussed in the following section.

Although the self-care behaviours play a significant part in the control of diabetes, there are also important physiological factors that contribute to metabolic control problems during the period of adolescence. For example, a recent report of a multiple group comparison study of adults, prepubertal and pubertal children with and without IDDM suggests the physical changes of puberty, such as the increased production of growth hormone, interfere with the insulin activity (Amiel, Sherwin, Simonson, Lauritano and Tamborlane, 1986). This leads to an impairment of insulin's blood glucose lowering effects. A second related hormonal imbalance that can affect an adolescent's ability to achieve glycemic control is "adrenalin response to low blood glucose levels" (Tamborlane, 1987). This triggers the release of stored glucose and sends the blood glucose

levels soaring from too low to too high. Adolescents with IDDM may be particularly vulnerable to wide fluctuations because of the co-existing insulin resistance referred to above. Other causes of resistance to insulin have to do with systemic factors such as the presence of insulin antibodies, insulin receptor abnormalities and postinsulin receptor abnormalities (Shade, 1988). These factors have been implicated in a small percentage of cases of recurrent diabetes ketoacidosis.

There is also a substantial body of research that suggests psychological stress has an adverse impact on metabolic control. Laboratory assessment studies have demonstrated quantitative changes in various "stress" hormones such as catecholamines, cortisol, glucagon and growth hormone in persons with and without diabetes in response to various stressful situations. These hormones are regarded as antagonistic to insulin and are considered to have a blood glucose-increasing capacity in diabetics (Tarnow and Silverman, 1981). However, not all of the findings are consistent. Some results indicate that the metabolic disruptions may also be in the direction of decreased blood glucose (Vanderbergh, Sussman and Titus, 1966; Vanderbergh, Sussman and Vaugn, 1967; Carter, Gonder-Frederick, Cox, Clarke and Scott, 1985). A more recent group comparison study by Kemmer, Bisping, Steingruber, Baar, Hardtmann, Schlaghecke et al. (1986) concluded that metabolic control was not likely to be disrupted by sudden, short-lived psychological stressors.

Much of the early work in support of the "stress-hormone-control" hypothesis is limited by methodological problems (Barglow, Hatcher, Edidin and Sloan, 1984; Lustman, Carney and Amado, 1981; Czyzewski, 1988). In particular, Czyzewski's review highlights the failure of most of the research to consider the patient's level of adherence to the medical regimen.

3. Family Factors Influencing Adherence and Control

The importance of the family in the management of diabetes is a recurrent theme throughout the medical and psychosocial literature on children with IDDM (Sargent and Baker, 1983; Newborough, Simpkins and Maurier, 1985). Several features of the diabetic regimen such as its complexity and lack of response-maintaining contingencies make the family's involvement crucial (Surwit et al., 1983; Gross, 1987). The daily routine of diabetes care, particularly with regard to meal planning and timing, must be integrated into the usual routine of family life. Family members must also help make treatment decisions regarding alterations in insulin dosage, diet and exercise routines; how to respond to intercurrent illness; and when to contact the physician. Moreover, many of the regimen behaviours do not usually produce immediate positive rewards but are justified by various long-term gains such as the avoidance of health problems. This means that parents must often provide immediate reinforcement contingencies in order to promote and maintain their youngsters' self-care behaviours. As a psychosocial determinant, the family can function in ways that can either facilitate or hinder the management of diabetes (Newborough et al., 1985).

In Johnson's (1980) comprehensive review of psychosocial issues and juvenile diabetes, five family patterns or parenting styles were identified as having a negative affect on diabetic control in children. They are: overanxious patterns, overindulgent patterns, overcontrolling patterns, patterns of resentment and rejection, and disinterest and neglect. Anderson and Auslander's (1980) review of the research on diabetes management and the family noted that families with diabetic children in good control were typified by low stress, high stability environments; good cooperation between parents; and few parent-child conflicts. Although mothers were found to take primary responsibility for the treatment

regimen in families with children in good control, cooperation among all family members was reported.

Several methodological problems characterized the earlier research such as unstandardized self-report questionnaires and interview data for assessing family functioning, unreliable indices of diabetic control, unclear definitions of diabetes management, outcome measures that failed to distinguish adherence behaviours from control, and failure to consider the child's age and developmental level as well as certain disease variables (Anderson and Auslander, 1980). If we are to understand the interrelationship between psychosocial factors in the family, adherence and diabetic control, it is important that researchers clearly define the constructs of adherence and metabolic control and assess them separately.

Theoretically, there are two pathways through which the characteristics of the family environment can impact on blood glucose control - through its influence on diabetes regimen behaviours or through its direct impact on the child's physiological system, by increasing the body's production of "stress" hormones that raise blood glucose levels. Of course, a third way that these variables may be related is that poor diabetic control may place additional problems on the family, which in turn leads to poorer family functioning and lower levels of adherence. This hypothesis has not been tested yet.

Generally, more recent investigations have taken the perspective that if the family environment does have an impact on diabetic control it is primarily through the enhancement of or interference with the diabetes self-care behaviours. One of the problems in studying factors that interfere with or improve adherence is the difficulty of assessing adherence behaviour itself (Glasgow, Wilson and McCaul, 1985). The diabetic regimen is not a unitary construct. Furthermore, a level of adherence to one aspect of the regimen, such as blood testing, is often

unrelated to the degree of adherence to other aspects of the regimen, such as dietary modifications (Glasgow, McCaul and Schafer, 1987). Thus, a single global measure of adherence may not be sufficient for capturing the complexity of the adherence behaviours. There is no "gold standard" for compliance measurement (Rudd and Marshall, 1987). Self-report measures are subject to response bias, especially overreporting, and errors of memory, while self-monitoring and observations may have reactive effects (i.e., a Hawthorne effect). Physician ratings have also been shown to be unreliable (Hays and DiMatteo, 1987). Yet these have been the most common procedures for measuring adherence to the diabetic regimen.

Another measurement problem has to do with developing adequate measures of specific family interactions in relation to the diabetes self-care behaviours. General measures of family functioning provide too little information for understanding how families support or interfere with the regimen behaviours (Schafer, McCaul and Glasgow, 1986). Schafer and colleagues devised, from a Social Learning Theory perspective, a 16-item Diabetes Family Behaviour Checklist (DFBC) The DFBC assesses the diabetic person's perception of supportive or nonsupportive actions of family members that are pertinent to four specific regimen areas - insulin administration, blood glucose monitoring, diet and exercise. For example, patients are asked how often family members help them decide if changes should be made based on glucose testing results, praise them for following their diet (supportive) or argue with them about their diabetes self-care activities, or criticize them for not recording their test results (nonsupportive). The DFBC has been employed in several research studies to date (Schafer, Glasgow and McCaul, 1983; McCaul, Glasgow and Schafer, 1987; Hanson, Henggeler and Burghen, 1987a, 1987b) with generally good results for the supportive

subscale.

The following review of the research on the contextual influences on adherence will be organized around one question: What do we know about families in relation to the diabetes self-care behaviours? Generally, only the family-related aspects of studies will be reported. The specifics of each study are presented in Table 1. Subject criteria, study design, measures of adherence, diabetic control and family variables, as well as the findings are shown.

The first study to explore the relationship between psychosocial variables in the family, adherence and glycemic control, using HbA1c values, was by Schafer et al (1983). A self-report measure was used to assess the frequency of completing different regimen activities, such as insulin injections, blood testing, following the diet and exercise regime, over the preceding 7 days. Two sets of family psychosocial variables were measured: (1) general family functioning, with regard to the degree of cohesion, expressiveness, conflict, independence and organization, was assessed with the Moos Family Environment Scale; and (2) diabetes-specific family behaviours were assessed with the Diabetes Family Behaviour Checklist (DFBC). Data from the DFBC indicate it was a better predictor of adherence (5 of the 15 correlations calculated were greater than .28) than were the more global measures (only one correlation, conflict, exceeded .28). The pattern of results suggest that unsupportive parental behaviours (e.g. nagging about blood tests, eating foods not part of the diabetic diet,etc.) and high levels of conflict with parents were more predictive of the extent to which the diet was followed and the number of daily glucose tests performed. Three of the seven adherence measures (extent diet was followed, care in measuring insulin, number of blood tests) were each significantly correlated with HbA1c levels (correlations ranged from .35 to .50). These results seem to suggest that

Table 1.
Studies Investigating the Relationship Between Family Variables, Adherence and Control

Reference	Subject Criteria	Study Design	Measures	Findings
Schafer et al. (1983)	N=34, campers with IDDM Ages: 12-14yr No size justification No selection criteria	Cross-sectional Correlational	A. Family: DFBC, FES B. Adherence: insulin, BGT, diet, exercise (self-report) C. HbA1c values	A. Family conflict, nonsupportive DFB related to poor adherence to diet and BGT B. Diet, BGT related to HBA1c
Bobrow et al. (1985)	N=50, females with IDDM Ages: 12-17 No size justification Limited selection criteria	Cross-sectional Correlational	A. Observations of mother-daughter interactions (HIM, Beavers) B. Global index of adherence (structured interviews)	A. Poor adherers had more conflictual and emotional exchanges with mothers
Hanson et al. (1987a)	N=93, subjects with IDDM No size justification Limited selection criteria	Cross-sectional MRA	A. Family knowledge of IDDM B. Family relations: Locke-Wallace, FACES-II, DFBC C. Global index of adherence D. HbA1c values	A. High family knowledge, positive family relations related to higher levels of adherence B. Adherence related to HbA1c
Hanson et al. (1987b)	N=104, subj. with IDDM Ages: 12-17yr No size justification Limited selection criteria	Cross-sectional MRA	A. Parental support: DFBC B. Global index of adherence (self-report, observations) C. HbA1c values	A. Parental support related to better adherence B. Adherence related to HbA1c
Marteau et al. (1987a)	N=72, parents of children Ages: 5-16yr No size justification	Cross-sectional Correlational	A. Family composition B. Adherence: management of hyperglycemia, no.	A. Children living with natural fathers demonstrated better management of

Table 1 (continued)

Reference	Subject Criteria	Study Design	Measures	Findings
	No selection criteria		of daily BGT (parental reports) C. Diabetic control: physician rating	hyperglycemia B. Children from homes with 2 natural parents better control
Marteau et al. (1987b)	N=65, Same as above	Cross-sectional Correla-lational	A. Parental goals and beliefs regarding treatment B. Adherence: same as above C. Diabetic control: same as above	A. Parents with normoglycemic goals had children who adhered better to treatment and were in better control
McCaul et al. (1987)	N=107, subj. with IDDM Ages: 12-65yr No size justification Selection criteria	Prospective Correlational MRA	A. Family support: DFBC, FES B. Multimethod assessment of of insulin, BGT, diet and exercise	A. Family support was related to timing of insulin, no. of BGT

Note. DFBC = Diabetes Family Behaviour Checklist; FES = Moos Family Environment Scale; FACES II = Family Adaptability and Cohesion Evaluation Scales; BGT = blood glucose testing; HIM = Hill Interaction Matrix; Beavers = Beavers-Timberlawn Family Evaluation Scale; MRA = multiple regression analysis

negative family interactions affect control by way of their interference with adherence. There are several limitations to this study. Subjects were drawn from a diabetic camp and the sample size was small. This limits the extent to which the results can be generalized. Furthermore, the magnitude of the relationships between psychosocial measures and adherence was modest, accounting for only about 10% of the variance.

Further evidence of the effects of negative interactions on adherence to the diabetic regimen during adolescence comes from an observational study by Bobrow, Risken and Siller (1985). The Hill Interaction Matrix and a modified version of the Beavers-Timberlawn Family Evaluation Scale were used to assess the interactions between 50 mother-daughter dyads. The level of adherence to the diet, regularity of meals,insulin scheduling, glucose monitoring, and exercise was measured via structured interviews with both the mother and adolescent and corroborated with physician reports. Interviews with the mother and daughter were recorded and rated. A composite score was used as the adherence variable. There was no measure of metabolic control. The results indicated that interactions between poorly adherent adolescents and their mothers were more emotionally charged and confrontational, and they were less efficient at problem-solving than were good adherers and their mothers ($r=-.41$; $p<0.005$). In agreement with the observational data, poor adherers reported having difficulty talking with their mothers about their feelings, problems and concerns about diabetes than did good adherers ($r=-.51$; $p<0.001$).

Although the above study represents an important first step in the use of observational procedures for investigating interactional styles in families with a diabetic adolescent, there are several limitations that should be noted. First, the focus was on mother-child relationships only. While characteristics

of mother-child relationships may be more predictive of adherence in younger children, it is more likely that characteristics of family interactions that include fathers and siblings may be more predictive of adherence among adolescents. Second, this is a cross-sectional study. Longitudinal studies are needed if conclusions are to be made about the relationship of family interaction to adherence, as well as for understanding changes in adherence over time. And third, adherence-control relationships were not established. Such linkages are important to determine in order to give credibility to the measurement of adherence.

A more recent study by Hanson et al. (1987a) attempted to further clarify the linkages between psychosocial variables, adherence and metabolic control. The family psychosocial variables studied were: (1) family knowledge about IDDM (Tests of Diabetes Knowledge developed by Johnson et al, 1982); and (2) a global index of family relations that was derived from an assessment of marital satisfaction (Locke-Wallace, 1959), cohesion and adaptability (Olson's Family Adaptability and Cohesion Scales II), and parent support (supportive subscale of the Diabetes Family Behaviour Checklist). Self-report and observational methods were used to assess five adherence behaviours - diet, insulin adjustment, hypoglycemia, glucose testing and foot care. Scores were summed to form a global index of adherence. Mutiple regression analysis indicated that adherence ($F=4.88$; $p<.029$) was directly associated with metabolic control (HbA1c levels), and that high family knowledge ($F = 4.80$; $p<.029$) and positive family relations ($F=2.79$; $p<.099$) were directly associated with better adherence. These data add further support to the assumption that psychosocial variables such as family behaviours will affect control indirectly through their influence on the adherence behaviours. However, the psychosocial

variables together accounted for only 18.5% of the variance in predicting adherence, leaving much of the variance unexplained.

In a separate publication, Hanson et al. (1987b) reported that parental support, as measured by the Diabetes Family Behaviour Checklist, was significantly correlated with adherence ($r=.32$, $p<.001$). Older adolescents were found to have lower levels of adherence ($r=-.26$, $p<.003$) and parental support ($r=-.40$, $p<.001$). These results concur with findings by Ingersoll, Herrold and Golden (1986) who studied 41 adolescents with IDDM (ages 12-21) and their parents. Using adjustment of insulin dosage as their definition of self-care behaviour, they found that most parents have disengaged from diabetes care of their child by the time the child has reached 15. Moreover, while patients in the older age group were expected to perform self-care, they often did not assume responsibility for the more complex aspects of care such as insulin adjustment. They did find, however, that patients at more advanced cognitive levels were more likely to engage in the task of insulin adjustment, and subsequently were in better control. These findings suggest chronological age and sexual maturity are not good indicators of the adolescent's readiness to assume a greater role in self-care. The authors recommend that younger adolescents (and the less cognitively mature) should receive structured, concrete and supportive ongoing help from parents.

The studies by Schafer et al. (1983), Bobrow et al. (1985) and Hanson et al. (1987) explored family process variables as they relate to adherence behaviours. A study by Marteau, Bloch and Baum (1987a) included a family structure variable that was based on a categorization of the family's composition (i.e. who lived in the household with the child). The authors used an index of adherence based on parental reports of how they manage their

child's hyperglycemia and on the frequency of blood glucose monitoring. The primary index of metabolic control was a 6-point rating scale used by the physician. Results indicated that children whose parents reported testing their blood before performing any action and whose blood glucose levels were monitored more frequently had better diabetic control than children whose parents acted first without testing and tested less than once a day. The only family factor that was found to affect the adherence variable pertained to fathers: biological fathers were more likely than non-biological fathers to manage hyperglycemic symptoms by testing first (chi-square=5.68, $p<0.05$). Furthermore, children from homes with either step-fathers or adoptive parents were in poorer diabetic control than children in homes with two biological parents ($p<0.05$).

The unreliable indices of both adherence and diabetic control leave unclear the significance of the findings by Marteau et al. Furthermore, as the age range of the subjects (5-16) spanned several levels of development, the data should have been analyzed accordingly. There are several reasons why this is important: (1) the personal-social tasks of adolescence present different challenges to the management of diabetes from that of the child with IDDM; (2) the child's level of development influences the family's level of involvement in the regimen tasks; and (3) basic metabolic processes change with growth and development. For example, the effects of puberty, as was noted previously, may make diabetes more difficult to control.

The results by Marteau et al. underscore the importance of the father's involvement in the management of the child's diabetes. This is consistent with a report by Newborough, Lorenz, Simpkins et al. (1986) whose results indicate poor adherence and poor control may be the result of inadequate distribution of

family responsibility. Results were based on 50 families of children with IDDM, ages 8-16. Shared family responsibility was defined as who was responsible for: remembering management procedures, overseeing compliance with diabetes tasks, planning for changes, and presenting information about diabetes to others. Results indicated that father and child reports of shared responsibilty were related to lower HbA1c levels (i.e. better diabetic control), whereas control and adherence were poorer when mothers reported sole responsibility. No statistical data were reported along with these findings.

A study by McCaul, Glasgow and Schafer (1987), with a predominantely adult population, studied four classes of predictor variables: knowledge about IDDM, beliefs related to self-efficacy and outcome expectations, problem-solving skills regarding diabetes management, and environmental (family) support. Multimethod assessment procedures (self-monitoring, interviews, objective indices) were used to measure four aspects of the regimen: insulin injections, blood monitoring, diet and exercise. Assessments were carried out on two occasions, 6 months apart. Data from adolescents was analyzed separately. Of the four predictor variables, two were significantly correlated with adherence behaviours. The environmental support composite measure was associated with both timing of insulin injections and frequency of blood testing (r_s=.39,.37;$p<0.01$). This composite included a measure of diabetes-specific family behaviours (Diabetes Family Behaviour Checklist) and a general measure of family cohesion, expressiveness and conflict (Moos Family Environment Scale). This result is consistent with the findings of Schafer et al. (1983), Hanson et al. (1987a).

McCaul and colleagues found their self-efficacy expectations composite measure to be the best predictor of timing of insulin injections, glucose

testing and the extent to which the diet was followed (r_s=.56,.71; $p<0.05$). This included a measure of the adolescents' perceived competence in performing a graded series of regimen behaviours (test once a day, test twice a day) and a measure of the adolescents' beliefs regarding the consequences resulting from performing the regimen behaviours. This finding is consistent with the findings by Wing et al. (1985), who found the best predictor of the frequency of blood glucose monitoring was the perception that such monitoring improved diabetic control. The study by Bobrow et al. (1985) found poor adherers, more than good adherers, reported believing less strongly that adherence would result in delaying or avoiding diabetes-related complications ($r=0.51$, $p<0.001$).

Factors such as family determinants that may influence the development of strong or weak expectations for diabetes self-efficacy have rarely been investigated. Becker and Green's (1975) review of the literature on families and compliance to medical regimens suggested that health-belief model variables (that is, perceived seriousness of the illness and perceived vulnerability to aversive outcome) played an important role in motivating family members to promote compliance.

A recent study by Marteau, Johnston, Baum and Bloch (1987) suggests parental goals and beliefs may exert a powerful influence on diabetes self-care and glycemic control. The measures of adherence and diabetic control were the same as in the study reported above by Marteau, Bloch and Baum (1987). Thus, the same limitations apply to this study. The authors compared the goals of treatment for parents and doctors by asking them to select their preferred glycemic control profile from seven sets of hypothetical blood tests. Attitudes and beliefs, related to their respective goals, were assessed with

the Health Belief Scales, developed by Becker et al. (1979). Results indicated that both mothers and fathers were more likely to choose profiles showing hyperglycemia than were physicians (chi-square=9.83, $p<0.05$; chi-square=18.60, $p<.001$). Diabetic control of children whose parents intended to achieve normoglycemia was significantly better than the diabetic control of children whose parents intended to achieve higher levels of glycemia. Furthermore, parents whose goals were normoglycemia were significanly more likely to manage suspected high blood sugars by testing before any other intervention (chi-square=4.80, $p<.05$). This finding suggests that parents' goals may act as motivators in treatment. Parents with hyperglycemic goals were also more likely to have stronger beliefs related to the short-term risks of hypoglycemia than to the long-term complications associated with hyperglycemia. The reverse seemed to be true for physicians. These results suggest that adherence to blood glucose monitoring and the achievement of good diabetic control may be a function of the extent to which physicians and parents share the same glycemic goal.

Summary

On the whole, the research on family factors and adherence to the diabetic regimen strongly suggests that the quality of parental involvement and support is important in determining the level of self-care attained by adolescents with IDDM. Adolescents deviate more from their diet and test their blood glucose less regularly when the mode of parental support is primarily in the form of criticism or nagging. Pervasive parent-child conflict impedes effective problem-solving and the expression of diabetes-related problems and concerns, creating barriers to good adherence. On the other hand,

parental support in the form of praise and encouragement, helping the adolescent decide if changes should be made based on glucose test results, and family routines that encourage the adolescent to eat and take insulin on time are associated with several adherence behaviours: regularity of insulin injections, performance of insulin adjustments, and frequency of blood testing. Other family determinants that appear to have a positive influence on the adolescent's regimen behaviours are: high level of knowledge about diabetes management among family members; involvement of fathers; and parental goals and beliefs about glycemic control that are congruent with clinic goals of normoglycemia.

These findings have implications for interventions aimed at enhancing the adolescent's adherence to the diabetic regimen. In addition to reviewing and updating the patient's technical skills and knowledge pertinent to diabetes management, it is also important to consider the familial context with respect to the family's level of knowledge and the quality of support available to the patient. Convening the family when issues of compliance are to be addressed would allow the goals of the clinic team, the patient, and the family to be made more explicit. It would also provide the family with an opportunity to be clear about what are the adolescent's responsibilities and what are the family's responsibilties. Many parents may have withdrawn support as a way of reducing parent-child conflicts over the diabetes tasks (Gross, 1987). Assisting families in determining appropriate modes of support may help reinforce good treatment practices at a time when adolescents are assuming more responsibilty for their self-care.

Future research needs to focus more specifically on several issues such as: (1) how families can promote adolescents' various regimen behaviours. We

need to know specific and practical ways families can be supportive without nagging. We also need to know more about the role siblings can play. This kind of behavioural specificity will provide a clearer focus for family-based interventions; (2) identifying family variables influencing diabetes self-efficacy; and (3) developing data-based guidelines for defining child versus parent responsibilities.

Methodological Issues

In general, the more recent studies of family variables and diabetes management have avoided several of the methodological limitations outlined by Anderson and Auslander (1980) with respect to: standardized self-report assessments of family interactions, a reliable index of diabetic control (glycosylated hemoglobin values), and independent assessments of adherence behaviours and metabolic control. Despite these improvements, several methodological limitations persist with regard to research design, measurement and subject selection.

Research design. Most of this research has relied on cross-sectional data. Several family variables and adherence variables are studied at a single point in time and relationships between the variables noted. Although correlational methods permit the identification of relationships, they do not allow us to understand changes in family support and adherence over time. Only prospective studies initiated soon after diagnosis can answer questions as to how vicissitudes in the course of diabetes may impact upon the family environment and how changes within the family may impact on diabetic control or influence the child's adherence to the treatment plan. Hauser, Jacobson, Wertlieb, Weiss-Perry, Follansbee, Wolfsdorf et al., (1987) have initiated a

4-year longitudinal study which may enable such cause-effect questions to be answered.

Measurement. Johnson's 1980 review ended with a plea for adequate measurement specific to diabetes. The measurement of family interactions specific to the diabetes tasks must at this time be regarded as being in the early stages of development. The usefulness of The Diabetes Family Behaviour Checklist is limited in its present form. Generating additional items might allow for the analysis of subscales in relation to the four regimen components - insulin injections, glucose testing, diet and exercise. This would provide more information with regards to how families support or interfere with the various self-care behaviours. Furthermore, the concept of family support may need to be broadened (McKelvey, Waller, Stewart, Kennard, North and Chipman, 1989). Waller, Chipman, Hardy, Hightower, North, Williams et al., (1986) suggest family support consists of at least three different critical dimensions: warmth/caring, guidance/control and problem-solving. A measure of diabetes- specific family behaviours that also takes into account these three dimensions may permit more systematic evaluation and focused intervention.

The use of direct observational methods, as demonstrated by Bobrow et al. (1985), needs to be extended to the study of patterns of interaction in the family unit. This would increase our understanding of the interdependencies between the child, diabetes management, and the family. It would also provide further evidence for the convergent validity of self-report measures like the Diabetes Family Behaviour Checklist.

A second measurement issue pertains to the assessment of adherence. Difficulties were alluded to previously that have to do with the fact that the main methods of collecting compliance information, such as self-report and

physician assessments, are subject to measurement errors. Several additions or modifications to these methods may improve their reliability: (1) the inclusion of a measure of social desirability, that is, the tendency to give the desired response, might help to distinguish reports of compliance from actual compliance (Friedman and Litt, 1986). This may enhance the quality of information obtained from self-report measures; (2) extending the 24-hour interview procedure from its previous use as a standard dietary assessment technique to a method for collecting information on all diabetes management behaviours. This form of self report is regarded by some investigators as the best of available self-report methods (Johnson et al., 1986); and (3) using multiple sources of information, as in the study by Glasgow et al., (1987). This has been advocated by other researchers as being necessary in order to produce more reliable results in the assessment of adherence (Hays and DiMatteo, 1987).

In general, results from investigations of adherence to the diabetic regimen suggest it is not a unitary construct or a general characteristic of the patient. Adherence to one aspect of the diabetic regimen may not be related to adherence to other aspects (Schafer et al., 1983; Johnson et al., 1986; McCaul et al., 1987). Thus, it is not appropriate to refer to "good adherers" or "poor adherers" as in the study by Bobrow et al., (1985), or to form a composite or global measure of adherence, as in the studies by Hanson et al., (1987). Investigators must first present data on the relationships among different regimen behaviours before treating them as being representative of the patient's overall level of adherence.

Researchers must also come to some agreement on what are the critical independent adherence variables in relation to diabetic control. For example,

is it the number of daily calories consumed, the number of daily blood tests performed and/or the timing of insulin injections? Many clinicians consider that it is not enough that patients test blood and take insulin on time. They must also be able to make appropriate interpretations of blood test results and make adjustments in their insulin dose and food intake accordingly in order to keep daily fluctuations in blood glucose levels at a minimum (Davidson, 1986; Belmonte, Schiffrin, Dufresne, Suissa, Goldman and Polychronakos, 1988). But measurements of adherence have rarely considered, as part of the insulin administration component, self-adjustment of insulin dosage. The study by Ingersoll et al., (1986) is an exception. In fact, few clinics spend the time and money needed to teach patients and families how to utilize the information obtained from blood testing (Davidson, 1986). It is possible that the initiative taken by patients and families to respond to blood glucose changes may be more strongly related to good control than adherence to a fixed perscription (Glasgow, McCaul and Schafer, 1987).

Most of this research, with the exception of the studies by Marteau et al., (1987), has used glycosylated hemoglobin values as the index of diabetic control. Although this remains the most stable and reliable measure available at this time, there are limitations in the laboratory technique most often used that can result in artificially high HbA1c values. The common cause of spuriously elevated HbA1c is a high concentration of fetal hemoglobin (HbF) (Allen and MacDonald, 1986). Approximately 1.5% of clinic patients with HbA1c levels above 10% have elevated HbF (Kraus, Stolc and Campbell, 1982). It would be prudent of researchers to test for this factor in suspected individual cases before subjects are selected for study.

Subject Selection. The review by Anderson and Auslander (1980) cautioned

researchers against considering patients as a homogeneous sample merely because of a similar disease. Researchers need to pay greater attention to individual differences in disease severity. For example, some children continue to secrete small amounts of residual endogenous insulin, as reflected by plasma C-peptide measurements (Clarson, Daneman, Drash, Becker and Ehrlich, 1987). This may make it easier for them to manage their diabetes than it does for children who do not have any residual endogenous insulin. This may also make lapses in adherence less of a problem for some youngsters. Moreover, different expressions of disease severity could account for some variability in the family's involvement in diabetes management.

With the exception of the studies by McCaul et al., (1987) and Hanson et al., (1987), the studies in this area have not employed large sample sizes. Furthermore, there has been no justification for the sample sizes that were chosen. This is an important consideration when multiple regression analysis is used.

4. Interventions for Improving Adherence and Diabetic Control

Generally speaking, there are two very different conceptual approaches that have been reported in the literature for improving diabetic control in children and adolescents with IDDM. The involvement of family members is an important feature of both approaches. They are: (1) behavioural interventions, based on the principles of behavioural change, for enhancing adherence to the diabetic regimen; and (2) family therapy, based on Minuchin's psychosomatic model, for reducing stressful family interactions thought to have a negative impact on the child's metabolic control.

Behavioural Interventions. There have been several studies documenting

the effectiveness of using behaviour modification techniques for enhancing various diabetes regimen behaviours. Most of the interventions have included a review of the patient's diabetes management skills and knowledge before the treatment phase. Parent training in the principles and procedures of behavioural management is also a common feature to each study. The specifics of each study are presented in Table 2. Subject criteria, experimental design and procedures, measures, and outcome are shown.

The first study, by Lowe and Lutzker (1979), examined the effects of a memo-cueing (written instructions) and contingency management procedure (point system) on the level of compliance to daily footcare, diet and urine testing. The patient was a 9 year old female diabetic. Memo-cuing was effective only for improving adherence to the diet, while the point system was most effective for improving adherence to foot care and urine testing. Compliance increased by nearly 100% and was maintained at a 10-week follow-up. The metabolic effects of increased compliance on diabetic control was not included in the assessment.

A study by Epstein, Beck, Figuera, Farkas, Kazdin, Daneman et al., (1981) assessed the effects of teaching parents how to reinforce their children for having no or small amounts (<1%) of glucose in their urine. Nineteen families were randomly assigned to one of three treatment groups which differed according to when treatment was implemented. Participants in each group received extensive instruction, covering several sessions, in various aspects of diabetes care. Adherence to urine testing was measured by the marked items technique which involves predetermined quantities of placebo Clinitest tablets being bottled with active tablets. Several measures of metabolic control, including HbA1 values, were collected. Results showed significant increases in

Table 2
Behavioural Interventions For Enhancing Adherence To The Diabetic Regimen

Reference	Subject Criteria	Experimental Procedures	Treatment Duration	Measures	Results
*Lowe & Lutzker (1979)	N=1 Age: 9	Single-subject, multiple baseline design BL:parent monitoring of compliance to UGT, diet, footcare TRT: memo-cueing and point system F-up:	 BL: 1wk TRT: 6wk F-up: 1mo	Monitoring data A.foot care B. UGT C. diet	 A. Point system > compliance to 100%,F-up B. Point system > compliance to 97%, F-up C. Memo-cueing > compliance to 99%, F-up
*Epstein et al. (1981)	N= 19 Age: 8-12 Selection criteria	Multiple baseline across groups BL: reinforcement for correct UGT, find-correct no. of marked items, agreement with parent checks TRT: reinforcement for negative urines F-up:	 BL: 3-6wk TRT: 3-12 wks F-up: 2mo	A. % of negative urines B. HbAlc C. plasma glucose	A. Significant increases, maintained at F-up B. No improvement C. No improvement
Schafer et al. (1982)	N=3 Age: 16-18 yr Limited selection criteria	Within-subjects multiple baseline across behaviours BL: self-monitoring of compliance to UGT, timing of insulin, exercise TRT: goal-setting and contracting F-up:	 BL: 1-6wk TRT: 8wk F-up: 2mo	A. Mean daily UGT B. No. of days per wk exercised C. 24-hr UGT	A. Goal-setting > UGT to 4x daily, maintained at F-up for S1 and S2 only B. Goal-setting > to 5x for S1 and 6x for S2, maintained at F-up C. Marked improvement for S1 and S2

Table 2 (continued)

Reference	Subject Criteria	Experimental Procedures	Treatment Duration	Measures	Results
				D. Daily UGT	D. Marked improvement for S1
				E. 2hr post-pradial BGT	E. Marked improvement for S1 and S2 (from PreTRT to F-up)
*Carney & Schechter (1983)	N=3 Age: 10-14yr Limited selection criteria	Multiple baseline across subjects BL: self-monitoring of BGT TRT: parent training in using a point system F-up:	BL: 2-6wk TRT: 5wk F-up: 4mo	A. BGT records B. HbA1c	A. Point system > BGT 5% at BL to 87% for S2, 93% S3, sustained at F-up B. Clinically significant improvement for each S
Gross et al. (1985)	N=14 Age: 9-13yr No selection criteria No size justification	Randomized control outcome Experimental: behaviour modification projects with parents and child, separately Control: Problems associated with IDDM discussed F-up:	TRT: 8wk F-up: 6mo	A. diabetes related conflicts B. Parent reports of compliance C. HbA1c	A. Exp'tal: reductions, maintained at F-up Control: no change B. Exp'tal: improvements Control: deterioration C. Exp'tal: improvements Control: improvements

Note. (1) Bl = baseline; TRT = treatment; F-up = follow-up; UGT = urine glucose testing; BGT = blood glucose testing; S = subject; > = increased.
(2) Studies marked with a asterisk included a diabetes skills and knowledge review at the pretreatment phase.

percent of negative urines, from 27% to 39% to 45% from baseline to posttreatment to 2-month follow-up, respectively. These changes were not associated with general improvements in metabolic control.

A third study to use contingency management procedures with 3 nonadherent adolescents is by Carney, Schechter and Davis (1983). Parents were instructed to praise their children for appropriate blood glucose monitoring and were trained to implement a point system with them. Points were awarded for completion of monitoring at appropriate times each day and for recording blood glucose values. Blood glucose monitoring improved for all three children to about 85% of the appropriate occasions and was maintained at a 4-month follow-up. In addition, HbA1c levels improved significantly following implementation of the program, from 10%, 15%, and 9.1% at baseline to 9.4%, 11.7% and 6.0% at follow-up.

Schafer, Glasgow and McCaul (1982) examined the effects of sequentially introducing self-monitoring, goal-setting and behavioural contracting procedures (if needed) on compliance to urine or blood glucose testing, timing of insulin injections, and exercise. In addition to self-monitoring of adherence, measures of metabolic control were collected before and after an 8-week treatment and a 2-month follow-up. Reliability checks of the self-monitoring data were performed by the mothers of the subjects. At the beginning of the goal-setting phase, the subjects, parents and therapist worked collaboratively to reduce barriers to adherence by deciding upon the least disruptive manner in which to integrate regimen requirements into the subjects daily routine. Explicit graduated goals were set based on baseline data. The contracting phase was to be initiated only if the subject had not achieved a compliance rate of 90% by the end of the previous phase. Two of the three

subjects showed increases in the frequency of urine testing and in exercise behaviours following the introduction of the goal-setting procedure. These improvements were maintained at the 2-month follow-up. These subjects also demonstrated clinically significant improvement from pretreatment to follow-up on several measures of metabolic control: daily urine tests, 2-hour postprandial blood glucose tests and 24-hour urine test. HbAlc determinations were not performed. The third subject whose family was experiencing a variety of severe problems (alcoholism, marital distress) did not show reliable improvements.

The only randomized controlled behavioural intervention study to be reported in the literature is by Gross, Magalnick and Richardson (1985). Fourteen families were randomly assigned to an experimental or control condition. Experimental group subjects conducted behavioural modification projects designed to enhance compliance with the medical regimen and reduce diabetes-related conflicts. The parent and child control groups were led in discussions about problems associated with having diabetes or being a parent of a diabetic child. In both conditions, parents and children were seen separately. Generally, only one parent from each family attended the treatment sessions. Parents in both groups were asked to record daily the occurrence of diabetes-related conflicts. Other assessments, such as parent ratings of their child's adherence on a 4-item questionnaire and HbAlc determinations, were carried out pre- and posttreatment and at a 6-month follow-up. When compared with control group subjects, experimental subjects reported a large decline in diabetes-related family conflicts and an increase in compliance with the medical regimen. These changes were maintained at 6-month follow-up. Both groups displayed significant improvements in metabolic control between pretest

and follow-up ($p<.01$), from mean HbAlc values of 13.4% and 13.6% to 12.5% and 11.0% for experimental and control subjects respectively. These values are still above the acceptable range for diabetic control. The difference between the groups was not significant.

This study has several limitations: (1) there was no sample size justification nor exclusion-inclusion criteria for subject selection provided; (2) a four-item parent rating scale was the only measure of the child's adherence to the treatment regimen. This can not be considered a valid measure of adherence to the diabetic regimen; (3) there was also a lack of consistency in the method of glucose monitoring used by the subjects. Some were testing their urine, others their blood; and (4) a review of each patients skills and knowledge related to diabetes management was not included in the intervention protocol. This is an important omission in light of the documented technical errors and dietary deficits referred to earlier.

To summarize, a number of behavioural strategies have been shown to be effective for improving adherence to various components of the treatment regimen. They are: (1) **parent training** in behavioural management procedures (Lowe and Lutzker, 1979; Epstein et al., 1981; Carney et al., 1983; Gross et al., 1985); (2) **cueing**, in the form of written reminders, enhanced eating behaviours (Lowe and Lutzker, 1979); (3) **contingency management** via a point-system increased the frequency of glucose monitoring (Lowe and Lutzker, 1979; Epstein et al.., 1981; Carney et al., 1983; Gross et al., 1985); (4) **contracting** procedures brought some improvements in the timing of insulin injections (Schafer et al., 1982); (5) **goal-setting** based on baseline data brought improvements in the frequency of daily glucose testing and weekly and daily exercise behaviours (Schafer et al., 1982); and (6) **self-monitoring** of

glucose testing was effective when used with goal-setting or reinforcement procedures, but not when used alone (Epstein et al., 1981; Schafer et al., 1982; Carney et al., 1983).

Methodological Issues

The behavioural techniques need to be tested further in group comparison designs with a larger number of subjects. This will enhance the validity of the inferences regarding the efficacy of treatment as well as the generalizability of the results. Follow-up periods following treatment have ranged from one month (Lowe and Lutzker, 1979) to six months (Gross et al, 1985). Longer-term follow-up periods of about 12 to 18 months may provide a clearer picture regarding the maintenance of regimen adherence behaviours in relation to diabetic control.

Although the behavioural intervention studies have consistently noted improvements in adherence, there have not always been significant improvements in metabolic control. This is likely a function of the method of glucose testing employed by the subjects. Urine glucose monitoring is generally regarded as not being sufficiently accurate to allow for appropriate adjustments in insulin dosage or type (Saucier, 1984; Daneman, 1985). These results serve to illustrate the limitations of emphasizing adherence when the basic tool of treatment has inherent weaknesses. In contrast, the study by Carney et al (1983) targeted blood glucose monitoring only and noted significant reductions in HbA1c values. This finding demonstrates an association between engaging in appropriate behaviour, using a reliable tool, and achieving better control. It is important to establish adherence-control relationships in intervention studies designed to improve adherence. This

gives additional support to the measurement of adherence as well as enabling the evaluation of the therapeutic efficacy of the program to be determined with respect to the child's improved metabolic status. Monitoring adherence with as many sources as possible is also necessary if the reliability of the data is to be enhanced. Several of the intervention studies incorporated reliability checks, performed usually by the parents. In the study by Epstein et al., (1981), a technique called the marked items procedure was used to ascertain adherence to glucose monitoring, while in the study by Carney et al., (1983) adolescents were asked to attach their Chemstrips to their records. These are other ways of reducing the child's tendency to falsify records.

Another issue pertains to the selection of subjects. It is important that investigators conduct statistical procedures, such as power analysis (Cohen, 1977), in order to determine how large a sample size is needed to obtain a significant experimental effect when using group comparison designs. The selection of subjects should be accompanied by careful inclusion and exclusion criteria. The study by Epstein et al. was the only study to fulfill this requirement. This becomes important for ensuring similar metabolic characteristics among subjects and an adequate control group, as well as for cross-study comparisons.

Future studies that are based on blood glucose testing, as one of the main independent variables, and the long-term assessment of glycemic control by HbAlc determinations, as the main dependent variable, will increase the reliability of the information received about adherence-control relationships. Future research should also consider incorporating relevant psychosocial determinants, such as the family factors reviewed in the previous section, into the behavioural treatment programs. This may enhance the maintenence of

treatment effects.

Family-Based Interventions. There have been no reports of family-based interventions involving patients who are in poor glycemic control because of problems with compliance. What has been most often reported are studies demonstrating the effectiveness of psychosocial interventions, such as family therapy, with a very select group of patients, suffering from recurrent diabetes ketoacidosis and who require frequent hospitalizations. This section will review this work and evaluate the usefulness of the psychosomatic model for diabetic control problems. The specifics of each study are presented in Table 3.

Baker, Minuchin and co-workers were the first to study how family interaction patterns may produce stress and poor metabolic control. Much of this work is described in their book, Psychosomatic Families (Minuchin, Rossman and Baker, (1978). They observed four characteristics of these so called "psychosomatic families": (1) psychological overinvolvement or enmeshment between family members: (2) overprotective concern; (3) rigid family interaction patterns; and (4) lack of resolution of family conflicts. Moreover, the child's behaviour seemed to complement the parent's behaviour, allowing the family to maintain its dysfunctional interactional patterns. Thus, the psychosomatic family model describes how the family organization maintains and is itself maintained by the involvement of the symptomatic child.

This model was tested by subjecting children and families that seem to fit the model to family therapy (Minuchin, Baker and Rosman, 1975). Minuchin and his colleagues reported on 13 cases who received family therapy over periods ranging from 2 to 15 months. Most of these patients prior to treatment had experienced severe bouts of ketoacidosis requiring frequent

Table 3
Family-Based Interventions For Improving Metabolic Control

Reference	Subject Criteria	Experimental Procedures	Treatment Duration	Measures	Results
Minuchin et al. (1975)	N=13 Adolescents with RDKA Diagnosed psychosomatic	Case series study TRT: family therapy for reducing stressful interactions F-up:	TRT: 2-15mo F-up: 15mo-6yr	A. No. of episodes of RDKA B. No. of hospitalizations	A. Dramatic reductions B. Dramatic reductions
Orr et al. (1983)	N=15 Age: 11-20yr Patients with RDKA and hypoglycemia	Case series study TRT: (a) education; (b) psychotherapeutic interventions included F.T. (N=8) F-up:	TRT: not specified F-up: 6mo	A. No. of hospitalizations B. HbA1c C. Subjective psychosocial assessments	A. None B. No change C. Improvements
White et al. (1984)	N=30 Age: 6-16 Patients with RDKA Psychosocial problems	Retrospective case series TRT: individual and F.T. F-up:	TRT: not specified F-up: 8yr period	A. No. of episodes of RDKA B. HbA1c	A. Reductions B. Usually remained high
Golden et al. (1985)	N=44 Adolecents with RDKA	Case series TRT: (a) education; (b) family care responsibilities defined (N=31); (c) F.T. (N=14) F-up:	TRT: not specified F-up: 6mo	A. No. of episodes of B. HbA1c	A. Significant reductions without (c) B. Significant reductions from 14% 10.0%

Note. TRT = treatment; F-up = follow-up; RDKA = recurrent diabetes ketoacidosis; F.T.= family therapy

hospitalizations for periods ranging from 6 months to 4 years. A few suffered from chronically poor control. All patients were diagnosed as psychosomatic and referred for family therapy. The objective in each case was to reduce the stressful family interactions and disengage the child from his position between the parents. The parents were helped to deal with their problems more directly. The results presented by the authors suggest the treatment was successful in reducing the frequency of hospitalizations and ketoacidosis. No information was provided regarding the levels of metabolic control attained by patients after treatment nor any other information regarding their level of self-care both prior or after treatment.

Minuchin's work has provided the impetus for investigations linking aspects of family functioning and poor diabetic control. Orr, Myers and Marrero (1983) describe the medical and psychosocial findings and treatment outcome with 15 adolescents with poorly controlled diabetes. All had experienced frequent hospitalizations for either recurrent hypoglycemia or ketoacidosis. Inadequate knowledge of diabetes and its management was judged to be present in 12 patients. The authors observed many psychosocial problems including social isolation, school absence, anger and anxiety. Certain family patterns of interaction similar to what Minuchin described were identified and believed to contribute to continued poor metabolic control in 8 of the 15 families. These were all qualitative psychosocial assessments carried out by a social worker. For 5 patients, support, education and insulin adjustment were sufficient. Eight out of the 10 remaining patients accepted either individual, family and/or group therapy. Family treatment was described as being structurally oriented, similar to Minuchin's approach. No information was provided regarding the length of time patients remained in treatment. Several

outcome assessments were made: (1) no hospitalizations for unstable metabolic conditions were reported during the follow-up period; (2) HbA1c values remained unchanged in all 8 subjects; and (3) subjective assessments of both the individual and the family suggested psychosocial improvements.

White, Kolman, Wexler, Polin and Winter, (1984) carried out a retrospective, longitudinal study of 30 diabetic children who suffered frequent episodes of diabetes ketoacidosis (DKA) requiring many hospitalizations and emergency room visits. An eight-year retrospective review of the psychosocial summaries in the medical records revealed substantial psychosocial problems such as inadequate parenting, absent fathers, lack of family involvement with diabetes, financial stress and chronic interpersonal conflict. Insulin mismanagement or dietary indiscretions were reported in 5%-10% of the DKA episodes. As well, 10% of the patients were evaluated as "abusing" their diabetes occasionally to serve some social or emotional purpose. In the majority of incidences emotional stress was perceived as being directly related to DKA episodes. Many of these families were provided with ongoing counselling which was judged to be effective in reversing the pattern of recurrent ketoacidosis. There was little description of the treatment procedures other than that they were tailored to meet the needs of each family. It was noted that glycosylated hemoglobin levels usually remained elevated after treatment. This is consistent with the finding by Orr et al and suggests that the level of self-care for the majority of the patients in both studies remained inadequate.

The above studies have given little attention to the quality of adherence to the treatment regimen. This contrasts with a more recent report by Golden, Herrold and Orr (1985) who devised a program for preventing

recurrent diabetes ketoacidosis based on ensuring adequate insulin therapy. Results were based on 44 patients under the age of 18 with a history of recurrent diabetes ketoacidosis. A step-wise intervention approach that involved the family was taken. The first step began with individualized education of the family and patient that stressed skill training in insulin administration and adjustment. In 13 patients this was all that was required in order to reverse the episodes of ketocidosis. In the remaining 31 patients insulin omission was documented. The next step involved defining and renegotiating family care roles. Treatment for predominantly dysfunctional family patterns was recommended in 28 of these 31 patients, but only half of the families accepted. Nevertheless, a six month follow-up indicated the episodes of ketoacidosis decreased whether or not families had participated in therapy. Moreover, mean HbA1c values decreased from 14.1% pretreatment to 10.7% posttreatment. This mean value was said to be the same as that for the stable insulin-dependent diabetics in their clinic. These results serve to emphasize that while a number of psychosocial factors may be associated with recurrent diabetes ketoacidosis, the proximate cause is inadequate adherence to the insulin therapy.

Summary and Methodological Issues

To date there have been no well-controlled treatment outcome studies utilizing the family system in the treatment of diabetic control problems. The evidence that significant family stress is a major factor in unstable diabetic control and that family therapy may bring improvements in the metabolic condition is unsatisfactory. The report by Minuchin and colleagues described the successful treatment of 13 cases of patients with diabetes

ketoacidosis and their families. However, there was no control for regimen adherence or any other important variable such as maturational factors which could account for some of the improvements noted. Nor were any statistical analyses presented. This leaves unclear to what extent treating the family contributed to the outcome. The studies by Orr et al., (1983), using unstandardized, subjective assessments and by White et al., (1984), using a retrospective design, add only modest support to Minuchin's work.

The patient selection criteria in the family treatment studies have been restricted to patients suffering from recurrent diabetes ketoacidosis. These patients form a very small percentage of diabetic patients (Rosman and Baker, 1988). There is a considerable range of good to poor glycemic control besides the kind of symptomatology presented by this group. Furthermore, not all diabetics with chronically poor control are psychosomatic (Sargent, 1985).

In a recent critique of Minuchin's psychosomatic model, Coyne and Anderson (1988) caution that "new research progress on counter-regulation and metabolic disruptions during puberty, broaden considerably the potential explanations for recurrent control problems in diabetic children and should temper current tendencies to hypothesize single causes such as family stress for repeated metabolic control problems"(p.120). The report by Golden et al., (1985) underscores the importance of also considering the adherence factor in the treatment and prevention of recurrent diabetes ketoacidosis. They do this within a context of integrating educational, medical and psychosocial interventions. Furthermore, their work is illustrative of a family-based intervention that focused more on the family's role with respect to the diabetes tasks rather than their hypothesized psychosocial role in maintaining the patient's level of emotional arousal.

5. Conclusions, and Rationale for the Present Study

It has been well-documented that adolescents with IDDM are particularly vulnerable to compliance and metabolic problems. They may also have significant skill deficits with respect to their technique for administrating insulin and blood glucose testing as well as deficits in their dietary knowledge. While the social and emotional changes that characterize this period can complicate the management of diabetes, the hormonal changes that coincide with puberty may make their diabetes more difficult to control. Moreover, developmental tasks related to strong pressures for conformity to peer group norms in conjunction with the usual adolescent striving for greater autonomy and independence from the family are not congruent with the daily demands of managing diabetes. Families often have difficulty working out the right fit between the level of their involvement in the regimen tasks and allowing the adolescent more responsibility for his/her self-care.

Findings from increasingly sophisticated studies of adolescents with IDDM highlight the importance of supportive family behaviours to the maintenance of adherence to the various aspects of the medical regimen. It is important that families and health care professionals realize that the adolescent's ability to perform the regimen tasks on his/her own should not be interpreted as meaning he/she no longer needs supervision and support from family members. The adolescent with IDDM needs to exercise responsibility for his/her own self-care within the context of a positive reinforcment system and joint decision-making with family members with regard to alterations in diet,exercise, and insulin dosage. Further specificity of family behaviours relevant to diabetes management must await findings from prospective clinical

trial studies.

Clinical case studies of pediatric patients with recurrent diabetes ketoacidosis suggest the use of family therapy for changing stressful behaviour patterns brings noted improvement in the diabetic condition. On the other hand, other reports indicate that attention to the family's role in ensuring adherence to the insulin therapy is what is most important in the prevention of diabetes ketoacidosis, and that the addition of individual or family therapy does not improve the overall results. This finding illustrates the limitations of the psychosomatic model as a guide for understanding and intervening with most families of adolescents with poor diabetic control.

Behavioural intervention studies have demonstrated the effectiveness of a number of behavioural strategies for improving adherence to various aspects of the treatment regimen. Although most have included an educational component, they have generally been rather narrowly focused and have not taken into account various psychosocial determinants such as the family's involvement in the regimen tasks, expectations and beliefs. Furthermore, no family theory has been considered with respect to identifying the best means of involving the family in the treatment of compliance problems. Parents, usually only one, have been employed as agents for behaviour change strategies or to improve the long-term maintenance of self-management training. The usual approach has been to see parents and youngsters separately.

It is unlikely that a single theory or therapeutic strategy is sufficient to deal with compliance problems. Social learning theory and family systems theory can aid our understanding of the processes underlying the family's influence on the diabetes regimen behaviours as well as suggest ways of intervening. Theories of behaviour change such as social learning theory

(Bandura, 1977; Parcel and Baranowski, 1981), recently renamed social cognitive theory (Bandura, 1986), and derivatives such as the cognitive-behavioural perspective (Turk, Salovy and Litt, 1986) embrace an interactional model of causation in which behaviour, personal factors (particularly cognitive), and environmental influences function as interdependent determinants of each other. Of particular relevance to the management of diabetes is the importance of self-regulatory capabilities which are developed and often supported by external influences. The organizing theme in the social-cognitive perspective is the emphasis on reciprocal determinism.

The cognitive-behavioural model of adherence presented by Turk et al., (1986) highlights four variables that in interaction with one another may influence adherence. These include: (1) appropriate knowledge and skills; (2) beliefs about one's ability to perform (self-efficacy) and the value of performing various behaviours (expectancy outcome); (3) motivation or incentives (or lack of them) for engaging in particular behaviours; and (4) behavioural acts which can be impeded or facilitated by the patient's knowledge and problem-solving skills, sense of self-efficacy, self-regulatory capabilities and external sources of reinforcement (degree of social support).

Behaviour is a product of both self-generated and environmental sources of influence (Bandura, 1986). The environment in which behaviour is performed provides both the discriminitive stimuli (cues) and the reinforcers. The family can be conceptualized as an environment that can function in ways that make adherence to the diabetic regimen more or less likely to occur. First, the reactions of family members, whether they be verbal or behavioural, intended or inadvertent can positively or negatively influence regimen behaviours. For example, family members may reinforce appropriate behaviours

by frequently praising good adherence or reinforce inappropriate behaviours by responding infrequently only to criticize lack of adherence. Second, family members may provide "gentle reminders" or cue the desired behavioural response. For example, they may cue the diabetic youngster to follow his/her diet or to remember his blood test. On the other hand, family members may cue inappropriate behaviours by frequently eating foods that are not part of the diabetic diet. Third, members may also tailor a family routine to meet the demands of the treatment regimen, such as changing family eating habits or establishing morning routines so that the diabetic child will take insulin on time.

Behaviour is not constantly at the mercy of external influences but becomes self-regulatory (Bandura, 1986). The goal in diabetes management is self-regulation of glycemic control. There is a parallel in the steps involved in the self-regulation of behaviour with those involved in the regulation of blood glucose levels (Wing, Epstein, Nowalk and Lamparski, 1986). For example, diabetes self-regulation includes self-monitoring (that is, tracking behaviours such as blood glucose levels), self-evaluation (that is, comparing the present rate to the expected, such as comparing actual blood glucose levels to normal levels), and self-reinforcement (that is, reinforcing individual efforts such as efforts to maintain normal blood glucose levels).

Successful self-regulators are able to direct their activities toward anticipated distal outcomes in the absence of more immediate external rewards (Bandura, 1986). Nonadherence is common among children and adolescents because their self-care behaviours are under the control of "competing reinforcement contingencies"(Gross, 1987)). Although the long-term outcome of adherence is major and positive, such as avoiding the complications of

diabetes, following the daily regimen is often associated with some slight immediate unpleasant consequences. For example, finger pricks and insulin injections may produce some discomfort and inconvenience, while following a diet may require patients to deny themselves basic pleasures. High blood glucose readings may result in negative interactions with parents while taking snacks may result in unwanted attention from others. Furthermore, although the long-term consequences of nonadherence can be major and negative, nonadherent behaviours, with the exception, perhaps, of insulin omission, often do not result in immediate health problems. In fact, the nonadherent behaviours are more often supported by naturally occurring immediate reinforcement contingencies.

Learning to bring the regimen behaviours under the control of long-term consequences is shaped by the environment. If family members withdraw support too soon or are overly involved to the extent of taking primary responsibility for the regimen tasks, the family environment will fail to provide the response-maintenance contingencies necessary for the development and support of self-regulatory regimen behaviours.

One of the advantages of the cognitive-behavioural perspective is that it suggests specific techniques for enhancing adherence such as: (1) adopting a **problem-solving approach** to the self-care regimen for the purpose of identifying barriers to adherence and generating solutions (D'Zurilla and Goldfried, 1971); (2) employing **goal-setting procedures** to provide direction and enhance motivation (Locke, Shaw, Saari and Latham, 1981); (3) using **contingency contracting** as a means of formulating ways to achieve realistic goals and receive rewards (Patterson, 1975); (4) **attending to beliefs** or cognitive distortions that may undermine adherence (Beck, Rush, Shaw and Emery,

1979); and (5) arranging for appropriate social support and family involvement for the purpose of enhancing patient motivation (Baranowski, Nader, Dunn and Vanderpool, 1982).

Understanding the family's involvement in the diabetes regimen tasks is likely more complex than construing the family in terms of discriminitive stimuli and consequences it provides for self-care behaviours. The family systems approach suggests several additional dimensions and interventions that may be useful for a family-based approach for compliance problems.

Family systems theory, which is rooted in general systems theory (Bertalanffy,1968), provides the general framework that underlies major clinical approaches to the family (Minuchin and Fishman, 1981; Haley, 1987; Bowen, 1978). Several assumptions of systems theory are relevant to our understanding of the family's involvement in the regimen behaviours (Epstein, Bishop and Baldwin, 1982). They are: (1) the parts of the family are interrelated; (2) one part of the family cannot be understood in isolation from the rest of the system; (3) a family's structure and organization are important factors determining the behaviour of family members; and (4) transactional patterns of the family system shape the behaviour of family members. The implication seems quite clear - all family members are active and interdependent contributors to the effective management of diabetes.

In order to understand the structure, organization and transactional patterns of the family, family system proponents focus on several basic dimensions of family functioning such as problem-solving, communication, role differentiation, affective responsiveness and involvement, and behavioural control strategies (Epstein et al., 1982). These processes are considered to have an etiological relationship to both psychological dysfunction and

psychosocial competence (Walsh, 1982).

The family's primary objective is the successful accomplishment of a variety of tasks. These may be instrumental tasks (related to food and shelter), developmental tasks (related to child-rearing or life cycle changes), and crisis tasks such as those involved in the management of a chronic illness. Each of the tasks involved in the management of diabetes can give rise to events or barriers that can potentially interfere with adherence (Glasgow, McCaul and Schafer, 1986). How well the adolescent and his/her family overcome these barriers will depend to a large extent on their ability to identify problems and solve them effectively. Successful task accomplishment also involves the differentiation and performance of various roles within the family in such a way that shared responsibility for the regimen tasks would be possible. The level of family support will be determined by family modes of interacting with respect to adequate exchange of information, emotional involvement and effective behavioural control strategies.

Many of the techniques arising from the family systems formulation are aimed at changing dysfunctional transactional patterns in the family. Generally speaking, this mode of treatment is considered to be a long-term endeavor of several months or even years. However, there are several family therapy techniques that could be useful in treating problems of adherence in children and adolescents in brief interventions. They are: (1) utilizing the family system. The family's beliefs, perceptions and behavioural patterns are inextricably involved in the management of health (Rissman and Rissman, 1987). Holding a family conference can enable the health care professional to determine what information or misinformation family members have, what their beliefs and expectations are regarding treatment and how they perceive the

problem. Including the family makes it possible to minimize barriers to adherence that are posed by a family member's behaviour and to encourage supportive family behaviours to enhance behaviour change; (2) employing the interviewing techniques of "circular questions" (Palazzoli Selvini, Boscolo, Cecchin and Prata, 1980) and "reflexive questions" (Tomm, 1987, 1988) as therapeutic interventions. Circular questions can be useful for gathering information about the problem and family relationships, beliefs, thoughts and feelings, in this case about the family's organization around the regimen tasks. Some examples are, "Who is the first to notice when things are not going well? What usually happens? How do others react when tests are high? Who agrees (or disagrees) that this is what usually happens? Who believes most strongly (or doesn't believe) that daily blood glucose testing is related to better control?". Circular questions may increase the family's awareness of the reciprocal interrelatedness of behaviours, which may alone produce change. A pragmatic taxonomy of circular questions has been provided by Nelson, Fleuridas and Rosenthal (1986). Reflexive questions are intended to influence the patient or family in an indirect manner (Tomm, 1988). The intent behind these questions is to facilitate the family's problem-solving efforts. Some examples are, "What do you think the effect would be if instead of criticizing the patient's lapses in adherence you offered praise and encouragement when the diabetes tasks were carried out? If others in the family were to follow the diabetic diet most of the time, what kind of an effect do you imagine this would have on the patient's dietary adherence?"; and (3) using the technique of reframing, which is defined as "(changing) the conceptual and/or emotional setting of viewpoint in relation to which a situation is experienced and to place it in another frame ... which fits the "facts" equally well or even

better, thereby changes its entire meaning" (Watzlawick, Weakland and Fisch, 1974). For example, when the blood glucose testing results are viewed by the patient or family in terms of a good or bad evaluation of themselves, reframe the results as being just information that allows them to see how the patient's diabetic control is doing and to determine if changes need to made.

In conclusion, the findings from this review point to the need for a pragmatic, diabetes-specific approach to families that is based on the premise that poor diabetic control during adolescence is most often a result of inadequate adherence. This may be related to deficencies in diabetes information, self-care skills, and family support as well as interfering control problems. If psychological research in this area is to be useful to health-care professionals, protocols for intervening with families need to be developed and tested in well-controlled experimental investigations.

In the present study, the findings from the research on family determinants of adherence and effective behavioural strategies as well as the relevant theoretical principles outlined above were used to guide the development of a diabetes care family intervention protocol. This protocol was tested in a randomized controlled outcome study with adolescents who were not adequately complying with their treatment plan and who were in moderately poor to poor diabetic control. Patients in the experimental group attended several family compliance counselling sessions. Patients in the comparison group spent a comparable amount of time learning stress-management techniques. All patients received a review and update of their diabetes skills and knowledge with particular focus on their blood glucose monitoring technique and decision-making regarding insulin adjustments. In both conditions, patients (and families) were seen on an individual basis.

The intervention was evaluated for its effects on levels of regimen adherence, glycemic control, and diabetes-specific family support over a 6-month period. It was predicted that adolescents in the experimental group would demonstrate greater changes in levels of adherence and family support, as well as significant improvements in glycemic control when compared to the comparison group.

6. Objectives of The Study: Research Questions To Be Investigated and Hypotheses To Be Tested

The objectives of the study were:

(1) To develop a diabetes care family intervention protocol for the purpose of bringing improvements in regimen adherence and metabolic control of adolescents with IDDM;

(2) To test the therapeutic efficacy of a family-based approach in a randomized controlled study.

The specific research questions addressed were:

(1) Does a family-based intervention improve adherence to the diabetic regimen?

(2) Does a family-based intervention lead to improvements in diabetic control?

The following hypotheses tested were:

(1) The family intervention group will demonstrate higher levels of adherence (self-monitoring and self-report measures) to various components of the treatment plan at the 6-month follow-up than will be demonstrated by the comparison group. This is expected, because in the family intervention condition, the focus will be on the tasks that comprise the diabetes regimen and the patient's level of adherence to each component. This

will be in addition to their standard care. In contrast, patients in the comparison group will receive attention to their regimen adherence in the usual manner as part of their standard medical care.

(2) The family intervention group will demonstrate greater improvements in HbA1c levels at the 6-month follow-up than the comparison group. These differences will be both statistically and clinically significant. This is expected because good adherence to the diabetic regimen is considered to be necessary to achieving acceptable HbA1c levels.

(3) Measures of adherence will be inversely related to HbA1c values. That is, higher levels of adherence will be associated with lower HbA1c values.

(4) The family intervention group will demonstrate higher levels of supportive family behaviours at the 6-month follow-up, as measured by the Diabetes Family Behaviour Checklist and the Family APGAR, than comparison group subjects. This is expected because the intent of the family intervention is to enhance the level and quality of family support as it relates to the diabetic regimen.

(5) Overall, higher levels of supportive family behaviours will be associated with greater improvements in adherence over the 6-month period. The literature review focussed attention on the importance of supportive family behaviours to the adolescent's level of self-care.

METHOD

Subjects

Twenty-nine adolescents with IDDM and their families were recruited from the population of 300 patients regularly attending the Diabetic Clinic of the Children's Hospital of Eastern Ontario. Patients were approached who met the following criteria: (1) adolescents with IDDM, aged 12-17 years; (2) mean HbA1c values >9.0% over the preceding 9 months; (3) physician assessment of poor adherence. This conclusion may have been reached on the basis of: (a) clinical judgment (for example, perceived irregularities in food intake, lack of support at home, complacency about diabetes care, and parent-child conflict over diabetes tasks); (b) history of "no shows" for periods of over 6 months; and (c) diary-keeping records that suggested fabrication of results, testing infrequently or failure to bring records to the clinic visit; (4) a diagnosis of diabetes for at least a year; (5) not experiencing other major medical problems such as epilepsy, uncontrolled hypothyroidism, etc; and (6) not currently involved in other treatment programs for psychosocial problems. Of 40 patients and their families contacted, 32 subsequently agreed to participate. The results are based on the findings from 29 patients. This meets the sample size requirement for finding an experimental effect with the HbA1c measure (Cohen, 1977). Table 4 summarizes the clinical and demographic characteristics of the study population. The results of the t-tests and chi-square tests indicate that there were no statistically significant differences between the groups. Patients were randomly assigned to a family-based intervention or a comparison condition and were seen for 3-5 sessions over about a two to two and a half month period. Twenty patients (11 experimental, 9 comparison) were seen by the primary investigator and 9

Table 4
Baseline Clinical and Demographic Characteristics of Adolescents

Measure	Family Intervention Group (N=15)	Comparison Group (N=14)	p
Duration of IDDM(yr)	4.80 +2.59	6.64 +3.02	NS
No. of daily injections:			
one	1	2	
two	13	12	
multiple	1	0	
HbAlc levels(%)	11.6 +1.41	11.3 +1.22	NS
No. of females(%)	47	57	NS
Age(x)	14.5 +1.46	14.7 +1.75	NS
Grade level	8.67 +1.68	8.85 +1.87	NS
Occupation:	Mo Fa	Mo Fa	
managerial	3	1 1	
professional	4 3	3 3	
supervisory	1 2	1 2	
technical	1 2	1	
clerical	2	4 1	
skilled	1 2	1 3	
unskilled	1	1	
not employed	4 2	2	
Income level:			
<20,000	2 (13%)	2 (14%)	NS
20,000-29,999	2 (13%)	2 (14%)	
30,000-39,999	2 (13%)	4 (29%)	
40,000-49,999	4 (27%)	4 (29%)	
>50,000	5 (33%)	2 (14%)	
Two-parent homes(%)	87	79	NS

patients (4 experimental, 5 comparison) were seen by a Ph.D. candidate therapist. Assignment of patients to the second therapist was based on her availability and not on the basis of any other criteria.

At the outset, written consent to participate in the study was obtained from each family, and confidentiality and the privilege to discontinue at any time was assured. Two subjects in the family intervention group chose to drop out of the study after the first session. The findings from one patient, who completed the study protocol, were eliminated from the final analyses because she added another insulin injection to her daily regimen during the follow-up period. The consent form and all procedures were approved by the Research Ethics Committee of the Children's Hospital. The consent form is included in Appendix A.

Procedure

Family-based intervention. Patients assigned to the family intervention condition were asked to attend with both parents and siblings closest in age to the patient. In cases of divorce, both parents were asked to attend unless this was impractical. At the first session, family members met with the diabetes nurse educator for the purpose of having their diabetes management skills and knowledge reviewed and updated. In particular, the following were reviewed and/or introduced: (1) the goals of the clinic with respect to normoglycemia; (2) the technical skills involved in blood glucose monitoring; (3) the interrelationship between insulin, diet and exercise, and the decision-making criteria regarding modifications to each; (4) learning to make compensatory adjustments in insulin dosage based on the pattern of blood monitoring results over several days. Written guidelines were provided for this. Before leaving this first session, patients were directed to perform at least 2 blood tests daily and were instructed

in the use of the self-monitoring forms. Two patients from the experimental group were also referred to the dietician for a review of their dietary skills and knowledge.

Following the review session, family members attended 2 to 4 family adherence counselling sessions. Sessions were scheduled during the first two to two and a half months of the study period. These sessions were about two weeks apart, with the exception of the review and first adherence counselling session, which were about one week apart. Families understood, upon entering the study, that they would be required to attend a minimum of three sessions. The range 2 to 4 (or 3 to 5, counting the review) reflects an attempt to be flexible with respect to the fact that different families may have different needs. In this regard, the study protocol corresponded, to some extent, to clinical practice.

In general, these sessions had the following objectives: (1) to reinforce particular skills and directives arising from the review session; (2) to increase the family's awareness of how they may promote and support the adolescent's self-care behaviours; (3) to identify specific problem areas related to carrying out the treatment plan, and to assist the family in generating solutions. Various methods for facilitating behaviour change such as goal-setting, cueing, positive reinforcement and behavioural contracting were introduced and discussed when relevant; (4) to make explicit what were the adolescent's responsibilities and what were the family's responsibilties; and (5) to identify and challenge particular attitudes and beliefs held by a family member or the patient that may create barriers to good adherence. (See Appendix B for the family intervention study protocol and therapist manual.)

Comparison condition. Patients assigned to the comparison condition attended a review session with the diabetic nurse educator. The focus and

content were the same as was described above for the patients participating in the family-based intervention. One parent was required to attend with the patient. Before leaving the review session, patients were directed to perform at least 2 blood tests daily and were instructed in the use of the self-monitoring forms. One patient in the comparison group was referred to the dietician.

Subsequent to this session, patients were seen individually for 2 to 4 sessions for the purpose of learning strategies for coping with stress. The following were introduced and discussed: (1) the relationship between stress and diabetes; (2) training in a progressive muscle relaxation exercise. A personal audio cassette was provided; and (3) cognitive coping strategies. That is, patients were taught how to re-evaluate potentially distressing events. Patients were also given the opportunity to talk about their diabetes treatment plan and any difficulties they might have following it.

The primary intent of the comparison procedure was to give patients the same review and update of their diabetes skills and knowledge as the experimental group patients were given, as well as comparable contact time. However, learning stress management techniques may be regarded as a treatment on its own. Furthermore, some clinicians and researchers, as the literature review indicated, regard stress factors to be implicated in some glycemic control problems via hormonal pathways. Therefore, it seems that the comparison condition could constitute a "minimal treatment" in its own right. In addition to the major difference in content between the two treatments, there is also a difference with respect to the service delivery format. That is, the experimental treatment involved families, whereas the comparison condition involved individual adolescents. (See Appendix B for the protocol used with subjects in the comparison group.)

Measures

Metabolic control. At the pretreatment phase, metabolic control was determined by averaging the adolescent's glycosylated hemoglobin (HbA1c) levels taken at the time of the most recent clinic visit and during the 9 months prior to this evaluation. This measure has been described elsewhere (p.7). HbA1c values were also obtained at the 3rd month and 6th month follow-up clinic visits. All blood samples were analyzed in the same laboratory using BIO-Rad HbA1c Column Assay method. The normal range for nondiabetic persons in the lab at the Children's Hospital of Eastern Ontario is 4.0 to 6.1%. Good metabolic control for patients with IDDM is considered to be <8.0%.

Adherence behaviours. Subjects completed a Summary of Self-Care Activities questionnaire at pretreatment and at the 6th month clinic visit. This is a self-report measure of the frequency of completing different regimen activities over the preceding 7 days: e.g., how closely dietary prescriptions were followed, the number of glucose tests conducted at correct times, the regularity of insulin injections and the number of days at least 20 minutes of exercise took place. Scores from this scale have previously been found to correlate with HbA1c levels in adolescents with IDDM (Schafer et al., 1983). The wording of the questions was changed to the negative for this study in order to counteract socially desirable responding (e.g. How often did you FAIL to follow your recommended diet over the past week?).

Additional information about the regimen behaviours was obtained from self-monitoring data that was recorded for 7 days after the review session, 7 days before the 3rd-month and 7 days before the 6th-month follow-up clinic visits. At each of the follow-up periods, subjects were instructed to maintain their usual self-care patterns during the days they were self-monitoring. They were provided

with recording booklets and instructed to self-monitor daily their insulin injections and glucose testing results as well as rate their eating and exercise behaviours. The amount and timing of the insulin injections and blood tests as well as any changes in the insulin dosage were to be recorded. Daily diet and exercise behaviours were rated by the adolescent using a 3-point scale (0=poor, 1=fair, 2=good). The following guidelines were provided for assessing the diet behaviours: (1) POOR indicated 3 or more deviations in the diet plan; (2) FAIR indicated no more than two deviations; and (3) GOOD indicated the diet was followed. A deviation was defined as: overeating, eating "not allowed" foods, skipping meals and snacks, not eating meals and snacks, not weighing or measuring food at meal times. The following guidelines were provided for assessing the exercise behaviours: (1) POOR indicated the patient had no vigorous activity that day; (2) FAIR indicated the patient had participated in under 20 minutes of vigorous activity; (3) GOOD indicated the patient had participated in over 20 minutes of vigorous activity. Vigorous activity was defined as any aerobic activity such as brisk walking, swimming, skiing, bicycling, hockey, etc.

Adherence scores were calculated by computing: (1) the percentage of prescribed blood glucose tests conducted; (2) the percentage of time the diet was followed; and (3) the percentage of time exercise was incorporated into the patient's daily routine.

Diabetes-specific family support. This was assessed with the supportive items of the Diabetes Family Behaviour Checklist (DFBC) (Schafer, Glasgow, McCaul and Dreher, 1983; Schafer, McCaul and Glasgow, 1986). The DFBC has been described in detail elsewhere (p.15). The supportive subscale is composed of nine items. For adolescent ratings of parental support, internal consistency of

the DFBC is .63 and the 6-month stability is .60 (Schafer et al., 1986). Recent findings by Hanson et al., (1987), using a large sample size, have established the validity of the supportive subscale as an index of parental support in relation to adherence to the diabetic regimen. This suggests that it may be a useful tool for intervention studies for documenting changes in the frequency of supportive family behaviours.

The DFBC was administered at pretreatment and at the 6-month follow-up clinic visit. There was an adolescent and parent version. Adolescents rated each parent on 5-point Likert scales across nine behaviours that are supportive of the diabetic regimen. Ratings of each parent were summed to provide an overall index of parental support.

General family support. A simple screening instrument, the Family APGAR, was used to assess general family support. The Family APGAR is a 5-item questionnaire that was designed to examine satisfaction with variables of adaptation, partnership, growth, affection and resolve in the respondent's family. The Family APGAR has been validated by correlating it with a previously validated instrument (Pless Satterwhite Family Function Index, r=.80) (Good, Smilkstein, Good et al., 1979). A recent study by Shapiro, Neinstein and Rabinovitz (1987) established its validity as an index of general family support with teens seeking medical care. These authors suggest that it may provide a useful means of determining the adequacy of family support when compliance issues arise. The Family APGAR was administered to the adolescent patient only, both at the pretreatment phase and the 6-month clinic visit.

Socially desirable reponse tendency. The extent to which subjects give socially desirable responses on self-report measures was assessed with the Children's Social Desirability Questionnaire (CSD) (Crandall and Crandall, 1965).

In the clinical setting, the patient's report of compliance may be inflated by a high need for approval (Crowne, 1979). The CSD provides a means of measuring the extent to which this factor is operative in the adherence self-report and self-monitoring data. The CSD is composed of 48 true-false items. Split-half reliabilities range from .82 to .95 for various samples, and test-retest reliabilities (1-month) range from .85 to .90 (Crandall, 1966). The CSD was administered to each subject at the pretreatment phase.

Treatment credibility. A rating scale was devised to assess participants' views regarding the credibility of the treatment and its effectiveness. Participants were asked, How logical does (did) the program seem to you? How confident would you be in recommending this program to other adolescents with diabetes and their families? How beneficial do you think this program will be (was) in helping you make improvements in your diabetes care? The questions were answered on a scale from 1 (not at all) to 5 (very). Scores from each item were summed to form an overall credibility rating score. The scale was given to both adolescents and parents, in both treatment conditions, at the pretreatment phase and at the 6-month follow-up. Participants were also asked to indicate which part of the program they considered to have been most helpful.

Statistical analyses. The following statistical procedures were employed, using the SPSS-X statistical package. Multivariate analyses of variance (MANOVA) for repeated measures were conducted to evaluate within and between group differences on all the data. The MANOVA statistical procedure was used to analyse single dependent adherence variables (i.e., ANOVAs) rather than multiple dependent variables simulataneously (i.e., MANOVAs). This was done for two reasons. First, findings from increasingly sophisticated studies indicate that the intercorrelations among measures of adherence to different aspects of the regimen

are small and often nonsignificant (McCaul et al., 1987). Second, because this was an intervention study, it was important to understand the effects of the treatment on specific adherence behaviours.

Repeated measures analysis requires that all variances of the repeated measurements are equal, and that all correlations between the pairs of repeated measurements are equal (O'Brien and Kaiser, 1985). MANOVA provides tests of these two symmetry conditions. When the conditions were met, univariate test results which have greater statistical power were used. If the symmetry conditions were violated, multivariate test results were used. The 2X3 design employed in this study has unequal subjects (15 in the experimental group and 14 in the comparison group). By default, MANOVA uses a least-squares solution for unbalanced designs.

t-Tests were used to make intra- and intergroup comparisons of the levels of adherence and family support. Pearson Product Moment correlations were computed to evaluate linear relationships on the following variables: between adherence, family support and HbA1c values; between clinical/demographic baseline data and follow-up HbA1c levels; and between social desirability scores and measures of adherence. Multiple regression equations were computed for the purpose of testing the causal assumption that treatment effects glycemic control via the enhancement of family support and self-care.

RESULTS

Differential therapist effects were tested by a series of t-tests (Therapist x individual score on each follow-up measure of adherence, diabetic control and family support variable), in which the two therapists were treated as a fixed factor. No significant differences at the .05 level were found between the means on any of the adherence measures or HbA1c values. There was one significant difference between means on the general family support variable (t=2.10, p=.05). Thus, there was little evidence of differential therapist effects.

Correlations between scores on the Children's Social Desirabilty Questionnaire and the measures of adherence were uniformly low ($r_s < .22$). This suggests that adolescents' reports of compliance were not greatly biased in the direction of over reporting self-care behaviours.

The mean number of sessions attended by participants was about equal for both treatment groups. The means for the family intervention group and the control group were 3.3 +.59 and 3.2 +.57, respectively.

Correlations between baseline clinical and demographic characteristics (sex, age, family income, diabetes duration, two-parent households) and follow-up HbA1c levels did not reach the $p < .05$ level of significance. There was a nonsignificant tendency for adolescents with lower HbA1c levels to come from higher income families [$r(29) = -.30$; $p=.06$].

The internal consistency of the self-report measures of adherence and family support were examined on the follow-up data. The data reveal a Cronbach's alpha of 0.42 for the Self-Care Questionnaire, 0.79 for the Family APGAR scale and 0.55 for the supportive subscale of the DFBC. For the latter scale, adolescent and parent internal consistency scores were averaged. The relatively low alpha values for the self-care and diabetes-specific family support

scales reflect the fact that they measure behaviours as they relate to different areas of the diabetic regimen.

Treatment Effects

Changes in adherence. To test the effect of the family intervention on self-reports of regimen behaviours, a repeated measures MANOVA was performed. The results are shown in Table 5. Also shown are the intragroup changes (evaluated with paired-samples t-tests) and intergroup differences in scores at the 6 month follow-up (evaluated with independent-samples t-tests). One-tailed tests were used for the latter two analyses because they involve directional predictions. Figure 1 illustrates the changes in mean scores from pretreatment to 6 month follow-up.

Table 5
Pretreatment and Follow-up Mean Adherence Levels (Self-Report)

		Intragroup Changes						Intergroup Differences	
	F	Family			Comparison				
Behaviour	(1,27)	Pre	F-up(X)	t	Pre	F-up(Y)	t	X-Y	t
Insulin on time	2.14	3.5	3.4	0.22	2.8	3.2	-1.9*	-0.20	1.3
BGT on time	0.65	3.5	3.4	0.22	3.9	4.3	0.82	-0.90	1.7*
No. of BGT	6.80**	1.1	1.9	-5.5****	0.93	0.93	0.00	1.0	5.0****
Diet levels	0.41	4.5	4.5	0.00	4.6	4.3	0.75	0.20	0.33
Exercise levels	3.58	2.5	1.9	0.91	2.2	3.2	-1.7*	-1.3	-1.8*

*p<.05, **p<.025, ***p<.01, ****p<.001
Note. (1) High scores on the adherence subtests indicate poorer adherence with the exception of the BGT frequency subtest. In this case, a high score reflects better adherence; (2) F statistic is the time x group interaction; and (3) BGT = blood glucose testing.

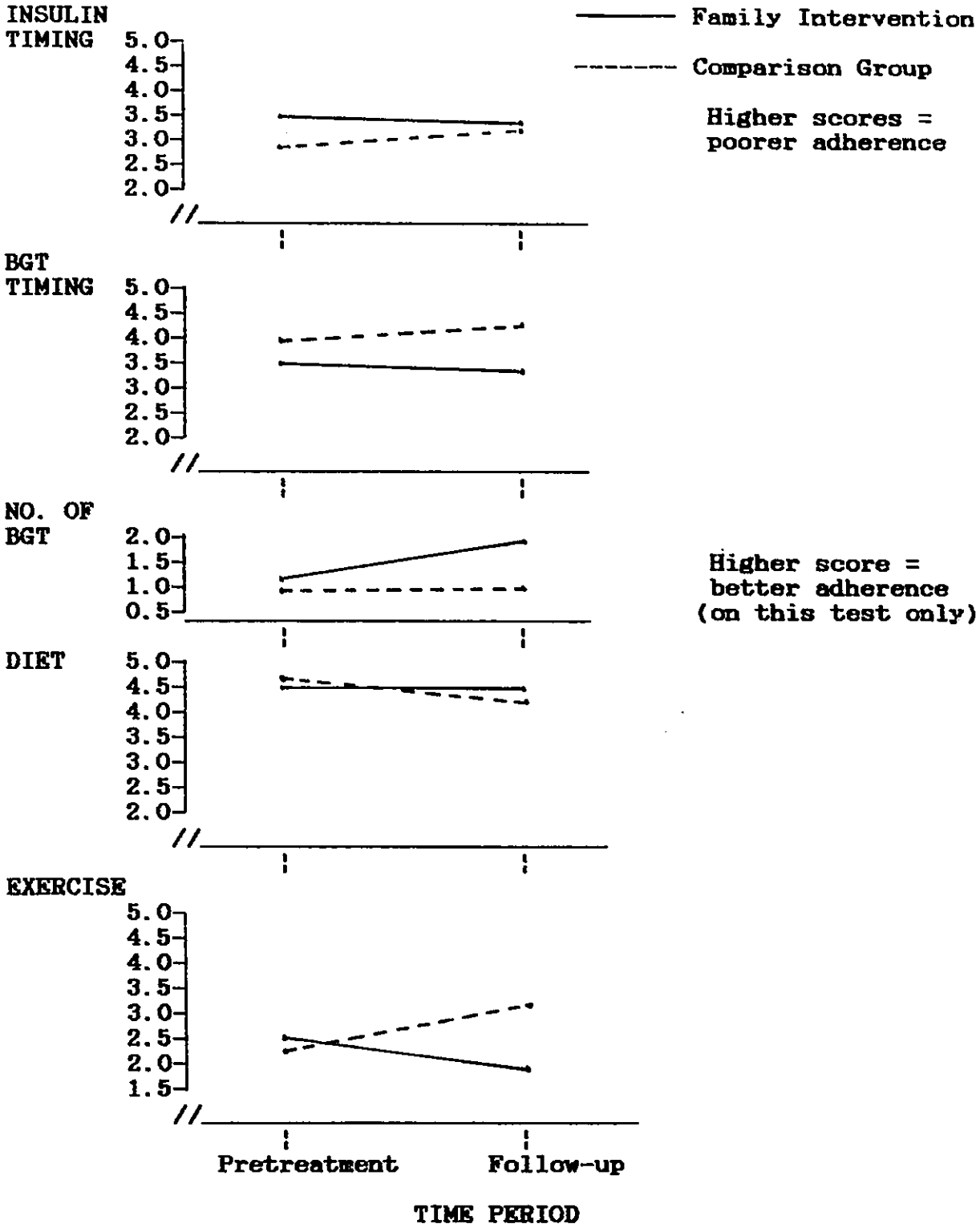


Figure 1. Mean levels of adherence for the family intervention and comparison groups at pretreatment and 6 month follow-up.

The two groups did not differ significantly at the .05 level on the measures of adherence before treatment with the exception of insulin timing ($t=2.12$; $p<.05$). Table 5 indicates there was one significant Time x Group interaction, suggesting the treatment groups were differentially effective at improving the regularity of blood glucose testing. Adolescents in the family intervention displayed significant increases in the mean frequency of daily blood glucose testing when compared to the comparison group patients who exhibited no change. Significant group differences at follow-up were indicated with respect to the correct timing of glucose tests. Comparison group adolescents reported higher levels of nonadherence on this subtest.

Intragroup analyses indicate adolescents in the comparison group showed significant decreases in adherence to correct timing of insulin injections and exercise routines. Only the latter resulted in significant group differences at follow-up.

The self-monitoring data were analyzed with a repeated measures MANOVA. The results are presented in Table 6. Figure 2 illustrates the percentage of time blood glucose was tested, diet was followed and at least 20 minutes of daily physical exercise took place at three weekly time periods throughout the course of the study.

The multivariate statistics indicate that there was a significant group and time effect for the blood glucose testing variable. As Figure 2 illustrates, the mean percentage of time that blood glucose was tested was significantly greater in the family intervention group than in the comparison group for each week after the review session, before the third month follow-up, and before the six month follow-up. It is important to point out that both groups reported equivalent levels of blood glucose testing the week before treatment began.

Table 6
Mean(%) Adherence Levels (self-monitoring data) Over Study Period

Behaviour	Group: Family Base	Family 3mos	Family 6mos	Comparison Base	Comparison 3mos	Comparison 6mos	F(1,27)
Blood glucose testing	.91	.88	.88	.74	.45	.45	a 24.97***
							b 8.70*
							c 5.86**
Diet	.70	.70	.67	.67	.64	.61	a .28
							b .85
							c .17
Exercise	.68	.68	.65	.74	.70	.63	a .07
							b .97
							c .33

*p<.008, **p<.001, ***p<.0005

Note. (1) a = Group F statistic; b = Time F statistic; c = Time x Group interaction; (2) Multivariate test results were used to asses treatment effects on BGT and diet behaviours.

There was also a significant effect for the time x group interaction. This was primarily a consequence of greater deterioration in blood glucose testing in the comparison group over the study period [F(2,54)=13.65, p<.001].

Post hoc pairwise comparisons (i.e., baseline vs. 3 months, baseline vs. 6 months, 3 months vs. 6 months) were carried out on the blood glucose testing variable. The critical significance level was set at .05/3=.017 (Bonferroni correction). Results indicate significant time x group interactions for comparisons made at baseline vs. 3 months [F(1,27)=6.60, p<.016], and at baseline vs. 6 months [F(1,27)=11.28, p<.002]. (See Appendix C, Table 6-1, for the detailed results). As can be seen from both Table 6 and Figure 2, the differences between the groups with respect to mean percentage of time the diet was followed and daily exercise occurred did not reach significance at any of the three time periods.

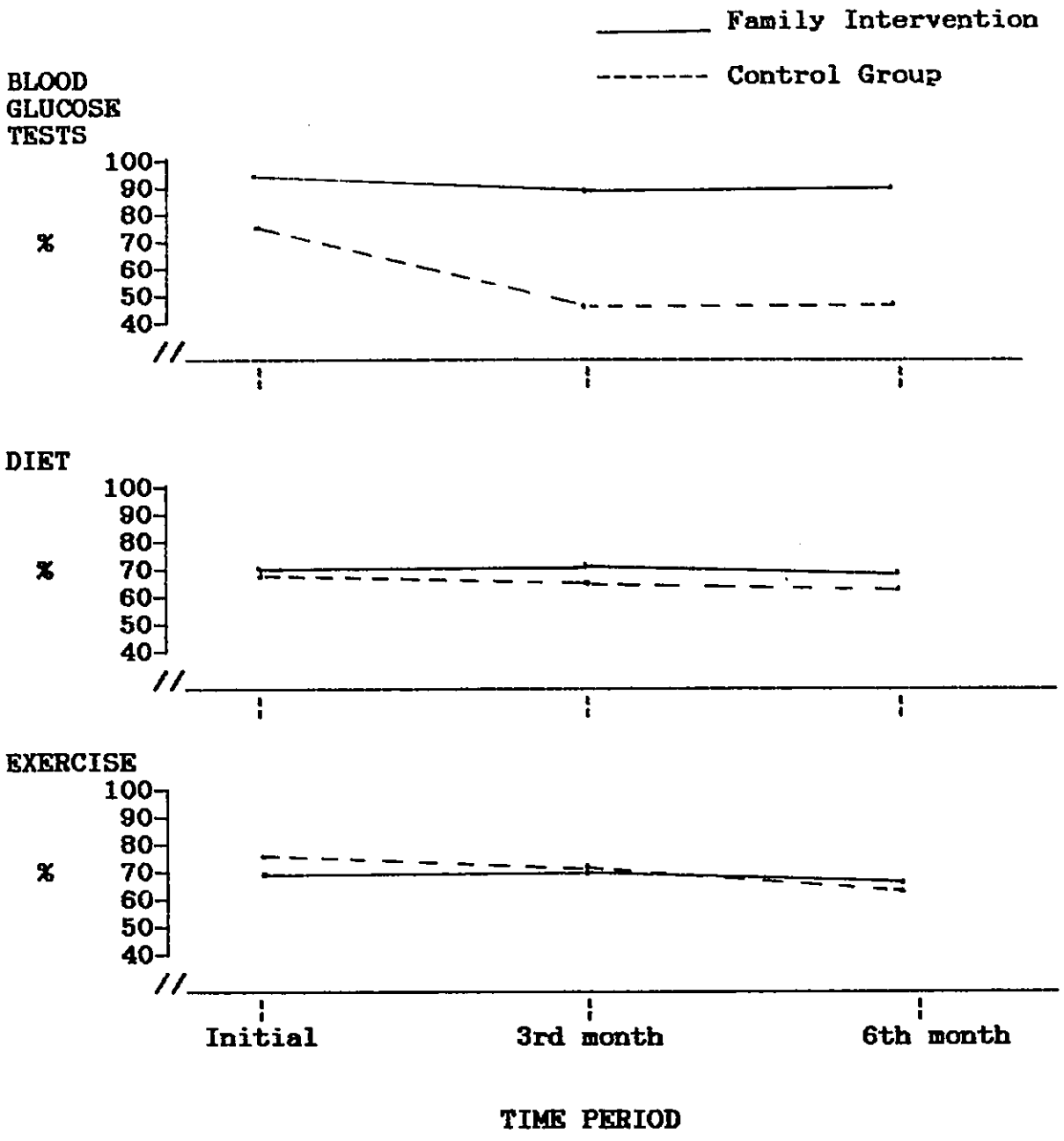


Figure 2. The percentage of time blood glucose was tested, diet was followed, and daily exercise of at least 20 min. occurred during the week after the review session, the week before both the 3rd month and 6th month clinic visits.

Changes in glycemic control. To test the effect of the family intervention on HbA1c levels compared to the comparison group a MANOVA (repeated measures) was performed. The means and results of the analysis can be found in Table 7. Figure 3 illustrates the means and their standard deviations across time.

The results show a significant effect for time indicating both groups showed improvements in glycemic control. The time x treatment interaction was nonsignificant.

Table 7
Mean HbA1c Levels (%)

Family Intervention			Comparison Group			
Pre	3mos	6mos	Pre	3mos	6mos	F(1,27)
11.6	10.0	9.8	11.3	10.1	10.5	a .07
+1.41	+1.81	+2.23	+1.22	+1.63	+1.57	b 13.63*
						c 1.47

*p<.0005
Note. (1) a = Group F statistic; b = Time F statistic; c = Time x Group interaction; (2) Multivariate test results were used.

Post hoc comparisons on the total sample were carried out at pretreatment vs. 3 months, pretreatment vs. 6 months and 3 months vs. 6 months. Again, a Bronferroni-type correction was applied. Each of the three comparisons was made at the .017 level. The results indicate that significant changes in glycemic control were found at pretreatment vs. 3 months [$F(1,28)=23.67$, $p<.0005$], and pretreatment vs. 6 months [$F(1,28)=12.44$, $p<.001$]. (See Appendix C, Table 7-1, for the detailed results).

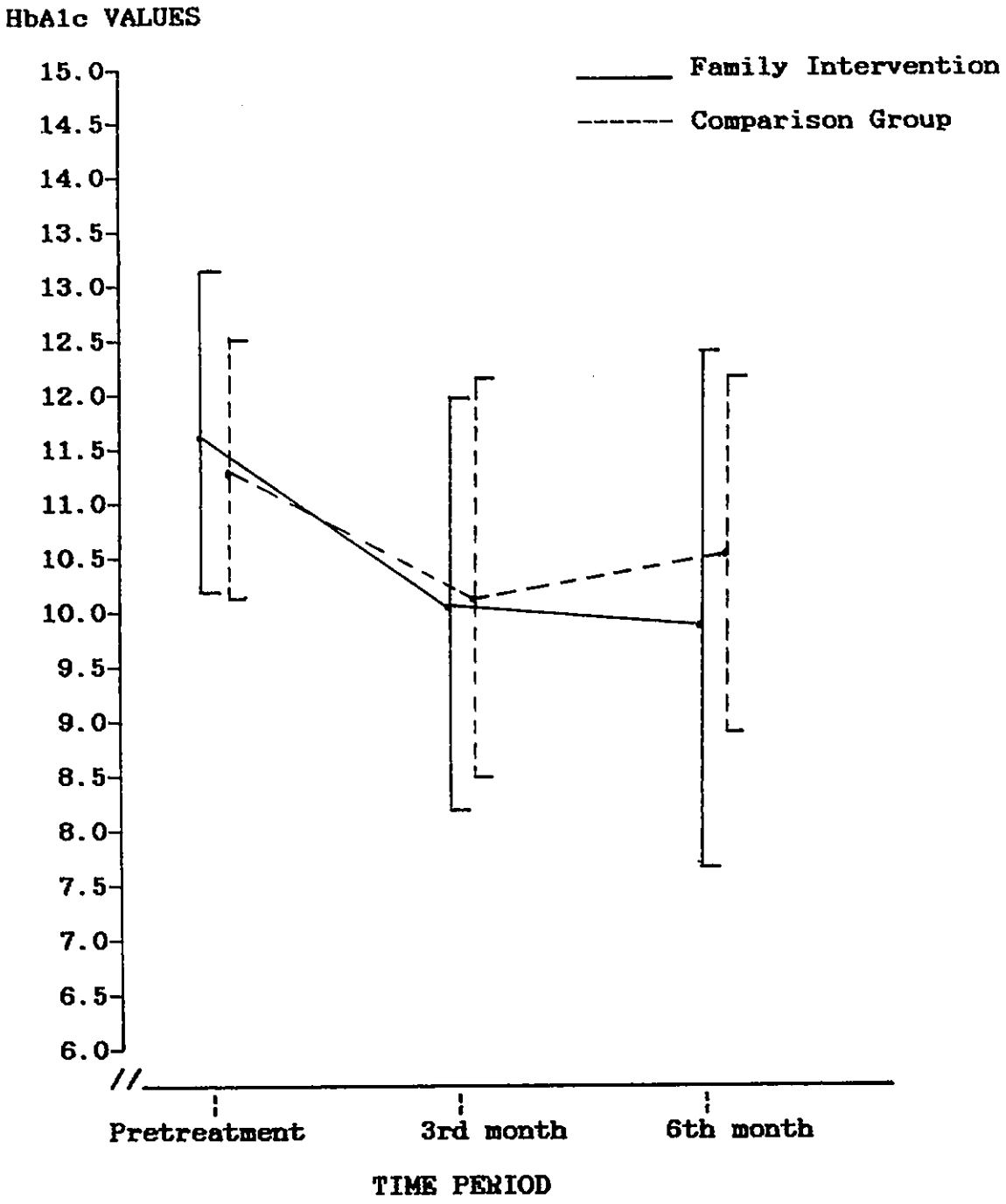


Figure 3. Mean HbA1c values with standard deviations for family treatment and comparison groups over the 6-month study period.

Adolescents in the family intervention group exhibited a mean decrease of 1.8% in HbA1c values at the 6-month follow-up, while comparison group adolescents exhibited a mean decrease of .80%. HbA1c values below 8.0% indicate very good diabetic control. In the family intervention group, five (33%) adolescents exhibited HbA1c levels below 8.0% at the 6-month follow-up. Their most recent pretreatment values ranged from 10.0% to 13.0%. There were no patients in the comparison group with HbA1c values below 8.0% at the 6-month follow-up [Chi-square (1)= 5.62, p=0.05].

To assess further the clinical relevance of these results, mean HbA1c values over the 9 months before treatment were compared with the mean values after treatment. Individual HbA1c values were classified according to a standard strategy used by Daneman (1981) and Anderson et al (1989). Adolescents in the family intervention and comparison groups were descriptively categorized on the basis of having improved (decrease of >1%), remained unchanged (within < 1%) or deteriorated (increase >1%). For example, a decrease of >1% from a mean HbA1c value of 10.0% before treatment would represent a decrease to below 9% at follow-up (a more acceptable level of diabetic control). This classification scheme reflects the difficulties that outpatient settings have in achieving significant decreases in HbA1c values using conventional medical interventions (Daneman, 1981).

All of the adolescents in the family intervention group exhibited either stable or improved glycemic control. In contrast, 71% of the adolescents in the comparison group exhibited either stable or improved control and 29% showed deterioration [Chi-square (2)=6.32, p=0.05]. Thus, the results from the nonparametric analysis suggest the two treatment conditions were differentially effective in halting the deterioration of diabetic control in adolescents.

Changes in family support. Table 8 presents the means for the family support variables at pretreatment and 6-month follow-up. These data were analysed with repeated measures MANOVA. Intragroup changes and intergroup differences at follow-up were assessed with paired-samples t-tests and independent-samples t-tests, respectively. The two groups did not differ significantly at the .05 level on any of the variables before treatment.

Table 8
Pretreatment and Follow-up Mean Family Support Levels

		Intragroup Changes						Intergroup Differences	
		Family			Comparison				
Family Support	F (1,27)	Pre	F-up(X)	t	Pre	F-up(Y)	t	X-Y	t
Adolescent Diabetes Specific	.83	18.6	20.8	-2.0**	19.8	20.4	-.55	.40	.20
General	F(1,22) 7.26***	6.1	7.2	-1.9*	7.4	6.4	1.9*	.80	.43
Parent Diabetes Specific	F(1,21) 1.02	20.8	24.1	-2.5**	21.5	22.9	-1.4	1.2	.57

*p<.05, **p<.025, ***p<.01
Note. F statistic is the Time x Group interaction.

The results indicate a significant effect for the time x group interaction on the general family support variable only. This suggests the treatments were differentially effective in bringing improvements in family support. These results are based on N=24. Intragroup analyses indicate adolescent reports of perceived general family support were significantly enhanced by the family intervention while adolescents in the comparison group showed a significant decline from pretreatment levels. Within group analyses also indicate that both adolescent and

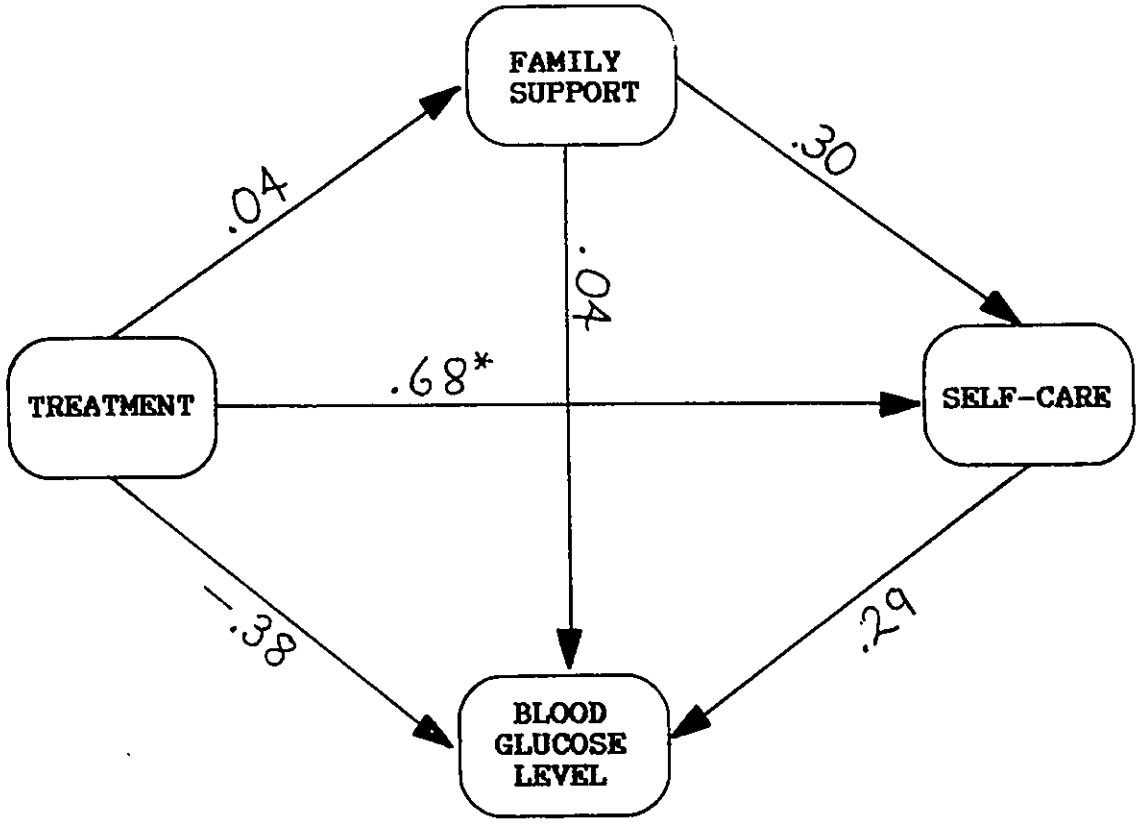
parent reports of diabetes-specific family support (DFBC) were significantly enhanced in the family intervention condition. However, the intergroup differences were nonsignificant.

Power calculations, that were carried out prior to the study, were based on the kinds of effect sizes that can be found with the HbA1c measurement. However, the effects sizes that were found with the diabetes-specific family support measures were relatively small (.20-.30). This means that with the present sample size of 15 and 14, the power of the study design was inadequate for detecting treatment differences on these measures (Cohen, 1977).

Correlational analyses. Correlations between the adherence variables and HbA1c levels at the 6th month follow-up were computed. The self-monitoring data for each regimen behaviour (blood glucose tests, diet and exercise) that had been collected over the three time periods was averaged and entered as percentages. None of the correlations reached the $p < .05$ level of significance. Correlations of family support variables with follow-up HbA1c values were uniformly low ($r_s < .14$).

Several adherence variables were related to measures of family support. Greater frequency of blood glucose testing was correlated with higher levels of adolescents' perceived diabetes-specific family support [$r(27)=.32$, $p=.04$] and general family support [$r(24)=.32$, $p=.05$], while lower levels of general family support correlated with nonadherence to correct timing of glucose testing, $r(24)=-.42$, $p=.02$.

Path analysis. Path analysis was performed to study the differential effects of the family intervention on family support, self-care and blood glucose levels. Figure 4 illustrates the path model. Multiple regression analysis was used to determine the magnitude of direct and indirect effects of treatment on the three



Treatment: Coded 1 for Family Intervention
Coded 0 for Comparison Group

Family Support: Adolescent reports of diabetes-specific family behaviour (DFBC)

Self-Care: No. of blood glucose tests/day

Blood Glucose Level: HbA1c values

Missing Values: None (N=29)

Figure 4. Path model illustrating the direct and indirect effects of treatment at the 6 month follow-up.

endogenous variables. Table 9 presents a summary of these effects.

Table 9
Summary of Direct, Indirect and Spurious Effects Of Treatment

Treatment	Zero-Order Correlations	Causal			Spurious
		Direct	Indirect	Total	
On Glucose Levels					
via family support			.002		
via self-care			.200		
via family support and self-care			.003		
	-.18	-.38	.205	-.18	none
On Self-Care	.69	.68*	.012	.69	none
On Family Support	.04	.04	none	.04	none

*p<.0001

The family intervention study was based on the causal assumption that treatment would lower glucose levels mainly indirectly via the enhancement of family support and self-care. When the negative direct effects of treatment on blood glucose levels are compared with the almost negligible indirect effects via family support and self-care, it can be concluded that the data do not lend support to this assumption. Furthermore, although the direct effects of the treatment are in the desired direction of lowering HbA1c levels (-.38), this is offset by the tendency (+.29) of adolescents in the family intervention who tested more frequently to have higher blood glucose levels.

The family intervention had its largest total effect on self-care, followed by a small total effect on diabetic control and a negligible effect on family support. Analyses of the residual effects reveal that over 90% of the variation in both

family support and blood glucose levels remain unexplained by the causal relations explicitly included in the model. In contrast, 57% of the variation in adherence to blood glucose testing is explained by the model. (See Appendix C for the path models using adolescent reports of general family support and parent reports of diabetes-specific family support.)

Credibility of treatment. Table 10 lists the mean credibility ratings for adolescents and parents in both the family intervention and comparison groups.

Table 10
Mean Treatment Credibility Ratings

	GROUP					
	Family Intervention			Comparison		
	Pre	F-up	t	Pre	F-up	t
Adolescent Ratings	11.6	12.1	-.93	11.1	9.9	1.23
Parent Ratings	12.4	11.7	1.32	10.7	11.2	-.58

Note. Total possible score is 15.

Intragroup analyses did not reveal significant changes from pretreatment to follow-up in either treatment condition. That is, both parents and adolescents viewed both treatment conditions as being highly credible before treatment began and this generally high opinion was maintained at follow-up. The between-group analyses indicate a significant difference in the pretreatment ratings from parents in the family intervention and comparison group ($t=2.09$, $p=0.05$). That is, parents in the comparison group were less certain of the benefits that might accrue from participating in the program than parents in the family intervention group. The difference in credibility ratings at follow-up from adolescents who participated in

the family intervention as compared to comparison group adolescents almost reached the .05 level of significance (t=1.94; p=0.06). That is, adolescents in the family intervention group rated their program as beneficial in helping them make changes in their self-care and were more confident in recommending it to others.

Adolescents and parents were also asked to indicate which part of the treatment program had been most helpful to them. Reports from parents and adolescents were averaged. Table 11 illustrates their preferences in percentages.

Table 11
Treatment Preferences

Group	Review	Adherence Sessions	Both	Neither
Family Intervention	23%	23%	51%	3%
		Coping Strategies		
Comparison	22%	18%	49%	11%

DISCUSSION

The purpose of this study was to evaluate the therapeutic efficacy of a diabetes care family intervention protocol with adolescents who were not complying adequately to the medical regimen and who were in moderately poor to poor diabetic control.

The first research question addressed by this study was,"Did a family-based approach improve adherence to the diabetic regimen?". Results indicate that there were significant group differences with respect to daily blood glucose testing. At the six month follow-up, adolescents in the family intervention group were testing blood glucose levels more frequently (on average 2 times daily) than they had been before treatment. Adherence to other components of the regimen did not change significantly from pretreatment levels. In contrast, adolescents in the comparison group did not demonstrate significant changes in the frequency of blood glucose testing from pretreatment to follow-up. They were testing on average less than once daily at both time periods.

Group differences with regard to the maintenance of treatment effects were evident in the blood glucose self-monitoring records. Adolescents in the family intervention group maintained, at the six month follow-up, the generally higher levels of adherence to blood glucose testing that had been established after the review session with the nurse. In contrast, adolescents in the comparison group showed significant deterioration in the blood glucose testing over the study period, that reached pretreatment levels.

Diet and exercise behaviours remained at about the 60%-70% adherence level throughout the study period for both treatment groups. It needs to be pointed out that the self-monitoring rating scheme used in this study provided only crude

estimates of diet and exercise behaviours. Consequently, these data may be less reliable than the blood glucose monitoring data. On the other hand, these findings may suggest, together with the findings from the self-report data, that the family intervention had less of an impact on these components of the regimen.

The second research question asked by this study was, "Did a family-based approach also bring improvements in HbA1c levels?". Results indicate that adolescents in both the family intervention and comparison groups demonstrated statistically significant improvements in diabetic control from pretreatment levels. Group differences became more apparent when the results were evaluated according to clinical significance criteria. When mean HbA1c levels over 9 months before treatment were compared with mean levels after treatment the findings indicate that although thesame number of adolescents in both groups exhibited improvements of > 1% (that is, decreases in HbA1c values), the family intervention was more effective in preventing deterioration in glycemic control. Anderson et al., (1989) reached similar conclusions after their randomized outpatient study of a peer-group intervention. Their findings indicate that a group-based problem-solving approach for teaching adolescents with IDDM how to use the information from the blood glucose tests can be effective in preventing increases in HbA1c levels.

The differential effects of the treatments were also evident when the degree of improvement in glycemic control within each group was examined on an individual basis. One third of the adolescents in the family intervention group who had pretreatment HbA1c levels of 10.0%-13.0% (poor control) had levels of6.1%-7.8% (very good control) at the six month follow-up. No adolescent in the comparison group achieved HbA1c values < 8.0%.

To summarize, the results indicated that the family intervention had its greatest effect in enhancing the regularity of blood glucose testing and in making clinically significant improvements in glycemic control. The fact that both treatments brought statistically significant improvements in glycemic control needs to be addressed. It can be argued that the comparison group used in this study, with its emphasis on stress and coping, may actually have constituted a "minimal treatment" in its own right. Therefore, it seems possible that smaller effect sizes were found, using this kind of comparative design, than would have occurred if a strictly standard care group had been used.

There were several relationships found between levels of family support and measures of adherence at the six month follow-up. Higher levels of family support were related to blood glucose testing frequency, while lower levels of family support were associated with poorer adherence to correct timing of blood tests. Measures of family support were unrelated to glycemic control. These results are consistent with previous findings (Schafer et al., 1983; Hanson et al., 1987).

This research was guided by the assumption that the family intervention, through the enhancement of diabetes-specific family support, would result in improvements in self-care and glycemic control. This assumption was examined further by studying the direct and indirect effects of the family intervention on family support, blood glucose testing and HbA1c values at the six month follow-up. The path analysis results indicated that the treatment had the largest effect on adherence to blood glucose testing; this effect, however, did not appear to be mediated by family support. This was due, in part, to the fact that the family intervention had almost negligible effects on the family support variable. There are several likely explanations for this finding. The first is that the

intervention, in fact, did not have an impact on supportive behaviours in the family and that improvements in adherence to blood glucose testing may have resulted from other, unknown reasons.

A second explanation is that the measures used may not have been robust or broad enough to register all the changes in family support that might have occurred. The supportive subscale of the DFBC and the Family APGAR consist of 9 and 5 items, respectively. It has been suggested that family support consists of several critical dimensions such as warmth and caring, guidance and control, and problem-solving (McKelvey et al., 1989). These dimensions are not fully evaluated by the measures employed in this study.

A third explanation is that supportive behaviours in the family may not be as important to adolescents' self-care asother family variables, such as the family's knowledge about diabetes management (Hanson et al, 1987a), their sense of competency in performing the diabetes tasks (McCaul et al, 1987),their glycemic goals (Marteau et al, 1987b), or beliefs and expectations regarding the consequences of following the diabetic regimen (Wing et al, 1985; Bobrow et al, 1985). Although attention was given to these other variables as part of thefamily intervention protocol, they were not specifically targeted for evaluation.

The final explanation relates to the issue of statistical power. The HbA1c measure was considered to be the primary outcome measure in this study, because of its direct relationship to the presenting problem (unacceptable levels of glycemic control). Consequently, *ante hoc* power calculations were based exclusively on this measure. However, this means that, given the small effect sizes that were found with the family support measures, there was inadequate power for detecting treatment differences. The absence of group differences on the Diabetes Family Support Checklist should not necessarily be interpreted as

nullifying the hypothesis. In other words, the assumption that the experimental treatment enhanced diabetes-specific family support may still remain viable.

The examination of the direct and indirect effects of the treatment also suggested that while the family intervention had the direct effect of decreasing blood glucose levels, this was offset by the tendency for adolescents who reported testing blood glucose more frequently to have higher glycemic levels. While at first this may appear contrary to what one would expect, further consideration reveals otherwise. Studies evaluating the frequency of blood glucose testing on levels of control have yielded inconsistent findings (Schafer et al., 1983; Wing et al.,1985; Glasgow et al., 1987; Belmonte, 1988). Many clinicians consider that simply testing blood and taking insulin on time are not sufficient for achieving significant glycemic effects. If daily fluctuations in blood glucose levels are to be kept at a minimum, it is essential that there be appropriate interpretation and usage of the blood glucose data with consistent adjustments of insulin dose and food intake accordingly (Davidson, 1986; Belmonte, 1988). In other words, the therapeutic value of daily blood glucose testing must be mediated by other facilitating factors.

There was some suggestion from qualitative assessments that adolescents in the family intervention group were more likely to use the results from the blood glucose tests to initiate insulin adjustments and/or changes in diet. An examination of self-monitoring records and interviews with the family indicated that approximately 53% of the adolescents in the family intervention group were using the blood glucose monitoring data at least some of the time, compared to 28% of the adolescents in the comparison group. This is an encouraging sign in light ofthe fact that the curriculum for teaching insulin adjustments in this study was not particularly potent (one 1.5 hour session with written guidelines

provided). Although the adequacy of the insulin adjustments was not determined in any systematic way, the nurse was frequently asked to review the self-monitoring records and give feedback to the patient at follow-up clinic visits.

Anderson el al. (1989) reported rates of 60%-70% of blood glucose data usage after their group-based problem-solving approach which took place over 18 months and included six 1.5 hour sessions. This is an area that previously has not received a great deal of attention in the literature inspite of its apparent importance to diabetic control. The studies that have been reported indicate that in general few adolescents and parents (less than 20%) utilize these data for intiating changes in their self-care (Wysocki, 1989). It is important that researchers direct more attention to developing reliable assessments of this very critical regimen behaviour and to evaluating the impact that interventions have on it in relation to the effects on glycemic control.

The diabetes care family-based intervention protocol that was tested in this study had two components - a diabetes skills and knowledge review session with the clinic nurse and several family adherence counselling sessions with a psychologist. Although the study design does not permit analyses regarding which part of the treatment contributed more to the outcome, reports from parents and adolescents in the family intervention group indicated that just over half considered both aspects ofthe treatment program had been helpful to them.

Parent and adolescent family treatment credibility ratings were fairly high both before the treatment took place (77%-83%) and at six-month follow-up (78%-81%). There was a somewhat greater tendency for adolescents in the family intervention to believe the program had been beneficial in helping them bring improvements in their self-care than was true for adolescents in the comparison group.

Adolescents who were referred to the study were assessed as being noncompliant most often to blood glucose testing and following the diet. However, there was frequent pseudononcompliance (i.e. unintentional errors) uncovered duringthe review session with the nurse. For example, several adolescents were found to be using: malfunctioning or dirty meters, the wrong, outdated or defective testing strips, incorrect blood glucose testing techniques and contaminated insulin. It is not clear to what extent the correction of these errors may have contributed to improvements in diabetic control. What is clear is the importance of clinics carrying out periodic evaluations of blood glucose testing technique and assessment tools.

There are further methodological issues pertaining to the methods for measuring adherence that the present study does not address. Self-report measures are notorious for being unreliable, biased indices. The decision to use self-report and self-monitoring measures in this study was based on their convenience and inexpense. Although correlations between the social desirability scale and measures of adherence were generally weak, we can not rule out the possibility that there were reactive effects from the self-monitoring that prompted inflated rates of self-care. The reliance in this study on self-report data, in the absence of more reliable and objective alternatives, such as variations of the marked item technique (Wing, 1985) or using reflectance photometers with memory (Wilson and Endres, 1986) for assessing glucose monitoring, or using the24-hour interview procedure on all regimen behaviours (Johnson etal, 1986), makes any conclusions very tenuous.

A further issue in the measurement of adherence relates to "a lack of appropriate temporal congruity between behaviour and biochemical measures" (Wysocki, 1989, p. 200). The HbA1c assay provides an estimate of mean glycemic

concentration over the preceding 90 days. Therefore, regimen behaviours sampled at the time that HbA1c levels were assessed may not be the behaviours that contributed to this value. Furthermore, the extent to which patients adhere seems to vary over time (McCaul et al., 1987). This points to the importance of conducting repeated assessments of regimen adherence throughout the three months prior to the HbA1c determination, if adherence-control relationships are to be better understood.

There are other compelling reasons for using an intensive design (i.e., repeated measures over time) as opposed to "point-in-time" assessments, when self-reports are utilized. The use of self-reports brings with it substantial intrasubject variability that results from both errors of measurement and inconsistency of subjects' responses. Kraemer and Thiemann (1989) discuss the difficulties of using "soft data" and suggest a strategy for reducing the unwelcome "noise". They show that by using an intensive design and a weighted average of the repeated measures (i.e., the slope as an outcome measure), the power of test procedures can be maximized without requiring increased sample sizes.

Another methodological problem in adherence research has to do with the fact that there has been no attempt to date to assess the appropriateness of a patient's diet or insulin prescription. In this study, there was a reliance on the physician's assessment that noncompliance to the medical regimen was the primary cause of unacceptable diabetic control. Progress in studying the therapeutic efficacy of interventions for improving adherence and diabetic control will also depend on the development of methods for controlling for the medical adequacy of the treatment.

In conclusion, the results from this study are promising. In contrast to most of the behavioural modification studies thatwere reviewed, modest

improvements in both adherence to blood glucose testing and glycemic control were noted. Furthermore, the findings also indicated that a diabetes care family-based intervention can prevent the usual deterioration in glycemic control that clinics often observe in adolescents with IDDM. Perhaps the most meaningful contribution that this study made was to offer a more practical alternative to the "psychosomatic" approach to families of adolescents with IDDM. Future investigations need to extend this research further by addressing the methodological concerns that have been raised.

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Appendix A: Assessment Materials

SUMMARY OF SELF-CARE ACTIVITIES

The questions below concern what you did related to your diabetes self-care activities **during the past 7 days**.

1. How many of your insulin injections were taken **MORE THAN** 10 minutes before or after your scheduled time?

   ___None of them (0)

   ___Some of them (1-6)

   ___Most of them (7-12)

   ___All of them (13 or more)

2. How many of your insulin doses did you **FAIL** to measure exactly the way you were suppose to?

   ___None of them (0)

   ___Some of them (1-6)

   ___Most of them (7-12)

   ___All of them (13 or more)

3. On the average, how many times did you test your blood for sugar each day? (Circle one)

   0 1 2 3 4 5 6

4. When you tested your blood for sugar, did you test it **WITHIN** 10 minutes of your scheduled time?

   ___Yes, always

   ___Yes, usually

   ___Yes, some of the them

   ___No, not at the correct times

   ___I did not test my blood sugar.

5. The last time you tested your blood, had you eaten a meal or snack during the hour before you conducted the test?

___Yes

___No

6. I hardly ever find it difficult to follow my diabetic treatment plan.

___Yes, this is true of me

___No, this is not true of me

7. On how many of the last 7 days were you **UNABLE** to participate in at least 20 minutes of physical exercise? (Circle one number)

0 1 2 3 4 5 6 7

8. How many of your meals and snacks were eaten **MORE THAN** a half-hour early or late?

___None of them

___Some of them (less than 7 times during week)

___Most of them (at least 1-2 times a day)

___All of them

9. How often did you **FAIL** to follow your recommended diet over the last seven days?

___Never

___Rarely (1 or 2 times during the week)

___Sometimes (3-7 times during the week)

___Usually (at least once a day)

___Always

ADOLESCENT QUESTIONNAIRE

We want to know how often family members do each of the following things. Just put down what usually happens at home. There are no right or wrong answers. Write down one number from the scale below that **best** shows how often the person being rated does each of the following things.

1 = never 2 = twice a month 3 = once a week
4 = several times a week 5 = at least once a day

How **often** does he/she:	Mo	Fa	Other
1. Praise you for following your diet	____	____	____
2. Nag you about testing your glucose level	____	____	____
3. Suggest things that might help you take insulin on time	____	____	____
4. Criticize you for not exercizing regularly	____	____	____
5. Help you decide if changes should be made based on glucose testing results	____	____	____
6. Nag you about following your diet	____	____	____
7. Argue with you about your diabetes self-care activities	____	____	____
8. Encourage you to particiate in sports activities	____	____	____
9. Plan family activities so that they will fit in with your diabetes self-care schedule	____	____	____
10. Congratulate you for sticking to your diabetes self-care schedule	____	____	____
11. Criticize you for not recording the results of the glucose tests	____	____	____
12. Eat at the same time that you do	____	____	____
13. Exercise with you	____	____	____
14. Let you sleep late rather than getting you up to take your insulin	____	____	____
15. Buy you things containing sugar to carry with you in case of an insulin reaction	____	____	____
16. Eat foods that are not part of your diabetic diet	____	____	____

PARENT QUESTIONNAIRE

We want to know how often the following behaviours occur. Just put down what usually happens at home. Write down one number from the scale below that **best** shows how often you do each of the following things.

1 = never 2 = twice a month 3 = once a week
4 = several times a week 5 = at least once a day

How **often** do you:

1. Praise your child for following his/her diet. ____
2. Nag your child about testing his/her glucose level. ____
3. Suggest things that might help your child take insulin on time. ____
4. Criticize your child for not exercising regularly. ____
5. Help your child decide if changes should be made based on glucose testing results. ____
6. Nag your child about following his/her diet. ____
7. Argue with your child about the diabetes self-care activities. ____
8. Encourage your child to participate in sports activities. ____
9. Plan family activities so that they will fit in with the diabetes self-care schedule. ____
10. Congratulate your child for sticking to the diabetes self-care schedule. ____
11. Criticize your child for not recording the results of the glucose tests. ____
12. Eat at the same time that your child does. ____
13. Exercise with your child. ____
14. Let your child sleep late rather than getting him/her up to take their insulin. ____
15. Buy your child things containing sugar to carry with him/her in case of an insulin reaction. ____
16. Eat foods that are not part of the diabetic diet in the presence of your child. ____

CREDIBILITY RATING (I)

1. How logical does this program sound to you?

___Not at all

___Just a little

___Moderately

___Quite a bit

___Very

2. How confident are you that this program could bring improvements in the management of diabetes?

___Not at all

___Just a little

___Moderately

___Quite a bit

___Very

3. How confident would you be in recommending this program to other adolescents and their families?

___Not at all

___Just a little

___Moderately

___Quite a bit

___Very

CREDIBILITY RATING (II)

1. How logical does the program you participated in seem to you?

not at all ___ just a little ___ moderately ___

quite a bit ___ very ___

2. How confident would you be in recommending this program to other adolescents with diabetes and their families?

not at all ___ just a little ___ moderately ___

quite a bit ___ very ___

3. Do you think the Diabetic Clinic should continue this program?

definitely no ___ perhaps ___ definitely yes ___

TREATMENT RATING

How beneficial do you think this program was in helping you make improvemnets in your diabetes self-care activities?

not at all ___ just a little ___ moderately ___

quite a bit ___ very ___

Which part of the program do you consider to have been most helpful?

1. Retraining session ___ Family sessions ___ Both ___ Neither ___

2. Retraining session ___ Coping strategies ___ Both ___ Neither ___

NURSE/THERAPIST RATINGS

1. How competent did you find the nurse to be?

not at all ___ just a little ___ moderately ___

quite a bit ___ very ___

2. How competent did you find the therapist to be?

not at all ___ just a little ___ moderately ___

quite a bit ___ very ___

BLOOD GLUCOSE TEST RECORD

NAME: _____ MONTH: _____

	BLOOD TEST RESULTS				INSULIN DOSAGE	DIET/EXERCISE 0=poor 1=fair 2=good	0=none 1=some 2=lots	
Date	AM	NOON	PM	BED	TIME TYPE/AMOUNT			COMMENTS
					1 2			
					1 2			
					1 2			
					1 2			
					1 2			
					1 2			
					1 2			
					1 2			
					1 2			
					1 2			

FAMILY APGAR

	Almost always	Some of the time	Hardly ever
I am satisfied with the help I receive from my family when something is troubling me.	_____	_____	_____
I am satisfied with the way members of my family discuss items of common interest and share problem-solving with me.	_____	_____	_____
I find that members of my family accept my wishes to take on new activities or make changes.	_____	_____	_____
I am satisfied with the way members of my family express affection and respond to my feelings, such as anger, sorrow, and love.	_____	_____	_____
I am satisfied with the way members of my family and I share time together.	_____	_____	_____

Name_____Date_____

This questionnaire lists a number of experiences that most children have at one time or another. Read each of these carefully. After you have read one, decide whether it does or does not fit you. If it **does**, put a **T** (for true) in front of the statement; if it **doesn't**, put an **F** (for false) in front of the statement.

__1. I always enjoy myself at a party.

____2. I tell a little lie sometimes.

____3. I never get angry if I have to stop in the middle of something I'm doing to eat dinner, or go to school.

__ 4. Sometimes I don't like to share things with my friends.

____5. I am always respectful of older people.

____6. I would never hit a boy or girl who was smaller than me.

____7. Sometimes I don't feel like doing what my teachers want me to do.

__8. I never act "fresh" or "talk back" to my mother or father.

____9. When I make a mistake, I always admit I am wrong.

___10. I feel my parents do not always show good judgement.

__11. I have never felt like saying unkind things to a person.

___12. I always finish all of my homework on time.

_ 13. Sometimes I have felt like throwing or breaking things.

___14. I never let someone else get blamed for what I did wrong.

__15. Sometimes I say something just to impress my friends.

___16. I'm always careful about keeping my clothing neat, and my room picked up.

___17. I never shout when I feel angry.

___18. Sometimes I feel like staying home from school even if I am not sick.

___19. Sometimes I wish my parents didn't check up on me so closely.

___20. I always help people who need help.

___21. Sometimes I argue with my mother to do something she doesn't want me to do.

___22. I never say anything that would make a person feel bad.

___23. My teachers always know more about everything than I do.

___24. I am always polite, even to people who are not very nice.

___25. Sometimes I do things I've been told not to do.

___26. I never get angry.

___27. I sometimes want to own things just because my friends have them.

___28. I always listen to my parents.

___29. I never forget to say "please" and "thank you."

___30. Sometimes I wish I could just "mess around" instead of having to go to school.

___31. I always wash my hands before every meal.

___32. Sometimes I dislike helping my parents even though I know they need my help around the house.

___33. I never find it hard to make friends.

___34. I have never been tempted to break a rule or law.

___35. Sometimes I try to get even when someone does something to me I don't like.

___36. I sometimes feel angry when I don't get my way.

___37. I always help an injured animal.

___38. Sometimes I want to do things my parents think I am too young to do.

___39. I sometimes feel like making fun of other people.

___40. I have never borrowed anything without asking permission first.

___41. Sometimes I get annoyed when someone disturbs something I've been working on.

___42. I am always glad to cooperate with others.

___43. I never get annoyed when my best friend wants to do something I don't want to do.

___44. Sometimes I wish that other kids would pay more attention to what I say.

___45. I always do the right things.

___46. Sometimes I don't like to obey my parents.

___47. Sometimes I don't like it when another person asks me to do things for him.

___48. Sometimes I get mad when people don't do what I want.

CONSENT FORM

An Intervention Study with Adolescents with IDDM and Their Families

I,_____consent to take part in a study which will examine the benefits of involving family members in a diabetes management program in order to improve blood glucose levels. The purpose of the study is to test the effectiveness of a family-based approach that could be integrated with regular treatment and educational practices of the Diabetic Clinic at CHEO.

It has been explained to me that I have been assigned to **ONE** of the following procedures:

___1. One skills and knowledge retraining session, conducted by the diabetic nurse educator, followed by 2 to 4 family counselling sessions that will focus on specific issues related to carrying out the treatment plan. I understand that parents and the diabetic child and siblings closest in age are to attend these sessions and that they will be scheduled to accommodate the family's routine as much as possible;

___2. One skills and knowledge retraining session conducted by the diabetic nurse educator. This will be followed by two sessions that will focus on learning about the relationship between stress and diabetes, and, strategies for coping with stress. One parent is required to attend with the patient.

It has also been explained to me that following the completion of these sessions my child will be expected to make clinic visits after 3 months and 6 months for the purpose of obtaining blood glucose measures. He/she will also be expected to record, for three one week periods, insulin injections and blood glucose testing results. These are to be done the week immediately following the retraining session and the week before the 3-month and the 6- month clinic visits. I also understand that my child will be asked to fill out a short questionnaire pertaining to how they look after their diabetes. Parents will also be asked to complete a brief general information questionnaire.

The primary intent of this study is to see if there are benefits to the patient. There are no known negative effects from any of the procedures that will be used. I understand that I may withdraw from the study at any time , even after signing this form, and this will in no way affect the regular care given to my child.

Any information that is collected about my family during this

study will be kept confidential. The responsibility for this study rests with Karen J. Coupland and Dr. John Goodman from the Department of Psychology, Children's Hospital of Eastern Ontario.

Any questions may be directed to Dr. Goodman at 737-2692.

_____	_____	_____
name	signature	date
_____	_____	_____
witness	signature	date

I have explained the nature of the study to the parent and feel he/she has understood it.

_____	_____	_____
name	signature	date

Appendix B: Research Study Protocol and Family Adherence Counselling Therapist Manual

RESEARCH PROTOCOL FOR FAMILY-BASED INTERVENTION STUDY FOR IMPROVING ADHERENCE IN ADOLESCENTS WITH IDDM

A Selection criteria:

Inclusion

1. Adolescents with IDDM aged 12 to 17.
2. Adolescents who demonstrate mean HbA1c values over previous nine months >9.0%. Most recent assessment must be >9.0%.
3. The physician will conclude inadequate adherence is the primary factor contributing to poor diabetes control. This may be reached on the basis of clinical judgment, history of "no shows" and diary keeping records.
4. Adolescents who are expected to be monitoring blood glucose levels.
5. Adolescents who have been diagnosed as having diabetes for at least one year.

Exclusion

1. Adolescents with IDDM who are experiencing other major medical problems or complications such as uncontrolled hypothyroidism, epilepsy, etc.
2. Adolescents with IDDM who are currently involved in other treatment programs for psychosocial problems.

B Random assignment of patients to either comparison or experimental condition.

C Random assignment of therapist to patient.

D Initial contact:

- explain reason for approaching and purpose of the study
- give results of most recent HbA1c assessment
- provide rationale for skills/knowledge review session
- briefly provide rationale for subsequent sessions according to group assignment
- schedule review session

E Pre-treatment data:

1. Most recent HbA1c values.
2. Consent form.
3. Summary of Self-Care Activities questionnaire.
4. Diabetes Family Behaviours Checklist; Family APGAR
5. Children's Social Desirability Questionnaire.
6. General information - parent interview
7. Credibility rating

F Frequency and duration of sessions/who is to attend.

- experimental group: 1 review session (1.5 hrs.), 2-4 family adherence counselling sessions (1 hr.)
- comparison group: 1 review session (1.5 hrs.), 2-4 sessions of teaching coping strategies for dealing with stress (1 hr.)

- **who is to attend**: In the exp'tal condition - parents, siblings closest in age to patient; in comparison condition - patient and at least one parent for the review, patient alone for stress management sessions.

G **Skills and knowledge review session**
1. Establish rapport
2. Establish purpose of meeting - goals of clinic with respect to diabetes control.
3. Review long and short term benefits of good diabetic control - review normal glucose values and ranges in which blood sugar is unacceptably high or low.
4. Review technical skills involved in BGM.
5. Inquiries regarding the family's problem-solving skills with respect to modifications in insulin, diet and exercise.
6. Determine if further review of knowledge by dietician is necessary
7. Introduce/review the decision-making criteria regarding adjustments in insulin, diet and exercise routines - Provide written guidelines.
8. Instruction in use of self-monitoring forms for recording BGT, insulin injections; rating diet and exercise.
9. Prescribe no. of BGT to be performed - 2x/daily, 14x/weekly.
10. Schedule next appointment in accordance with either comparison or exp'tal condition.

H **1st family adherence counselling session (EXPERIMENTAL)**
1. Establish rapport.
2. Establish the agenda for the session.
3. Identify problems - Using the self-monitoring data, focus on the past week - Address each component of the diabetic regimen while encouraging the family to be specific.
4. Gather information about the family interactions around the problem.
5. Assist the family in generating solutions. Provide guidance by addressing issues that are relevant to diabetes self-care behaviours such as notion of social support (cues and reinforcement); shared responsibility; or challenging attitudes or beliefs that create barriers to good adherence; etc.
6. Encourage family to seek agreement on a particular course of action(s).
7. Implement goal-setting strategy or parent-child contracts if appropriate.
8. Instruct patient to continue using self-monitoring records.
9. Summarize identified problems and agreed upon solutions - Schedule next appointment.
10. Instruct nurse to review BGM results and consult with patient and family if necessary.

Subsequent family sessions:

1. Review self-monitoring data - Set new daily/weekly goals if goal-setting technique has been used.
2. Review effectiveness of parent-child contracts if used.
3. Identify new or additional problems - Use problem-solving procedure as above.
4. Inquiry of how knowledge of blood tests prompted changes in self-care behaviour.
5. Inquiry regarding changes in family members' behaviour and the effectiveness of these changes.
6. Use criteria to determine if further family meeting is needed.

I Learning to cope with stress (COMPARISON GROUP)

1st session

1. Establish rapport.
2. Collect self-monitoring data; instruct nurse to review results and consult with patient/family if necessary.
3. Explanation of what stress is and how to become aware of stress.
4. Discussion of relationship between stress and diabetes.
5. Give rationale for learning relaxation techniques.
6. Train patient in progressive muscle relaxation - Tape this exercise for patient to use at home.
7. Instruct patient in use of self-monitoring form for recording stressful situations and negative thoughts - this will be reviewed and discussed next session.
8. Give patient Coping Strategies for Managing Stress to read.

Subsequent sessions

1. Review relaxation homework.
2. Review recording form - Use this information as a basis for introducing and discussing other coping strategies such as correcting negative thoughts, learning to communicate assertively, and so on.
3. Decide with patient if a further meeting is to be held

J Post-treatment data:

<u>3rd month clinc visit</u>

- assessment of HbA1c values;
- self-monitoring of BGT, insulin injections; ratings of diet and exercise behaviours during week before this visit.

<u>6th month clinic visit</u>

- assessment of HbA1c values;
- self-monitoring of BGT,etc. during week before this visit;
- Summary of Self-care Activities questionnaire;
- Diabetes Family Behaviour Checklist;
- Family APGAR
- Credibilty Rating

Family Adherence Counselling

Therapist Manual

I ESTABLISHING THE RATIONALE FOR MEETING AS A FAMILY

Occasions when a rationale for meeting as a family may need to be given or emphasized: (1) initial telephone contact when families are invited to participate in the study; (2) at the time of the review session with the nurse; and (3) at the time of the first family compliance counselling session.

Some ideas that may be presented:

There is more to managing diabetes than just technical skills and knowledge. For example, the diabetes tasks need to be integrated into the family's and patient's daily routines. As well, families often need to consider helpful ways of keeping the patient motivated to carry out the daily diabetes tasks. This often becomes more challenging for families during adolescence.

<u>How to conceptualize the difficulties that can occur in diabetes management</u>.
Often difficulties arise when daily routines fail to make allowances for the diabetes tasks. For example, not leaving enough time in the morning to carry out the blood tests; not taking insulin on time when out with friends.

Sometimes difficulties have more to do with getting "off track" with respect to the daily self-care activites and not being able to get back "on track". For example, getting out of the habit of following your diet and eating the right foods or testing regularly.

The failure to realize that an adolescent's ability to perform blood glucose tests and give injections does not mean that they no longer need some degree of diabetes care supervision and reinforcement from family members. It is important for us to realize that many of the daily regimen tasks are not in themselves immediately rewarding, but are justified because of the long-term benefits to the patient's health. Finger pricks and injections bring some discomfort and inconvenience, while high glucose readings may promote negative interactions with parents, etc. Adolescents often have trouble working for distant goals in the absence of more immediate rewards.

<u>Talking about diabetes management in terms of specific behaviours</u>. When we think of managing diabetes it is useful to think of it in terms of the various behaviours that have

to be performed. For example, blood tests have to be carried out at a particular time, insulin injections have to be given, and so on.

When we think in terms of making it more likely that certain behaviours will occur, it becomes important to look at them in context. Family routines and family behaviours can be thought of as a context in which the diabetes self-care behaviours are embedded. Some family routines may be helpful, some may not be as helpful.
For example, it is probably more helpful if others provide "gentle reminders" before an important diabetes care behaviour is to be performed rather than nagging at you when you fail to carry out a task on time.

Introducing the notion of social support. It is important to look at the kind of support the patient needs from others and how responsibilities are shared in the family, i.e., who does what, when, how much. How are the diabetes tasks divided up? How much can the patient do on his/her own? What kind of support is needed from others?

One thing that we have learned about people managing a chronic illness is the importance of the family in terms of the support they can give. This does not mean that the family should be totally responsible for the diabetes management tasks. This wouldn't be helpful. But that family members can play an important role with respect to the patient's adherence to and attitudes toward the treatment plan. For example, a family member exhibits supportive behaviour when he/she helps the patient problem-solve in response to high blood sugars, plan menues that conform to the diet plan, or even just notice when the patient has been trying hard to follow the regimen. Phoning the clinic for advice may be another way others can offer support to the patient.

The kind of support that is given, the way responsibilities are shared will be different for every family.

II GUIDELINES FOR THE FIRST FAMILY SESSION

Take a minute or two to greet and express interest in each family member

A Establish the agenda for this session

Tell the family what you want to accomplish during this meeting. That is, we need to be clear about what the patient needs to be doing in order to achieve better diabetic control, the kinds of difficulties he/she has following the treatment plan, and the kind of support from others that is needed at this time.

It is important that everyone express their views on how they see things.

After we have identified together what the specific problem area(s) is, we need to agree on a solution or a new course of action. When we meet again we can discuss and appraise how things have been going.

The best place to begin is to look at how things went last week.

B Identification of compliance problems

Begin by focussing on the past week (or the time since the review session). Use the information from the self monitoring data to guide your inquiry.

<u>General Guidelines</u>

Ask each family member what they see to be the primary problem(s) in carrying out a particular regimen task. Begin questionning the patient first. Seek agreement from others. Ask for explanations... How is this a problem for you? What about it makes it seem difficult?

You may have to prompt family members with questions such as, "Many people find it difficult to... Is this a problem for you?"

Help the family be specific and concrete - when, time of day, place, with whom, day of week, etc.

Specific Guidelines

Address each component of the diabetic regimen.

1. Blood glucose monitoring

Check both timing and number as indicated on self-monitoring record.

What difficulties were encountered? Was it difficult doing two tests a day? What about it made it seem difficult?

Consider the number of tests out of 14, that were carried out. If it falls below 80% (< 11) begin considering the goal-setting guidelines and address this issue later in the session.

Praise the patient for his/her efforts, particularly if the blood testing was an improvement over what had been reported on the Self-Care Activities questionnaire.

Determine if other family members are aware of the BGT results. This is important information about the degree of openness that exists in the family with regard to diabetic control. Some kids may be very secretive, particularly when tests have been high. Some families consider inquiries about blood test, etc. as intrusive. This is something that will need to be addressed at some point and reframed. See Collateral Guidelines #5.

Determine how the patient and family react when tests are high. Do they get discouraged? Do they get angry? How do they deal with their disappointment or anger, etc.? Are they inclined to give up? Are conflicts likely to arise? See Collateral Guidelines #1, 2, 11.

2. Interpretation of the blood test results

Did patient/family use the information from blood tests? Have them consider when or if changes were made in either the diet or exercise behaviours or insulin on the basis of BGT results. Encourage them to give you an example or two. Check the self-monitoring record to see if any adjustments in insulin dosage were made.

Ask the family how the decision to adjust the insulin was made, i.e. Did patient make it himself? Did parents make

it? Did parents/child consult together? Did they consult with the diabetic nurse by telephone? Did they follow the guidelines in the diabetes care manual?

Generally speaking, adolescents should be cautioned against making insulin adjustments on their own without first consulting with their parents or the diabetic nurse by telephone. Exceptions to this may be if the adolescent is 15 or over, and/or has demonstrated competence and has the approval of the parents. In some cases, the kids are more knowledgeable about their diabetes management than the parents are. In such cases refer to the patient as "the expert" in the family. It may be necessary to point out to the family that this does not mean supervison or supportive behaviours are no longer needed. See Collateral Guidelines #5, 7, 10.

When test results have been generally high (>10.00mmol/L) and the family and patient have not taken any action on their own or the action that has been taken has not been effective in lowering the blood glucose levels, have the diabetic nurse review the BGT records and the family's decision-making.

For general guidelines for evaluating the BGT results see Collateral Guideline #2, 3, 4.

3. Insulin injections

Ask about the frequency of omissions ("We know that some kids forget to give their second shot. Does this ever happen to you? How many times during a week or month would this happen to you?). Identify circumstances under which omissions usually occur.

Inquire about leakages. Ask parents to supervise for several days if it seems that his may be a problem.

Inquire about the timing and regularity. Identify the frequency with which injections may be given after meals. State why this is unacceptable and how it may be contributing to blood glucose fluctuations.

4. Diet

Be clear about the areas of the diet in which deviations are most likely to occur. Refer to ratings from the daily record. Inquire as to why a particular rating was given.

In general, summed weekly ratings of <10 indicate more attention is needed in this area.
Seek agreement on where deviations occur. That is, do they occur from not weighing/measuring food, overeating, eating "not allowed" foods, omitting meals/snacks or not eating meals/snacks on time.

Be specific. Ask how often, time of day, particular days more than others, with whom.

Once the deviation is clearly identified, consider if it is a problem where greater family support is needed such as in weighing/measuring food, timing of meals/snacks, being careful not to eat foods that are not part of diabetic diet in presence of patient, storing foods not on the diet plan, etc.

Consider if it is a problem that would lend itself to the goal-setting procedure. For example, setting goals for reducing the frequency of overeating or eating of "not allowed" foods.

5. Exercise

Refer to patient's ratings on the daily record. Inquire about the typical exercise pattern.

Does patient exercise regularly? What do others think?
What has patient learned about the effect of exercise on glycemic control?

Consider if goal-setting procedure would be an appropriate procedure.

Variation

When the family comes to the first family session and does not report any particular difficulties during the time period being considered, have them focus on the period before the review session with the nurse. Have them consider how it was that the diabetes management got "off track" and the blood sugars started to rise? Seek explanations from each family member. Proceed with addressing various components of the regimen as outlined above.

C Interactions around the regimen behaviours

As well as identifying the compliance problems, also gather information about the interactions around the diabetes self-care behaviours. Problems in adherence often occur at the level of family interactions.
The following are some examples of questions that are useful in assessing interactions:
Who is the first to notice when things are going well?
Who is the first to notice when things are not going well?
What usually happens? How do others react? What does the patient do?
How do family members show you that they notice when you are doing a good job? How do they let you know this?
What solutions for improving compliance have been tried before? How did that work?
What is their explanation for why this did not work?
What are things family members do that help you follow your treatment plan? What isn't as helpful?
How is the patient's diabetic care different from the way it was before? What explanation do family members have for the change?

These questions may not only provide the therapist with important information regarding the kind of support the patient receives from his/her family but also about the family's problem-solving skills. Relationship or circular questions can also provide family members with important information about themselves. This alone may promote more positive family behaviours. See Collateral Guideline #15 for references on the use of circular questions with families.

D Examination of family beliefs

Difficulties following the diabetic treatment plan may develop at the level of conflictual beliefs between the health-care professional (in the clinic context) and the family system, or between family members.

The folowing are some examples of questions that may be useful in assessing beliefs:
Beliefs about the problem. Who thinks the concern about the patient's diabetic control is exaggerated? Who is most worried? Who else in the family was diabetic and had control and compliance problems? What was done about it? Who believes the patient can achieve better diabetic control? Who disagrees?

Beliefs about the treatment plan. Who is most convinced that daily blood glucose testing is related to better diabetic control? Who disagrees? Who believes most strongly that the patient's adherence to the diabetic regimen will help delay or avoid the complications associated with diabetes? Who disagrees? What are the family's glycemic goals? Do they agree with clinic goals?
Beliefs about the role of the physician. Who believes most strongly that adjustments in insulin dosage should only be made in consultation with the physician? Who disagrees? Who believes the patient should know more about his diabetes than the physician? Do family members understand this notion?
Beliefs about the role of the family. Who in the family is most responsible for the diabetic regimen? Who agrees with this arrangement? Who disagrees? Who believes the adolescent should be more responsible? Who disagrees? Who believes the adolescent should be able to carry out the diabetic tasks with no supervision? Who disagrees?

Also see Collateral Guidelines #10 and 11.

E Generating solutions: Facilitating the family's problem-solving efforts

1. The therapist may trigger the family's problem-solving efforts by formulating "influencing questions". The following are some examples:
What can others do to help the patient become more responsible for...?
What would help the patient to take his/her insulin on time, test on time, etc?
If father believed more strongly that the blood testing was important for achieving good diabetic control, how do you imagine this would motivate the patient to want to do better?
How do you think the patient would react if he knew that instead of getting angry every time his blood glucose tests were high you would help him make changes in his treatment plan?
What do you think the effect would be if instead of criticizing the patient's lapses in adherence, you instead offered praise and encouragement when the diabetic tasks were carried out?
If others in the family were to follow the diabetic diet most of the time, how do you imagine this would affect the patient's dietary adherence?
See Collateral Guideline #15 for references on the use of

influencing or "reflexive questions" as therapeutic interventions.

2. It may be necessary for the therapist to make statements about the kind of support family members can give that some kids find helpful. Also address the notions of cueing and shared responsibility. See Collateral Guidelines #7,8,9.

3. If appropriate, suggest the goal-setting procedure and provide a rationale for its use. Point out to the patient and the family that often people find it easier to work toward changes in a gradual manner.

4. If appropriate, suggest the use of parent-child contracts. Describe it as a way of motivating the patient, but only if the patient collaborates fully with the parents in setting goals and agreeing upon both positive and negative consequences. It is important that the patient understand that this is a technique to help motivate him/her and that he/she concurs that the problem is one of lack of motivation.

F Implementation of Plan

1. Goal-setting-procedure.

<u>Blood glucose testing</u>

Use a guideline of setting weekly goals halfway between baseline and 90% adherence level.

For example, it is recommended at the time of the review session that blood tests be carried out 2 times a day (14 times a week). If at the time of the first family meeting, the patient has tested only 7 times during the last 7 days, set a weekly goal of testing at least 10 times for the next week. Also set daily goals. For example, on 3 days test at least 2 times, on the remaining 4 days test at least once.

Write out the objective for the coming week on top of the daily record form. Let the patient know that the overall goal is to be testing 2 times on more days of the week than testing once or not at all.

<u>Diet</u>

When it has been determined that considerable deviations occur in the area of overeating and/or eating sweets,

collaborate with the patient on deciding where reductions can be made and on setting objectives for the coming week.

State that following the diet plan perfectly all the time is probably not possible for most kids to do. However, they should try to follow a guideline of no more than 2 or 3 deviations a week to help keep themselves on track.
Using the BGT self-monitoring record form, set weekly and daily goals. Have the patient rate his/her diet daily on the self-monitoring form.

Generally speaking, for most patients deviations in the diet plan are reflected by the blood glucose levels. When the regularity of the blood testing has not been a problem for the patient, it may be appropriate to set goals for daily and weekly blood glucose levels as a means of encouraging positive diet behaviours. Assist the patient in setting goals based on average readings during the previous week, keeping in mind that blood glucose levels of <10.0mmol/L. are acceptable before meals. A weekly goal of 75% of BGT <10.0mmol/L is a reasonable objective for the patient. It is important that families have a good understanding of diet and exercise behaviours in relation to the patient's diabetic control if this procedure is used.

Exercise

When it has been determined that exercising regularly is an area of difficulty for the patient, collaborate with the family on how improvements can be made. That is, generate ideas for meeting exercise requirements in a manner that is appealing to the patient and set objectives for the coming week.

State that some days it may not be possible to get in at least 20 min. of vigorous activity. Have them keep in mind that exercising for at least 20 min., 5 or 6 days of the week, should be their minimum objective most of the time.
Use the BGT self-monitoring record for setting goals and having the patient rate his/her behaviour.

2 Parent-child written contracts.

Use in conjunction with goal-setting when the family decides upon this as an appropriate solution for them.

Convey the following elements of contracting to the family:

(1) Goals must be clearly specified for a defined period of time. For example, on 5 days of the week test blood glucose levels 2x, on 2 days test 1x when setting a weekly goal of testing at least 12x.
(2) The contract should clearly specify what the consequences will be for meeting the objectives. For example, receiving extra allowance, or a privilege such as a having a sleepover with friends, or a reward such as a new article of clothing.
(3) The contract should impose sanctions for failure to meet the objectives. For example, reductions in the base weekly allowance, or withdrawal of a privelege, etc.

The therapist needs to encourage discussion, negotiation and compromise when facilitating the formulation of a parent-child contract.

3. Defining the family's role in relation to the patient's self-care.

If it has been established that greater parental supervision/consultation is required for reviewing and making decisions related to the BGT results, have the family consider how this will be done. That is, when will the patient consult (every day, or at specified times during the week), with whom and when will he/she begin, etc.

If it has been established that greater support is needed in the area of following diet or exercise, have family members in consultation with the patient consider specifically how this will be implemented and when they will begin. That is, who will do what, when, how often, etc. The goal is to bring clarity to what are the adolescent's responsibilities and what are the family's responsibilities.

G Summarize the identified problems and the agreed upon solutions.

Instruct the patient to continue using the BGT self-monitoring records. Provide extra recording sheets.

H Schedule next appointment time.

Usually appointments will be scheduled at least two weeks apart.

III SUBSEQUENT FAMILY SESSIONS

A Review Self-Monitoring Data

General: How have things been going?

Be sure to offer praise/encouragement accordingly.

Blood testing/diet/exercise

Have goals been met? Set new daily/weekly goals according to guidelines outlined under goal-setting procedure.

Review effectiveness of parent-child contracts

B Identify Any New or Additional Problems Carrying out the Diabetes Tasks.

Use the procedure outlined in Section II.

C Did Knowledge of Blood Tests Lead to Changes in Behaviour

Encourage the family/patient to consider times when decisions were made based on knowledge of BGT results. For example, have them describe a time when changes in the diet or exercise routines were made. What was the outcome? Reinforce appropriate behaviour.

Consider if the family/patient is able to make effective decisions about treatment.

If tests have been high with or without changes, have the family/patient consult with the diabetic nurse. If the nurse is not available at this time, leave records for her to examine and let the family know she will contact them by telephone the following day.

D Review Effectiveness of Any Changes in Family Behaviour

Have the patient consider what other family members did that was most helpful to them with respect to their diabetes management. Who was most helpful? Why? Who next? And so on.

How do family members let you know that they notice when you are doing a good job managing diabetes? Who is the first to notice? Who is next? And so on.

How effective do family members consider the changes in their behaviour was? Did the family try any new strategies? Who is most pleased with the patient's efforts? Is there agreement with how family members view the patient's efforts? If family members disagree, seek an explanation from each member.

How do family members know when things are going well? How do they know when things are not going well? What do they do?

E Other Relevant Issues May Need Addressing

It may be necessary to re-emphasize or address other issues such as unreasonable beliefs that create barriers to good adherence, the notion of social support, etc. See Collateral Guidelines, section IV.

F Criteria for Determining Whether Or Not a Further Appointment is Needed

1. Has the adolescent achieved an 85-90%* adherence level based on the self-monitoring data?
2. Have additional problems been identified that need further monitoring?
3. Does the family/patient use the information from the self-monitoring data to make effective decisions about treatment?
4. Do family members report improvement in the patient's management of his/her diabetes and are they satisfied with the level of adherence attained by the patient?

G Scheduling of 3rd month clinic visit

If this is the last session, inquire when 3rd month clinic visit has been scheduled. Tell patient that he/she will be receiving a letter to remind them when to begin using self-monitioring record. If no appointment has been set, go to Diary in Med I and set one.

H Follow-up contact

<u>At 3rd month clinic visit</u> - HbA1c values are to be assessed and self-momitoring data collected.

<u>At 6th month clinic visit</u> - HbA1c values are to be assessed and self-monitoring data collected.
- Summary of Self-care Activities questionnaire, Diabetes

Family Behavior Checklist and Family APGAR are readministered; Credibility ratings

IV COLLATERAL GUIDELINES

At times, particular issues related to diabetes managment will arise that will need to be addressed.

1. **Blood glucose test results provide useful information.**

When tests have been high, adolescents may become secretive about the BGT results. The following reframe may help bring about more openness.

Point out that the BGT results should not be viewed as a good or bad evaluation about yourself. Reframe: They do provide important information that allows you to see how your diabetic control is doing and to let you know when changes need to be made. For example, when you think your tests might be high because of not following the diet plan closely enough, it is of course important that you realize this. But it is even more important that you are able to get back on track the next day. In other words, how you use the information to bring positive changes in your diabetic control is what really matters.

2 **It is impossible to keep blood glucose levels in the normal range all the time.** Fluctuations will always occur. It is useful to think of diabetes control in weekly or monthly terms rather than daily levels. If, for example, you have tested 14 times during the week and 75% of the results (i.e. 10-11) are <10.0mmol/L your weekly control has been very acceptable.

3. **Blood glucose levels before meals and at bedtime.**
Ideal - between 3.3- 8.5mmol/L
Acceptable - usually below 10.0 mmol/L
Undesireable - between 10.0 - 12.0 mmol/L
Unacceptable - usually above 12.0mmol/L
Too low - below 3.3 mmol/L

4. **Useful times to measure blood glucose levels.**
- before meals
- 2 hours after meals
- with reactions
- or when high blood sugars are suspected

5. **Parents need to review the BGT results on a regular basis with the patient.**

In some cases, parental involvement may be at an all time low. Most likely the parents have not been comfortable with this arrangement. This may have come about as a result of the patient's secretiveness along with parents not wishing to appear intrusive. Furthermore, parents often tend to back off when their involvement in the diabetes tasks has resulted in considerable parent-child conflict. A rationale for increasing parental involvement should be presented in a way that does not detract from the patient's growing responsibility for his/her self-care.

Parental involvement may range from consultations with the patient every time testing is carried out to "spot checks" every other day or so.

Speak directly to the patient when making the following statements:

- parents need to be reassured that every thing is alright.

- it gives parents an opportunity to let you know how pleased they are with the way you have been managing your diabetes, i.e., it provides an opportunity for parents to give you positive feedback.

- when tests are high, it will encourage you and your parents to problem-solve together. That is, decide what changes should be made, if any, in your diet, insulin dosage, exercise pattern, or if the diabetic nurse needs to be consulted. It also will let them see how you go about making decisons yourself.

6. **Benefits of BGT**

Helps the patient become a more active, intelligent participant in his/her management. Can lead to greater independence.

Lends itself to the personal scientist approach.

Enables the patient who is trying to change to see the impact of these changes on his/her control.

Enhances the patient's/family's understanding of how the following factors influence blood glucose levels: food, exercise, emotions (stress), illness, medication, activities of daily living.

7. **Supportive family behaviours.**

Discuss in terms of cueing and reinforcement.

Supportive behaviours related to blood glucose monitoring:

- family members help patient decide if changes should be made based on blood glucose testing results.
- family members plan family activities so that they will fit in with the diabetic routine.
- family members congratulate or praise the patient for sticking to the diabetic regimen.
- family members help patient clean up after patient has tested his/her blood.
- during school year, family members make patient's lunch in the mornings so he/she has enough time to complete diabetes self-care tasks.

Supportive behaviours related to the diet:

- gentle "reminders" not to take another helping of chips, etc.
- family members praise patient for following the diet.
- family members eat at the same time that the patient does.
- family members limit the amount of sweets kept in the house.
- siblings bring an alternative for the patient when they get snacks.
- make desired behaviour easiest to do, e.g., place carrots sticks in front of refrigerator or fresh fruit in plain sight.
- family members follow the diabetic diet most of the time

Supportive behaviours related to insulin injections:

- family members suggest things that would help the patient take insulin on time.
- family members help patient make adjustments in insulin dosage.

Supportive behaviours related to exercise:

- family members encourage the patient to participate in sports.
- family members exercise with the patient.

General:

- provide social rewards such as noticing when patient is doing a good job.
- put up reminders such as special cards on bathroom mirror or refrigerator that convey a positive message (e.g., "I feel better when I eat foods that are right for me").

8. **Pointers on cueing.**

Cues should be as pleasant as possible. It is not the same as forcing.

Cues must be clear. They should not be subtle.

Cues should occur just before a desired behaviour is to occur.

9. **Shared responsibility.**

How responsibilities are shared in the family can influence adherence to the diabetic regimen. The following ways of sharing responsibilities are appropriate for a family with an adolescent patient:

- family members help the patient remember the various tasks he/she must perform.

- family members consult with the patient when decisions need to be made regarding adjustments to diet/ insulin/exercise.

- family members inform or consult with others about diabetes-related concerns, e.g., doctor, diabetic nurse, teachers, etc.

10. **Changing attitudes that can create barriers to good adherence.**

When the parents' attitude is that diabetes care is the child's responsibility. A parent may believe it is important that the child learn to manage his diabetes alone because he won't always be living at home. Reframe: How can the family help the patient become more responsible? What can others do to make it more likely that the patient will follow the diabetic regimen? Discuss with reference to Collateral guideline #7, 8 and 9. Particularly highlight the notion of social support when managing a chronic

illness.

11. **Uncovering unrealistic beliefs that can create barriers to good adherence.**

"I MUST DO THIS PERFECTLY." Some patients may feel that if they cannot perform diabetes self-care tasks perfectly all the time then there is no point in doing it at all. Point out to the patient that it is unreasonable to expect themselves to perform at 100% all the time. What is important is recognising when deviations have occurred and getting yourself back on track. Telling yourself, "I can always do better tomorrow", will help you put things in perspective.

"IT IS TERRIBLE WHEN THINGS DO NOT GO MY WAY." When blood sugars have been high for several days, some patients become discouraged and feel like giving up. Point out to the patient that rather than exaggerating this situation, it is more helpful to think about what you might do to bring about improvement. You might try exercising vigorously for 20-30 min. after dinner, taking snacks on time or following the diet plan more closely. You might also want to test your blood more frequently so that you can see whether these changes made a difference. As well, you may decide to make adjustments in your insulin dosage or call the diabetic nurse for consultation. A useful motto to have is: When feeling discouraged about your diabetes control, take constructive action. Consider using the personal scientist approach.

"IT IS NOT FAIR THAT I HAVE DIABETES." Some patients or family members may operate with the unreasonable expectation that there should be fairness in life. This can lead to feelings of anger which in turn interferes with their ability to solve problems. You may challenge this belief with something like, "Life is full of misfortunes of one kind or another... Rather than fairness, what seems to be true about life is the need for individuals to learn to cope with and master the difficulties that befall them in a way that enhances their well-being and growth."

12. **What should family members do when the patient is feeling low because of his/her diabetes.** It is natural that patients will experience low moods from time to time. These feelings usually pass. Sometimes it is most helpful if family members just try to be comfortable with the feelings the patient is expressing, and accept them without trying to

talk him/her out of them. Conveying understanding may help the feelings pass more quickly.

13. **What to tell patients who complain of not feeling as well even though their blood tests are in the normal range.** Reassure the patient that this will most likely be of short duration as his/her body adjusts to more normal blood glucose levels.

14. **Some reasons why it is important to keep blood sugars in the normal range that may have more appeal for adolescents.** Your body functions at its best when your blood sugars are in the normal range. This means that your problem-solving, activity level and coordination will be at their best.

15. **References.**

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Tomm, K. (1987). Interventive interviewing: Part II. Reflexive questioning as a means to enable self-healing. Family Process, 26, 167-183.

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Appendix C: Data

EXPERIMENTAL GROUP

Patient	HbA1c			Self-monitoring Data			
	x/recent	3mos	6mos		1st	3mos	6mos
1. D.S. (14-3)	10.4/10.0	9.9	7.5	BGT:	86%	100%	100%
				Diet:	57%	57%	43%
				Exer:	64%	100%	100%
2. C.W. (14-8)	12.0/12.4	8.1	7.8	BGT:	100%	93%	100%
				Diet:	43%	64%	79%
				Exer:	64%	50%	50%
3. T.S (12-7)	11.2/12.1	11.4	11.2	BGT:	100%	100%	79%
				Diet:	93%	43%	36%
				Exer:	93%	50%	56%
4. M.B. (15-11)	11.8/12.9	12.3	12.8	BGT:	100%	93%	71%
				Diet:	86%	86%	71%
				Exer:	93%	86%	79%
5. C.D. (12-2)	9.8/11.4	7.6	8.7	BGT:	100%	57%	71%
				Diet:	43%	85%	71%
				Exer:	36%	71%	71%
6. M.A.B. (12-2)	9.6/10.4	9.2	10.2	BGT:	100%	79%	86%
				Diet:	43%	50%	50%
				Exer:	64%	64%	71%
7. K.R. (15-8)	9.9/10.0	10.1	11.0	BGT:	57%	86%	100%
				Diet:	100%	100%	86%
				Exer:	79%	100%	79%
8. S.Q. (12-6)	11.8/11.8	12.8	12.1	BGT:	100%	71%	86%
				Diet:	86%	79%	64%
				Exer:	64%	79%	50%
9. D.F. (13-7)	9.3/9.7	9.0	9.2	BGT:	93%	86%	100%
				Diet:	65%	50%	71%
				Exer:	79%	7%	50%

Experimental Group (continued)

Patient	HbA1c			Self-monitoring Data			
	x/recent	3mos	6mos		1st	3mos	6mos
10. S.D. (16-11)	11.3/13.0	8.5	7.6	BGT:	100%	100%	100%
				Diet:	79%	93%	64%
				Exer:	79%	93%	86%
11. J.G.B. (16-5)	11.0/11.0	11.7	11.1	BGT:	86%	86%	86%
				Diet:	50%	50%	50%
				Exer:	93%	100%	64%
12. A.S. (13-3)	9.6/10.1	7.7	7.0	BGT:	79%	100%	93%
				Diet:	57%	93%	100%
				Exer:	50%	71%	79%
13. C.V. (15-11)	12.8/12.8	11.7	12.4	BGT:	100%	93%	100
				Diet:	100%	79%	71%
				Exer:	64%	57%	29%
14. L.L. (15-9)	13.9/14.6	12.2	12.3	BGT:	86%	79%	86%
				Diet:	43%	57%	57%
				Exer:	64%	43%	79%
15. D.Mc (15-5)	11.1/12.2	9.2	6.1	BGT:	79%	93%	64%
				Diet:	79%	79%	76%
				Exer:	29%	79%	100%

COMPARISON GROUP

Patient	HbA1c			Self-monitoring Data			
	x/recent	3mos	6mos		1st	3mos	6mos
1. F.L. (15-5)	10.7/9.6	6.9	9.4	BGT:	50%	43%	43%
				Diet:	100%	86%	100%
				Exer:	93%	63%	100%
2. G.M. (17-4)	10.0/9.4	8.2	8.2	BGT:	50%	14%	0%
				Diet:	14%	86%	86%
				Exer:	29%	86%	93%
3. C.B. (14-5)	10.2/11.1	12.0	12.8	BGT:	71%	0%	0%
				Diet:	14%	0%	0%
				Exer:	29%		
4. T.K. (17-8)	9.8/13.2	12.8	11.5	BGT:	100%	100%	64%
				Diet:	86%	100%	79%
				Exerc:	29%	43%	50%
5. C.H. (12-2)	9.1/11.2	10.9	12.6	BGT:	100%	93%	100%
				Diet:	100%	100%	100%
				Exer:	71%	57%	29%
6. A.B. (14-3)	11.1/11.3	9.9	9.4	BGT:	71%	57%	43%
				Diet:	43%	100%	50%
				Exer:	79%	100%	50%
7. M.K (11-7)	10.9/12.6	10.4	9.0	BGT:	93%	0%	43%
				Diet:	71%	50%	86%
				Exer:	86%	79%	50%
8. K.B. (15-6)	9.3/11.5	12.3	12.0	BGT:	50%	21%	0%
				Diet:	50%	7%	0%
				Exer:	93%	93%	86%
9. S.P. (15-5)	12.2/12.4	11.2	11.8	BGT:	43%	57%	36%
				Diet:	43%	57%	43%
				Exer:	100%	86%	100%

COMPARISON GROUP (continued)

Patient	HbA1c x/recent	3mos	6mos		Self-monitoring Data 1st	3mos	6mos
10. N.G. (15-7)	11.4/11.9	9.8	9.0	BGT:	50%	43%	36%
				Diet:	80%	57%	64%
				Exer:	43%	7%	14%
11. A.T. (14-11)	9.1/9.5	8.9	10.1	BGT:	93%	71%	64%
				Diet:	86%	86%	86%
				Exer:	64%	57%	36%
12. J.L. (12-10)	10.0/10.0	9.8	11.3	BGT:	100%	93%	86%
				Diet:	93%	93%	86%
				Exer:	71%	93%	86%
13. L.S. (13-4)	10.6/12.1	8.8	8.6	BGT:	79%	43%	36%
				Diet:	93%	100%	100%
				Exer:	86%	100%	93%
14. C.C. (15-0)	12.0/12.0	10.3	10.9	BGT:	86%	0%	86%
				Diet:	43%	0%	00%
				Exer:	79%	50%	50%

Mean HbA1c Values Over Time (%)

Family Intervention			Comparison Group		
Pre	3-mo	6-mo	Pre	3-mo	6-mo
11.6 ±1.41	10.0 ±1.81	9.8 ±2.23	11.3 ±1.22	10.1 ±1.63	10.5 ±1.57

Mean adherence ratings over time (%)

	Family Intervention			Comparison Group		
Self-monitoring	Base	3-mo	6-mo	Base	3-mo	6-mo
BGT	.91 ±.16	.88 ±.12	.88 ±.12	.74 ±.22	.45 ±.35	.46 ±.32
Diet	.70 ±.21	.72 ±.19	.67 ±.17	.67 ±.31	.64 ±.40	.61 ±.39
Exercise	.68 ±20	.68 ±.25	.65 ±.19	.74 ±.22	.70 ±.29	.63 ±.30

Appendix C

COMPARISON OF MEAN HBA1C LEVELS 9 MONTHS BEFORE TREATMENT WITH MEANS AFTER TREATMENT

	Family Intervention		Control Group	
	Before	After	Before	After
1.	10.4	8.7	10.7	8.2
2.	12.0	8.0	10.0	8.2
3.	11.2	11.3	10.2	12.4
4.	11.8	12.6	9.8	12.2
5.	9.8	8.2	9.1	11.8
6.	9.6	9.7	11.1	9.7
7.	9.9	10.6	10.9	9.7
8.	11.8	12.4	9.3	12.2
9.	9.3	9.1	12.2	11.5
10.	11.3	8.0	11.4	9.4
11.	11.0	11.4	9.1	9.5
12.	9.6	7.4	10.0	10.6
13.	12.8	12.1	10.6	8.7
14.	13.9	12.3	12.0	10.6
15.	11.1	7.7		

	Improvements (decreases >1%)	Unchanged (within <1%)	Deterioration (increases >1%)
Family Intervention (N=15)	7	8	0
Control Group (N=14)	7	3	4

Chi-square(2)=6.32, p=0.05

Appendix C

CORRELATION MATRICES

VARIABLE LABELS

SD = Socially Desirable Responding

INS = insulin timing (SR)

BG = blood glucose timing (SR)

FR = blood glucose testing frequency (SR)

ACT = exercise levels (SR)

FOOD = extent diet followed (SR)

BGT = % time blood glucose tested (SM)

DIET = % time diet followed (SM)

EXER = % time vigorous exercise took place (SM)

ADFB = adolescent reports of Diabetes Family Behaviour

PDFB = parent reports of Diabetes Family Behaviour

FAPG = Family APGAR - adolescent reports

HbA1 = glycosylated hemoglobin

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	SD	INS	BG	FR	ACT	FOOD	BGT	DIET	EXER	ADFB	PDFB
SD	1.0000 (29) P= .	.0634 (29) P= .372	.0784 (29) P= .343	-.0929 (29) P= .316	-.1383 (29) P= .237	-.2245 (29) P= .121	-.0032 (29) P= .493	.1613 (29) P= .202	.1397 (29) P= .235	-.0944 (29) P= .313	-.0916 (25) P= .332
INS	.0634 (29) P= .372	1.0000 (29) P= .	.3161 (29) P= .047	.1071 (29) P= .290	.0210 (29) P= .457	.2847 (29) P= .067	.0665 (29) P= .366	-.1111 (29) P= .283	.0884 (29) P= .324	.0034 (29) P= .493	-.3236 (25) P= .057
BG	.0784 (29) P= .343	.3161 (29) P= .047	1.0000 (29) P= .	-.5217 (29) P= .002	.1821 (29) P= .172	.4729 (29) P= .005	-.5213 (29) P= .002	-.5889 (29) P= .000	-.0616 (29) P= .375	.0353 (29) P= .428	-.0961 (25) P= .324
FR	-.0929 (29) P= .316	.1071 (29) P= .290	-.5217 (29) P= .002	1.0000 (29) P= .	-.3974 (29) P= .016	-.2705 (29) P= .078	.8452 (29) P= .000	.3407 (29) P= .035	.1193 (29) P= .269	.3259 (29) P= .042	.0849 (25) P= .343
ACT	-.1383 (29) P= .237	.0210 (29) P= .457	.1821 (29) P= .172	-.3974 (29) P= .016	1.0000 (29) P= .	.3972 (29) P= .016	-.2530 (29) P= .093	.1168 (29) P= .273	-.3493 (29) P= .032	-.1326 (29) P= .246	-.0361 (25) P= .432
FOOD	-.2245 (29) P= .121	.2847 (29) P= .067	.4729 (29) P= .005	-.2705 (29) P= .078	.3972 (29) P= .016	1.0000 (29) P= .	-.0400 (29) P= .418	-.3448 (29) P= .034	.1068 (29) P= .291	-.0367 (29) P= .425	-.0876 (25) P= .339
BGT	-.0032 (29) P= .493	.0665 (29) P= .366	-.5213 (29) P= .002	.8452 (29) P= .000	-.2530 (29) P= .093	-.0400 (29) P= .418	1.0000 (29) P= .	.4431 (29) P= .008	.0625 (29) P= .374	.1901 (29) P= .162	.1244 (25) P= .277
DIET	.1613 (29) P= .202	-.1111 (29) P= .283	-.5889 (29) P= .000	.3407 (29) P= .035	.1168 (29) P= .273	-.3448 (29) P= .034	.4431 (29) P= .008	1.0000 (29) P= .	.2147 (29) P= .132	.0864 (29) P= .328	-.0715 (25) P= .367
EXER	.1397 (29) P= .235	.0884 (29) P= .324	-.0616 (29) P= .375	.1193 (29) P= .269	-.3493 (29) P= .032	.1068 (29) P= .291	.0625 (29) P= .374	.2147 (29) P= .132	1.0000 (29) P= .	-.0608 (29) P= .377	-.2924 (25) P= .078
ADFB	-.0944 (29) P= .313	.0034 (29) P= .493	.0353 (29) P= .428	.3259 (29) P= .042	-.1326 (29) P= .246	-.0367 (29) P= .425	.1901 (29) P= .162	.0864 (29) P= .328	-.0608 (29) P= .377	1.0000 (29) P= .	.4620 (25) P= .010
PDFB	-.0916 (25) P= .332	-.3236 (25) P= .057	-.0961 (25) P= .324	.0849 (25) P= .343	-.0361 (25) P= .432	-.0876 (25) P= .339	.1244 (25) P= .277	-.0715 (25) P= .367	-.2924 (25) P= .078	.4620 (25) P= .010	1.0000 (25) P= .

(COEFFICIENT / (CASES) / 1-TAILED SIG) " . " IS PRINTED IF A COEFFICIENT CANNOT BE COMPUTED

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	INS	BG	FR	ACT	FOOD	BGT	DIET	EXER	ADFB	PDFB	FAPG
INS	1.0000 (29) P= .	.3161 (29) P= .047	.1071 (29) P= .290	.0210 (29) P= .457	.2847 (29) P= .067	.0665 (29) P= .366	-.1111 (29) P= .283	.0884 (29) P= .324	.0034 (29) P= .493	-.3236 (25) P= .057	.0439 (26) P= .416
BG	.3161 (29) P= .047	1.0000 (29) P= .	-.5217 (29) P= .002	.1821 (29) P= .172	.4729 (29) P= .005	-.5213 (29) P= .002	-.5889 (29) P= .000	-.0616 (29) P= .375	.0353 (29) P= .428	-.0961 (25) P= .324	-.4226 (26) P= .016
FR	.1071 (29) P= .290	-.5217 (29) P= .002	1.0000 (29) P= .	-.3974 (29) P= .016	-.2705 (29) P= .078	.8452 (29) P= .000	.3407 (29) P= .035	.1193 (29) P= .269	.3259 (29) P= .042	.0849 (25) P= .343	.3195 (26) P= .056
ACT	.0210 (29) P= .457	.1821 (29) P= .172	-.3974 (29) P= .016	1.0000 (29) P= .	.3972 (29) P= .016	-.2530 (29) P= .093	.1168 (29) P= .273	-.3493 (29) P= .032	-.1326 (29) P= .246	-.0361 (25) P= .432	-.2447 (26) P= .114
FOOD	.2847 (29) P= .067	.4729 (29) P= .005	-.2705 (29) P= .078	.3972 (29) P= .016	1.0000 (29) P= .	-.0400 (29) P= .418	-.3448 (29) P= .034	.1068 (29) P= .291	-.0367 (29) P= .425	-.0876 (25) P= .339	-.2657 (26) P= .095
BGT	.0665 (29) P= .366	-.5213 (29) P= .002	.8452 (29) P= .000	-.2530 (29) P= .093	-.0400 (29) P= .418	1.0000 (29) P= .	.4431 (29) P= .008	.0625 (29) P= .374	.1901 (29) P= .162	.1244 (25) P= .277	.2620 (26) P= .098
DIET	-.1111 (29) P= .283	-.5889 (29) P= .000	.3407 (29) P= .035	.1168 (29) P= .273	-.3448 (29) P= .034	.4431 (29) P= .008	1.0000 (29) P= .	.2147 (29) P= .132	.0864 (29) P= .328	-.0715 (25) P= .367	.2776 (26) P= .085
EXER	.0884 (29) P= .324	-.0616 (29) P= .375	.1193 (29) P= .269	-.3493 (29) P= .032	.1068 (29) P= .291	.0625 (29) P= .374	.2147 (29) P= .132	1.0000 (29) P= .	-.0608 (29) P= .377	-.2924 (25) P= .078	.2181 (26) P= .142
ADFB	.0034 (29) P= .493	.0353 (29) P= .428	.3259 (29) P= .042	-.1326 (29) P= .246	-.0367 (29) P= .425	.1901 (29) P= .162	.0864 (29) P= .328	-.0608 (29) P= .377	1.0000 (29) P= .	.4620 (25) P= .010	.2623 (26) P= .098
PDFB	-.3236 (25) P= .057	-.0961 (25) P= .324	.0849 (25) P= .343	-.0361 (25) P= .432	-.0876 (25) P= .339	.1244 (25) P= .277	-.0715 (25) P= .367	-.2924 (25) P= .078	.4620 (25) P= .010	1.0000 (25) P= .	.0695 (25) P= .371
FAPG	.0439 (26) P= .416	-.4226 (26) P= .016	.3195 (26) P= .056	-.2447 (26) P= .114	-.2657 (26) P= .095	.2620 (26) P= .098	.2776 (26) P= .085	.2181 (26) P= .142	.2623 (26) P= .098	.0695 (25) P= .371	1.0000 (26) P= .

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	INS	BG	FR	ACT	FOOD	BGT	DIET	EXER	ADFB	PDFB	FAPG
HBA1	-.0564	.2677	.0424	-.2293	-.1056	-.0286	-.1849	-.1296	.1244	.0951	-.0393
	(29)	(29)	(29)	(29)	(29)	(29)	(29)	(29)	(29)	(25)	(26)
	P= .386	P= .080	P= .414	P= .116	P= .293	P= .441	P= .169	P= .251	P= .260	P= .326	P= .425

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	SEX	INCOME	PARENTS	AGE	GRADE	DURATION	HBA1
SEX	1.0000	.2139	-.2898	-.2151	-.0250	-.0634	-.0996
	(29)	(29)	(29)	(29)	(29)	(29)	(29)
	P= .	P= .133	P= .064	P= .131	P= .449	P= .372	P= .304
INCOME	.2139	1.0000	.3882	-.1483	-.0237	.0452	-.3029
	(29)	(29)	(29)	(29)	(29)	(29)	(29)
	P= .133	P= .	P= .019	P= .221	P= .451	P= .408	P= .055
PARENTS	-.2898	.3882	1.0000	.1112	.1487	-.2385	-.1866
	(29)	(29)	(29)	(29)	(29)	(29)	(29)
	P= .064	P= .019	P= .	P= .283	P= .221	P= .106	P= .166
AGE	-.2151	-.1483	.1112	1.0000	.9031	.0489	.0321
	(29)	(29)	(29)	(29)	(29)	(29)	(29)
	P= .131	P= .221	P= .283	P= .	P= .000	P= .401	P= .434
GRADE	-.0250	-.0237	.1487	.9031	1.0000	-.0151	-.0459
	(29)	(29)	(29)	(29)	(29)	(29)	(29)
	P= .449	P= .451	P= .221	P= .000	P= .	P= .469	P= .407
DURATION	-.0634	.0452	-.2385	.0489	-.0151	1.0000	.1931
	(29)	(29)	(29)	(29)	(29)	(29)	(29)
	P= .372	P= .408	P= .106	P= .401	P= .469	P= .	P= .158
HBA1	-.0996	-.3029	-.1866	.0321	-.0459	.1931	1.0000
	(29)	(29)	(29)	(29)	(29)	(29)	(29)
	P= .304	P= .055	P= .166	P= .434	P= .407	P= .158	P= .

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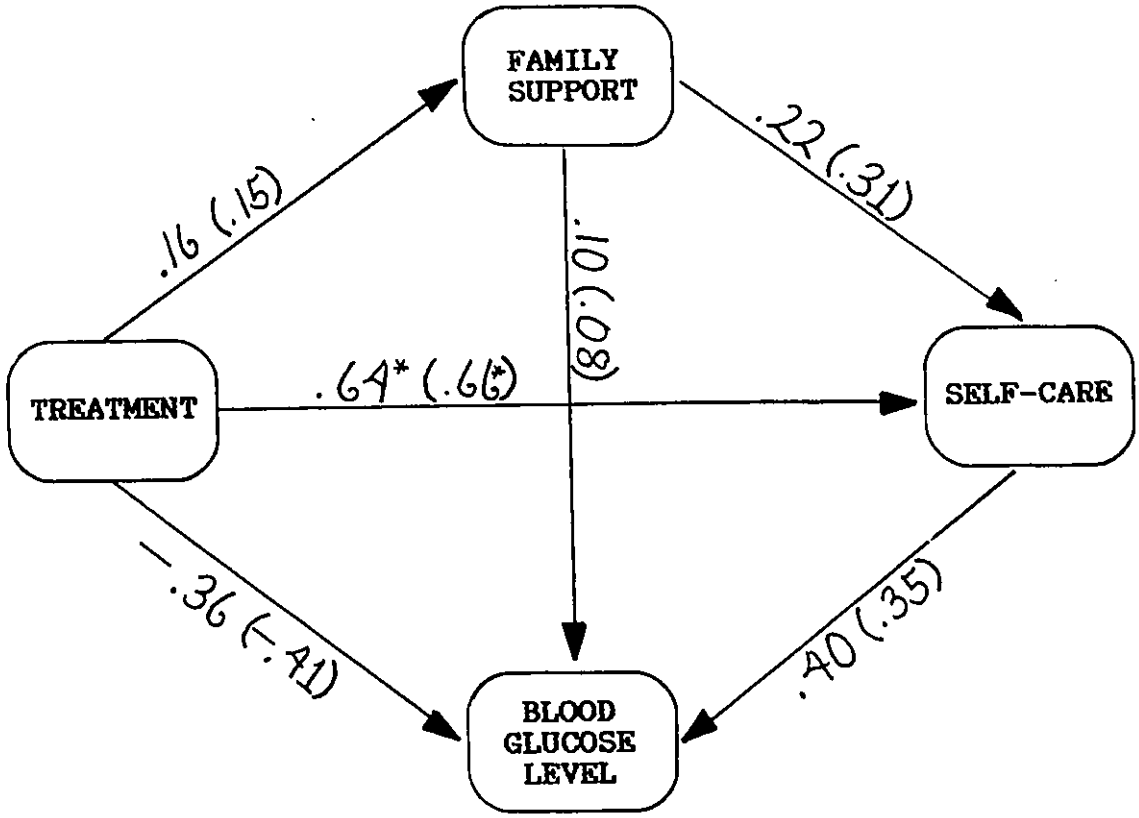
Path Analysis.



Treatment: Coded 1 for Family Intervention
Coded 0 for Comparison Group

Family Support: Adolescent reports of general family support (Family APGAR)

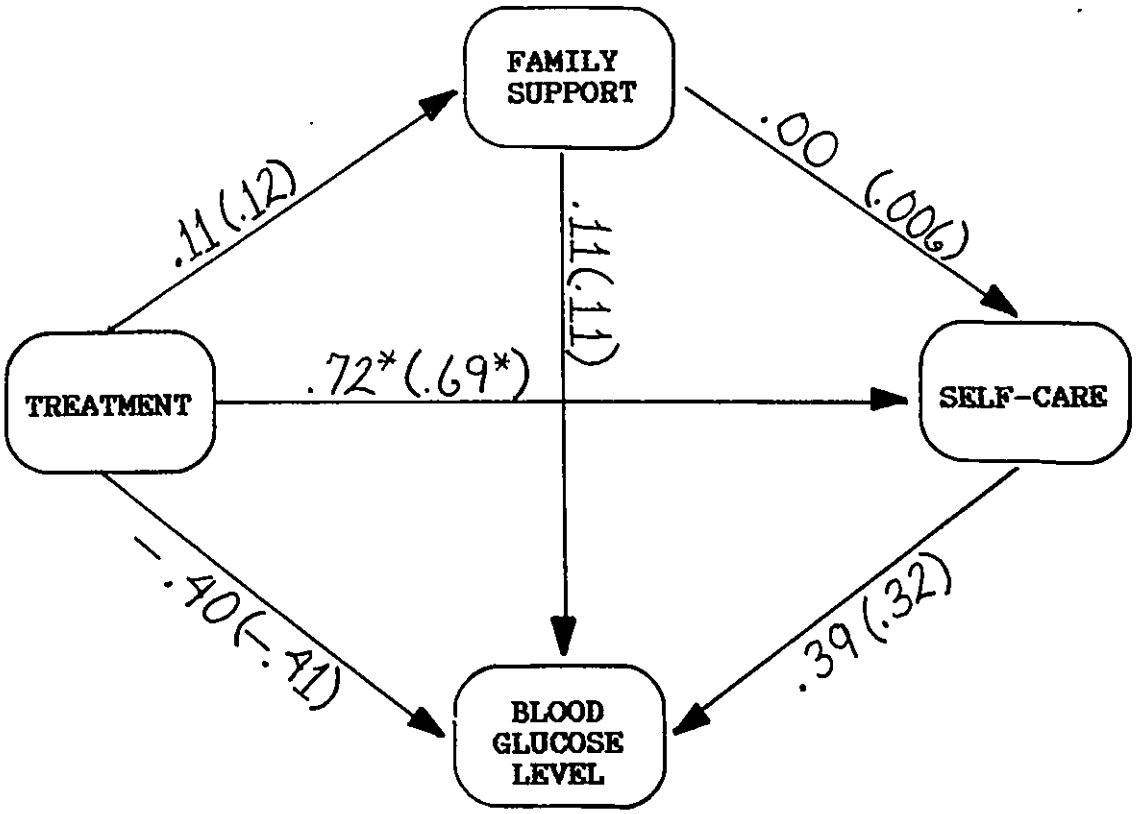
Self-Care: No. of blood glucose tests/day

Blood Glucose Level: HbA1c values

Missing Values: Cases deleted listwise(N=26)
With meansubstitution ( )

Figure 4a. Path model illustrating the direct and indirect effects of treatment at the 6 month follow-up.

Path Analysis.



Treatment: Coded 1 for Family Intervention
Coded 0 for Comparison Group

Family Support: Parent reports of diabetes-specific family behaviour (DFBC)

Self-Care: No. of blood glucose tests/day

Blood Glucose Level: HbA1c values

Missing Values: Cases deleted listwise (N=25)
With meansubstitution ( )

Figure 4b. Path model illustrating the direct and indirect effects of treatment at the 6 month follow-up.

Table 6-1
Pairwise Comparisons On the BGT Variable

Time	Family Intervention	Comparison Group	F(1,27)
1.	.91	.74	a 20.09***
2.	.88	.45	b 10.53**
			c 6.60*
1.	.91	.74	a 19.06***
3.	.88	.45	b 17.05***
			c 11.28*
2.	.88	.45	a 26.71***
3.	.88	.45	b .00
			c .00

*p<.017, **p<.005, ***p<.0005
Note. a = Group F statistic; b = Time F statistic; c = Time x Group interaction.

Table 7-1
Pairwise Comparisons on the HbA1c Variable (Total Sample)

Time 1	Time 2	F(1,28)
11.5 ±1.32	10.1 ±1.70	23.67***
Time 1	**Time 3**	
11.5 ±1.32	10.1 ±1.93	12.44**
Time 2	**Time 3**	
10.1 ±1.70	10.1 ±1.93	.01

ANOVA Tables (for Table 5)

Variable	SS	DF	MS	F	SigF
Insulin on time					
Within Cells	30.87	27	1.14		
Group	2.72	1	2.72	2.38	.135
Within Cells	11.18	27	.41		
Time	.47	1	.47	1.15	.294
GroupxTime	.89	1	.89	2.14	.155
BGT on time					
Within Cells	84.05	27	3.11		
Group	6.58	1	6.58	2.11	.158
Within Cells	27.07	27	1.00		
Time	.31	1	.31	.30	.586
GroupxTime	.65	1	.65	.65	.428
No. of BGT					
Wihin Cells	9.32	27	.35		
Group	5.30	1	5.30	15.34	.001
Within Cells	9.20	27	.34		
Time	2.32	1	2.32	6.80	.015
GroupxTime	2.32	1	2.32	6.80	.015
Diet levels					
Within Cells	76.93	27	2.85		
Group	.00	1	.00	.00	.996
Within Cells	20.61	27	1.13		
Time	.46	1	.46	.41	.529
GroupxTime	.46	1	.46	.41	.529
Exercise levels					
Within Cells	110.41	27	4.09		
Group	3.32	1	3.32	.81	.376
Within Cells	70.33	27	2.60		
Time	1.05	1	1.05	.40	.531
GroupxTime	9.32	1	9.32	3.58	.069

ANOVA Tables (for Table 6 & 7)

Variable	SS	DF	MS	F	SigF
Blood glucose					
Within Cells	2.72	27	.10		
Group	2.52	1	2.52	24.97	.000
Within Cells	1.51	54	.03		
Time	.49	2	.24	8.70	.001
GroupxTime	.31	2	.15	5.86	.006
Diet					
Within Cells	5.21	25	.21		
Group	.06	1	.06	.28	.602
Within Cells	1.11	50	.02		
Time	.04	2	.02	.85	.433
GroupxTime	.01	2	.00	.17	.841
Exercise					
Within Cells	2.54	23	.11		
Group	.01	1	.01	.07	.787
Within Cells	1.51	46	.03		
Time	.06	2	.03	.97	.386
GroupxTime	.02	2	.01	.33	.721
HbA1c levels					
Within Cells	161.72	27	5.99		
Group	.44	1	.44	.07	.789
Within Cells	68.40	54	1.27		
Time	34.54	2	17.27	13.63	.000
GroupxTime	3.71	2	1.86	1.47	.240