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HOME CARE IN CHILDHOOD DIABETES

A controlled evaluation study

Thuisbehandeling bij kinderen met diabetes mellitus

Een gecontroleerde evaluatiestudie

PROEFSCHRIFT

TER VERKRIJGING VAN DE GRAAD VAN DOCTOR

AAN DE ERASMUS UNIVERSITEIT ROTTERDAM

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INTRODUCTION

This thesis considers children with insulin-dependent diabetes mellitus and their psychological and medical functioning during 31 months of participation in a home-care program compared to traditional hospital-based care.

In general, diabetes mellitus -derived from the greek diabainein (to fall through) and mellos (as sweet as honey)- reflects a range of chronic metabolic disorders in which we distinguish two main forms: first, juvenile-onset diabetes or insulin-dependent diabetes mellitus and second, the maturity-onset form or non-insulin-dependent diabetes mellitus.
Insulin-dependent diabetes mellitus (IDDM), also named type I diabetes, is diagnosed almost exclusively before the age of thirty years. In case of IDDM, the pancreas produces no insulin at all and the child needs life-long insulin injections to control disease symptoms. Non-insulin-dependent diabetes mellitus (NIDDM), or type II diabetes, is a less severe form, which develops usually after middle age. The pancreas of most NIDDM patients produces sometimes excess insulin and the lack of insulin-effect can be compensated with a dietary regimen or oral medication. In some NIDDM patients, however, insulin production may decrease progressively over the years and, consequently, these patients may also need insulin injections.
In this thesis the focus will be on children and adolescents with insulin-dependent diabetes mellitus.

IDDM is a complex disease. In children, the medical regimen of IDDM may create psychosocial problems, which may, in turn, affect metabolic regulation and the course of treatment. To understand the complex character of the disease, chapter 1 delineates a clinical picture. Clinical workers presume the existence of psychological and social problems associated with IDDM. In chapter 2, the results about several psychosocial issues in research are reported on, indicating the complex relations of psychosocial and disease-related characteristics. Since there is no cure for IDDM, several lines in research have been directed to the optimization of care and treatment strategies. A review of these treatment strategies is outlined in chapter 3.

Recently, home care has been introduced for IDDM children and their parents as a relatively new strategy in order to further optimize paediatric care. Home care is characterized by an extension of care into the home environment of the child: a specialized nurse-practitioner visits the children at home and provides information and support.

To examine the effects of home care on participants in comparison to traditional hospital-based care, a controlled evaluation study was started. In chapter 4 the aims and design of this study are described. 104 IDDM children and their parents were enroled into the study. They participated in a baseline measurement and, additionally, in 3 psychosocial and 9 medical follow-up measurements.
The baseline characteristics of the IDDM children and their parents are reported in chapter 5. In particular, the differences between children from different hospitals are mentioned.

Chapter 6 addresses the main goal of the study, i.e., the long-term effects of home care versus traditional hospital-based care on psychosocial and medical functioning of the participants. Furthermore, in chapter 7, it is hypothesized that unfavourable baseline scores would induce a higher number of home visits, which may affect favourable outcome scores at the end of the study. In chapter 8 the results of the study are discussed and implications for future research and for optimal IDDM treatment are suggested.

CHAPTER 1

THE NATURE OF INSULIN-DEPENDENT DIABETES MELLITUS

1.1 Introduction

The diagnosis of IDDM in a child has major consequences for the child's health and daily life due to complex disease management (Johnson, 1980). In the long term, the disease is associated with considerable morbidity and reduced life-expectancy mainly because of its chronic complications (Cahill et al., 1976).

The aim of this chapter is to shed some light on the clinical aspects of insulin-dependent diabetes mellitus and its lifelong implications, for readers unfamiliar with the subject. First, the historical background of IDDM will be described in paragraph 1.2. In paragraph 1.3, epidemiological data will be reviewed. Subsequently, the clinical picture and physical symptoms will be outlined in paragraph 1.4. Paragraph 1.5 will address self-care behaviors and their implications for daily life -an important subject further on in this thesis-. In paragraph 1.6, diabetes will be described from a developmental perspective. Finally, in paragraph 1.7, the issues of this chapter will be summarized.

1.2 Historical background

The first description of diabetes mellitus was about 100 AD by the Greek Arataeus, who identified the disorder as "a rare disease associated with a melting down of flesh and limbs into urine" (Greydanus et al., 1979). In 1679 Thomas Willis described glucose excretion into the urine and suggested that the disease was the result of "a long sorrow" (in Eiser, 1985). In the 1880s experimental studies showed that pancreatectomy in dogs resulted in diabetic symptoms. A breakthrough in medical treatment was established in 1922 by the introduction of insulin injections. From that time life-saving treatment of young patients with diabetes was available and mortality at disease onset declined dramatically (Banting et al., 1922).

Only in the course of the 1930s did it become apparent that the price for this life-saving treatment after 10-20 years consisted of an array of so-called chronic complications. These involve irreversible damage to the cardiovascular system, severe limited kidney functioning, blindness, disorders of the nervous system and shortening the life expectancy of IDDM patients by 20 or more years (Cahill et al., 1976; Pirart, 1978; Skyler, 1978). It is still uncertain to what extend near-normoglycaemia can prevent or delay chronic complications. Recent evidence indicates that psychosocial factors may play a role in the development of chronic complications in the long term (Kuypers, 1991; Lloyd et al., 1992).

1.3 Epidemiological data

Europe includes regions with the highest incidence rates of IDDM in the world (Bruining, 1988; Bingley et al., 1989; Drykoningen et al., 1992). In this part of the world the incidence rates range from 4.5 in Israel to 48.5 in two regions in Finland per 100.000 minors per year (Green, 1991). Rate estimations suggest that the incidence of diabetes will double in the next 25 years (Drykoningen et al., 1992; Ekoe, 1991; WHO Diamond Project Group, 1990).

In the Netherlands the annual incidence (1988-1990) appears to be 13 per 100.000 for the 0-19 years old (Hirasing et al., in press). Peak incidences of first insulin injection in children are found between 11 and 13 years of age (Vaandrager et al., 1984; Eiser, 1985; WHO, 1985). The ratio between boys and girls has been established as 1.1 : 1.0 (Bruining, 1988). In 1981 the prevalence of IDDM in children from 0 to 19 years of age was 4000 in the Netherlands (Vaandrager et al., 1984). Every year about 500 children 0-19 years of age are newly-diagnosed as patients with IDDM.

1.4 Clinical picture of diabetes

The World Health Organization defined IDDM as well as NIDDM as "a state of chronic hyperglycaemia (i.e., the state of having an excessive concentration of glucose in the blood), which may result from many environmental and genetic factors, often acting jointly" (WHO, 1980). The precise origin of diabetes is still uncertain (Bruining et al., 1989; Dahlquist et al., 1991). Genetic and viral factors may play a role in triggering diabetes onset (Dahlquist et al., 1991). Significant evidence from research lines during the last decade suggests that auto-immune processes are involved in diabetes etiology (Srikanta et al., 1983; Hitchcock et al., 1988; Bruining et al., 1989). The findings show that islet-cell antibodies appear in individuals who may develop diabetes in later life. After auto-immunity has been activated the destruction of beta-cells appears. Consequently, the insulin production of the beta-cells dies off.

Insulin is a vital hormone needed for the enhancement of tissue uptake of glucose and for the storage of carbohydrates as vital sources of energy. A lack of insulin causes high levels of blood glucose (hyperglycaemia) and hence excretion of glucose into the urine. In many patients excessive passing of urine (polyuria) and excessive thirst (polydipsia) are the first appreciated symptoms of the disease, often confused with urinary-tract infection. Furthermore, patients loose weight due to dependence on previously stored glycogen and fat, and complain of fatigue, nausea, and abdominal pain. Parents often report irritability of their child as a prominent symptom over the months prior to diagnosis. Hyperglycaemia, if not followed by appropriate treatment, leads to ketoacidosis, coma and ultimately death. Insulin injection is necessary to stabilize blood-glucose levels.

It is generally agreed that chronic hyperglycaemia is associated with life-threatening complications in the long-term (Orchard et al., 1990). Consequently, treatment strategies focus upon the prevention and delay of chronic complications by striving for near-normoglycaemia.

For newly-diagnosed patients it is difficult to maintain the vulnerable balance of metabolic control. For instance, after physical exercise or after a period without food intake, e.g., during sleep, the blood glucose will lower. This low blood-glucose condition or hypoglycaemia may generate symptoms of headache, paleness, hungry feelings, dizziness, faintness and changes in mood. Immediate food intake or even intramuscular or subcutaneous injection of glucagon in case of unconsciousness will be necessary to normalize blood glucose (Bergada et al., 1989).

1.5 Self-care behaviors: implications for daily life of patients

IDDM requires a regimen of self-care behaviors, which should be balanced and, if considered necessary, adjusted to changes in metabolic control and daily life.

Insulin injections

Insulin injections are needed to respond to the body's inability to produce it's own insulin. All young insulin-dependent patients need at least two insulin injections per day within a year after diagnosis. After diagnosis children or parents will have to cope with the injection techniques. Several studies have shown that injections are the most distressing aspect of diabetes management (Galatzer et al., 1977; Frish et al., 1977; Laron et al., 1979). When children administer injections themselves, it will help them to feel responsible for disease management (Allen et al., 1983).

Today, there is no consensus about the chronological age, at which children are capable of self-injection themselves: age-limits diverge from six to ten years of age (Köhler et al., 1982, Fonagy et al., 1987; Wysocki et al., 1990). It has been argued that the intellectual and emotional stage of development of the child should be reviewed in order to decide if a child is ready to cope with self-injecting skills (Eiser, 1985; Wysocki et al., 1990).

Recently, technical aspects of injection devices and directions for use have been improved significantly. More and more patients with diabetes use so-called insulin pens. They are easy to operate, but may involve a disadvantage, namely an insulin regimen with four instead of two daily injections. The injection of insulin will be most effective when an appropriate insulin dosage is applied at the right time. This is very difficult in practice, as the resorption of insulin from the injection site is variable, even under standardized conditions in the same patient on the same day. Therefore, patients must regulate their insulin dosage on the basis of frequent blood glucose determination at home in order to achieve and maintain optimal control.

Self-monitoring of blood glucose

Self-monitoring of blood glucose is nowadays the preferred method for determining the blood concentration of glucose and for adjustments of insulin dosages (Geffner et al., 1983). Children collect small blood samples by fingertip punctures and use reagent strips and a reflectance photometer to monitor blood glucose. Monitoring blood glucose gives insight in metabolic stability, provided that families are trained in the interpretation of the blood-glucose data.

Adequate blood-glucose monitoring at home will prevent hospital admissions due to severe hypoglycaemia and ketoacidosis (Belmonte et al., 1988; Bruining, 1984). A major problem of self-monitoring of blood glucose is the failure among children to adhere to monitoring in a consistent fashion. Belmonte and associates (1988) found in their study sample that only 50% strictly adhered to blood-glucose monitoring, which may have caused a lack of improvement in glycaemic control. Other research findings have underlined the importance of adherence to the diabetic regimen per se (e.g. Schafer et al., 1982; Fisher et al., 1982; McCaul et al., 1987).

Diet

Children with diabetes are usually advised to adopt a prescribed diet. In general, physicians and dieticians recommend the avoidance of concentrated sweets, advise a regular intake of food, and an intake of calculated weights of carbohydrates, proteins and fats. Authorities have discussed how strict or lenient diet guidelines should be followed (Johnson, 1980; Craig, 1977). However, strict adherence to diabetes guidelines does not guarantee the prevention of long-term complications (Nuttall, 1983) and may impede healthy development in young children (Johnson, 1980). More recently, a relatively free diet has been advised without careful weighing of foods (Eiser, 1985; Erkelens, 1985).

Regular exercise

Regular exercise is recommended for children with diabetes favouring optimal metabolic control. Doing so, children and their parents have to learn to adjust insulin and diet to the daily physical activities of the child. Exercise will cause a lowering of blood glucose immediately or several hours thereafter. However, with appropriate precautions, anticipatory lowering of insulin dosage and/or extra carbohydrate intake, children with diabetes are able to participate in all physical activities.

It is evident that the impact of IDDM and self-care behaviors are associated with the age and developmental level of the child. This perspective will be discussed in more detail in the next paragraph.

1.6 Diabetes from a developmental perspective

It has been generally recognized that children's cognitive, emotional and social development can be seriously affected by any childhood disease requiring specialist treatment for several years (Cerreto et al., 1984; Johnson, 1980; Fisher et al., 1982). Diabetes changes the interactions of a child with its environment -involving parents, siblings, peers or school systems-, and this changed environment in turn influences the affected child and his or her course of development (Perrin et al., 1984). The extent to which a chronic disease influences the child and the environment depends to a certain degree on disease characteristics, such as duration, severity, expected prognosis, disease history, visibility and limitations associated with the disease (Cerreto et al., 1984; Perrin et al., 1984). In addition, the transactional process between the child and the environment is determined by a number of individual variations involving personality characteristics, temperament, family functioning and social support systems (Perrin et al., 1984).

Moran (1984) has argued from a psychoanalytic point of view that IDDM may interfere with the developmental process of differentiation between bodily and mental life, and may lead to misinterpretation of internalized conflicts in terms of physical symptoms. In this way, aggressive and sexual wishes may be translated into hypoglycaemic symptoms or genuine strong emotions may be attributed to abnormal blood-glucose levels.
Anna Freud (in Moran, 1984) has described that disease itself as well as treatment may damage child development as early as the prelatency period. Disease and treatment may cause a "narcistic blow of having a damaged body", and may trigger "fantasies associated with a defective body image, mental pain of being different from other children, and feelings of being victimized, deprived and physically assaulted".

Despite the multitude of negative influences of a chronic disease, children develop coping behaviors which enable them to adapt to the demands of a chronic disease (Eiser, 1985). Stubblefield (in Eiser, 1985) has suggested that healthy children master disappointments and frustrations in life, because they expect that development and maturation will enable them to manage life crises. For children with a chronic disease the future is less certain and, consequently, they might be sceptical about future acquisition of skills and achievement of independence. In this way chronic disease may impede the attainment of developmental tasks. By contrast, Lipowski and Mattson (in Eiser, 1985) have argued that a chronic disease should not only be identified as a threat to healthy development (see Lazarus, 1966), but also as a possibility to develop coping behaviors that result in psychological maturation.

The acquisition of the disease concept by the child and the associated influences of a disease have been discussed within the framework of cognitive and personal-social developmental approaches (Perrin et al., 1984; Cerreto et al., 1984: Eiser, 1985). These developmental approaches have been described best by Piaget (1969) and Erikson (1964), respectively. Their views on psychological development and the influences of chronic disease on development in turn will be briefly reviewed in subsequent age-related stages.

Infancy and toddlerhood (0-5 years of age)

During the first months of their life infants are totally dependent of their parents and are unable to differentiate between self and their surrounding world due to their "egocentric" view. Cognitive development and the maturation of sensorimotory functioning enable infants to explore their outside world. Furthermore, parents induce feelings of "basic trust" in the child as a result of their consistent provision of food, warmth and protection. Feelings of security stimulate the young child to explore their environment and to develop feelings of separation, individuation and autonomy. The experience of successful performance and achievement of goals encourages the child to undertake more initiatives and responsibilities.

Diabetes may influence the attainment of developmental tasks in several ways. Hospital admission after diabetes onset may distort the consistency of parental care and, consequently, may hamper development of trust and increase fear of separation (Cerreto et al., 1984; Perrin et al., 1984). Furthermore, parents may respond to chronic disease with overindulgent and overprotective parental styles (Cerreto et al., 1984; Johnson, 1980; Johnson et al., 1982; Swift et al., 1967). They may restrict the child's activities, because of their fear for hypoglycaemic reactions. In this way they may impede exploratory behavior and the acquisition of autonomy (Perrin et al., 1984). Feelings of anger, depression and guilt in parents may lead to inconsistent care and to divergent parental behaviors, such as overcontrolling behaviors or rejection and neglect (Johnson, 1980; Davies et al., 1988a). In addition, disease onset and treatment implementation will introduce restriction in sweets and candies, which were previously used by parents as important reinforcers after attainment of developmental tasks (Perrin et al., 1984). The child in this period will not be able to discriminate fantasy from reality and thought from behavior. As a consequence, the child may perceive disease, treatment and associated restrictions as punishment for being "bad" or may have concrete and supernatural explanations (Cerreto et al., 1984; Perrin et al., 1984, Johnson, 1980).

Middle childhood (6-11 years of age)
During this period children normally develop independent functioning within the family system, develop contacts with the peergroup and experience recognition or disapproval from peers, attain reality-orientation and discrimination between self and world. Diabetes may cause problems in these developmental areas and, in particular, may threaten feelings of industry and self-esteem in the child (Johnson et al., 1982). Furthermore, feelings of body control may reduce as a result of loss of control during hypoglycaemic incidences (Cerreto et al., 1984). Children with diabetes acquire awareness of being "different" from peers, which may lead to isolation and lack of peer support (Perrin et al., 1984; Johnson, 1980). Peers may stigmatize and tease children with diabetes, which decreases self-esteem (Johnson et al., 1982).

In this so-called concrete-operational period cognitive skills show further maturation, which normally enables the child to understand the concepts of time and conservation and to comprehend causal relations. Disease onset is initially experienced in terms of contamination; later on in this period, children attain better understanding about the cause of their disease than peers (Perrin et al., 1984). As a result of the increase in management skills and the development of a sense of responsibility for disease management children can now be stimulated to active participation in self-care behaviors (Cerreto et al., 1984; Greydanus et al., 1979).

Adolescence (12-18 years of age)
During this formal-operational period the adolescent is no longer restricted by concrete thought and can rely on flexible and abstract thought. Growing cognitive abilities are reflected in the achievement of complex physiological understanding of disease and health. The teenager describes physiological causes of chronic disease and also understands the influences of psychological factors on the course of the disease (Cerreto et al., 1984). However, especially during puberty, a chronic disease adds another confusing element to the age-related conflicts which teenagers experience in their life. (Perrin et al., 1984; Johnson, 1980). By some adolescents diabetes will be used as a scape-goat for normal age-related conflicts (Sullivan, 1978), by others as a battlefield for parent-child conflicts (Johnson et al., 1982). Furthermore, teenagers may show depressive

feelings concerning future expectations about health and employment (Johnson et al., 1982).

Peer conformity is crucial during puberty. As a result, teenagers find it difficult to adhere to the diabetic regimen (Kaplan et al., 1985; Perrin et al., 1984). In addition, the adolescent with diabetes experiences evident differences from peers and may feel a sense of shame and, consequently, may withdraw into isolation (Johnson et al., 1982).

Furthermore, adolescents develop their own value system and body image (Cerreto et al., 1984; Rodin, 1983). Adolescents with diabetes must adapt their idealized body image to reality and accept an imperfect body which needs insulin injections. An impaired body image or lowered self-esteem may contribute to hesitance in social participation and development of relationships with peers, which may delay or distort psychosexual development (Perrin et al., 1984). Finally, the intense emotional and physical reactions of the teenager during puberty and the problems of parents to cope with upheavals of rebellious behavior and metabolic instability may intensify parents' endeavour to regain strict adherence to prescribed regimen rules. This attitude will foster adolescent dependency on parents and medical care and, thus, hinder the processes of defining their own identity and establishing independence from parents (Perrin et al., 1984; Davies et al., 1988a).

The psychosocial and cognitive developmental approaches demonstrate clearly that biological and psychosocial development may be adversely affected by disease and treatment management varying with each stage of development (Cerreto et al., 1984; Perrin et al., 1984; Eiser, 1985; Moran, 1984). In order to support these views extensive research has been undertaken aiming at the examination of psychosocial consequences of IDDM in an empirical and systematical way (see Chapter 2).

The developmental approaches have also indicated that knowledge of children's development and attention to the risks to normal development imposed by diabetes may contribute to optimization of health care (Perrin et al., 1984). If parents and health care providers understand the child's normal developmental process and are aware of the impact of diabetes on that process, they may be able to provide optimal care tailored to the needs of the individual child.

1.7 Summary

Insulin-dependent diabetes mellitus (IDDM) is a chronic metabolic disorder which has a major impact on a child's life and family after disease onset. Next to subtle as well as serious temporary acute complications, it is associated with severe and life-threatening complications in the long term. Epidemiological research shows that incidence rates of IDDM are high in the north-western regions of Europe and are rapidly rising, the incidence doubling every 25 years.

Life-saving treatment of IDDM has been available since the introduction of insulin in 1922. Ongoing treatment management involves complex self-care behaviors, as it aims at the maintenance of a delicate balance between insulin dosages, diet, and physical exercise, resulting in varying degrees of metabolic control. The aim of optimal metabolic control is to decrease acute complications and to reduce the likelihood of chronic complications. However, optimal control can not guarantee absence of complications in the long term.

Disease as well as treatment put children with IDDM at risk for complex physical and psychosocial interactions. The psychosocial effects of the disease can be understood within a developmental framework, described in this chapter.

CHAPTER 2

PSYCHOSOCIAL RESEARCH IN INSULIN-DEPENDENT DIABETES MELLITUS

2.1 Introduction

Since the introduction of insulin in 1922 physicians and paediatricians have recognised the importance of psychological and social factors in diabetes to establish and maintain good metabolic control. Psychosocial and cognitive developmental approaches have demonstrated the profound impact of diabetes and its treatment on children in each stage of development (Cerreto et al., 1984; Perrin et al., 1984; see chapter 1). In order to further explore these views, extensive research has been undertaken aiming at the examination of psychosocial aspects of diabetes by empirical and systematical means. Many of these studies have focused on behavioral and emotional disturbances in small samples of children with wide age-ranges (Johnson, 1980). The relatively low prevalence of children with IDDM has caused pooling of age groups for investigation (Cerreto et al., 1984).

Previous reviews (e.g., Dunn et al., 1981; Fisher et al., 1982) showed that early studies in this research area were mainly directed at the influence of psychological factors in etiology of diabetes (see paragraph 2.2). Later, the following research issues were identified: the psychological impact of age at diabetes onset (paragraph 2.3), the influence of psychological factors after diabetes onset (paragraph 2.4), specific psychosocial consequences of diabetes (paragraph 2.4.1), psychosocial factors and metabolic control (paragraph 2.4.2), the role of stress in diabetes (paragraph 2.4.3), and the role of regimen adherence (paragraph 2.4.4).

The field of research is complex and vast. In the next paragraphs the above mentioned issues will be reviewed. A final section will consider the outcomes of research and the strategies that are most promising and relevant in the near future.

2.2 Etiology of diabetes and the role of psychological factors

Despite extensive research the cause of insulin-dependent diabetes is still uncertain (Bruining et al., 1989; Dahlquist et al., 1991). To some extent heredity contributes to the predisposition for the disease, but it is generally assumed that diabetes as such can not be inherited. Early studies were directed at the finding of a "diabetic personality", which would predispose the child to the development of IDDM (Bruch, 1948; Dunbar, 1954). The results of these studies, however, did not demonstrate clear evidence about personality characteristics that could be held responsible for disease onset (Dunn et al., 1981). Consequently, the interest has declined in finding a predisposing personality.

Research shifted to the role which life stresses may play as precipitating factors of IDDM (Slawson et al., 1963; Stein et al., 1971). Slawson and associates (1963) reported from their (uncontrolled) study that 14 of 25 adults with diabetes had a history of object loss prior to disease onset. Stein and associates (1971) found in a group of 38 patients a tendency of more parental loss and severe family disturbances compared to a matched control group. These studies were criticized for their clinical observation measures, their small sample sizes (Hauser et al., 1979a), for their retrospective and unsystematical data collection, and the inclusion of life stresses that occurred several years prior to the diagnosis (Johnson, 1980).

The study of Kovacs and associates (1985) has been executed in a more systematical way. In this longitudinal study the life events of 74 children were assessed by the Coddington Life Events Scales -a standard measurement instrument- at the time of diagnosis. Compared to normative data (Coddington, 1972) the authors found average life stress prior to the onset of diabetes. Yet, they underline the possibility that even "normal" stress may have triggered the onset of disease. Recent results of Smith and associates (1991) support the view that life events do not necessarily influence metabolic stability.

The studies summarized here show no substantial evidence that personality factors nor specific life stresses can be pointed at as the only etiological factors in the onset of diabetes.

It is hypothesized that the disease pathogenesis may be facilitated by interacting physical and environmental factors and that psychological or stress factors might facilitate its clinical manifestation only (Johnston et al., 1981; Siemiatycki et al., 1989). Other research findings point at a viral cause of diabetes (Cahill et al., 1981). Recent and more substantial evidence suggests an auto-immune pathogenesis, years before clinical manifestation (Srikarta et al., 1983; Hitchcock et al., 1988; Bruining et al., 1989). The findings indicate that 50% of the children who will later develop diabetes may have islet-cell antibodies 4-8 years before clinically identifiable symptoms appear. Recent research has addressed the evaluation of islet cell-antibody screening programs, in order to predict diabetes manifestation (Bruining et al., 1989; Johnson et al., 1990). Instead of personality features or life stress as direct causes of diabetes, it is hypothesized that psychological factors might influence the appearance of islet-cell antibodies or might eventually trigger clinical manifestation of the disease (Jacobson et al., 1984)

2.3 The role of age at diabetes onset

A new line in research has focused on subsets of children which had differed in age at

diabetes onset. Ack and associates (1961) reported in an early study that those who developed IDDM before the age of five had significant lower IQ levels than their siblings. It has been argued that the younger the child is at diagnosis of diabetes, the higher the risk of neurocognitive impairment. The results of several studies have confirmed this assumption and have indicated that earlier age at onset is associated with lower scores on cognitive tests -measuring visuospatial, verbal and mathematical abilities- compared to later-onset children and controls (Ryan et al., 1985; Ryan, 1988; Rovet et al., 1988; Anderson et al., 1984). Underlying explanations for the cognitive impairments are the presence of multiple episodes of hypoglycaemias and comas and the vulnerability of the brain for metabolic disturbances during the first years of a child's life.
Furthermore, long duration of the disease showed a relation with poorer verbal skills due to school absence. Another explanation might be the parental restrictions of exploratory behavior and motor activities caused by fear for hypoglycaemias, which might be held responsible for limited development of spatial skills (Cerreto et al., 1984; Perrin et al., 1984; Rovet et al., 1988).
In conclusion, several studies provide substantial evidence that children with diabetes onset before the age of five, run the risk of neurocognitive impairment.

2.4 The impact of psychosocial factors after diabetes onset

The actual development of the disease has extensive and complex consequences for the child and its parents. The reactions of each child, parent or family after disease onset will be different and will depend on their personal and developmental history and on their sources of support provided by health care personnel and significant others (Jacobson et al., 1984; Perrin et al., 1984). After diagnosis, families will experience feelings of grief, sometimes associated with denial of the consequences of diagnosis, and questioning of their ability to cope with the management skills necessary to control diabetes. Professional experienced clinical workers are needed to help families to cope with these management problems by means of information, education and psychological assistance in addition to technical medical care.
Studies have outlined that the diagnosis of diabetes can induce feelings of guilt in the child as a result of bad behavior, temper tantrums, refusal to attend school and negative expectations about the future (Johnson, 1980; Hauser et al., 1979a; Dunn et al., 1981; Kovacs et al., 1985). Furthermore, the child perceives diabetes as a "hidden disease" and its invisibility might give rise to problems in social functioning (Johnson, 1980; Tattersall et al., 1985). For example, it is known that class-mates of an IDDM child may think of the disease as being contagious. To the parents, the diagnosis of diabetes may generate

feelings of guilt due to hereditary aspects or other unknown causal factors for disease onset. Additionally, symptoms of anxiety, depression and distress can be elicited in parents after diagnosis. (Hauenstein et al., 1989; Koski, 1969; Sterky, 1963; Tarnow et al., 1978; Khurana et al., 1970; Kovacs et al., 1985; Wysocki et al., 1989).

Not only disease manifestation as such, but also the treatment regimen has major implications for the child and the family. The need for responsible decisions during the child's life to protect good health induces severe pressure on both the child and family. Insulin injections and regular blood-glucose monitoring become necessary to maintain stable metabolic control and must be integrated in the life style of the patient and the family. These particular aspects of treatment and anxiety about future complications appear to be the most distressing consequences of the disease (Fallstrom, 1974; Frish et al., 1977; Eiser, 1985). The consequences of the clinical manifestation of diabetes are further complicated by the interdependent character of emotional distress and the course of the disease. For example, emotional disturbance in a child or family may be the result of disease onset, but in turn also influences metabolic control, usually by enhancing blood-glucose levels. Furthermore, stressful events may lead to changes in emotions or to deviations in adherence behaviors which, in turn, may influence neurohormonal regulation and glucose metabolism (Jacobson et al., 1984). Eventually, it is difficult or even impossible to identify the cause and effect of a particular metabolic or emotional disorder.

In the next sections, research will be reviewed into the emotional, behavioral and intellectual consequences in children after diabetes onset. Furthermore, the interdependency of the psychological consequences with metabolic control will be discussed and, finally, the influence of mediating variables will be presented.

2.4.1 Psychosocial consequences of diabetes in children

Emotional and behavioral disturbances

Many researchers have studied the occurrence of emotional and behavioral disorders in children after diabetes onset compared to non-diabetic controls. Convincing evidence for psychopathology in patients has been presented in an early study by Swift and associates (1967). They studied 50 children with diabetes and 50 matched non-diabetic controls using psychiatric interviews and projective tests. The children with diabetes showed more psychological disturbances than controls. Swift and associates described these children as more dependent, more hostile, having a less adequate self-image, having higher levels of anxiety, more disturbed sexual identification and having poorer relationships with family members and peers. These results were supported by Fallstrom (1974) using comparable projective methods. In subsequent studies mixed results were obtained: some authors reported high levels of depression in children with diabetes compared to non-diabetic children (Hauser et al., 1979a; Joslin, 1985; Kimball, 1971; Koski, 1969; Sullivan, 1979b; Wysocki et al., 1989), or observed more anxiety and aggression (Joslin, 1985; Koski, 1969; Swift et al., 1967; Appelboom-Fondu, 1977; Lavigne et al., 1982; Wysocki et al., 1989), or indicated more behavioral disturbances (Court et al., 1988; Groen et al., 1973; Gortmaker et al., 1973), whereas others did not find significant differences in emotional nor in behavioral disorders (Olatawura, 1972; Sterky, 1963; Guthrie et al. 1975; Ahnsjo et al., 1981; Simonds; 1977).

Self-esteem

More consistent were the data on the level of self-esteem in children with diabetes. Sullivan (1978) studied adolescent girls using purposely designed assessment instruments and found lower self-esteem in girls with diabetes compared to controls. Hauser and associates (1979b) confirmed these results and reported lower self-esteem in adolescents with a long history of diabetes. However, other authors have argued that diabetes as such might have a strengthening influence on the child's self-esteem instead of causing low self-esteem (Tavormina et al., 1976).

Intellectual and educational disturbances

Some studies have found intellectual deficits in children with diabetes (Rovet et al.,1987a; Simonds, 1977), but others did not confirm this (Koski, 1969; Ack et al., 1961; Ahnsjo et al., 1981; Hauser et al., 1979a; Joslin, 1985; Steinhausen et al. 1977).

In other investigations school performance of children with diabetes has been studied, but again mixed results were obtained. Sterky (1963) and Ahnsjo and associates (1981) did not find different school performance in children with diabetes compared to healthy peers. Others found backwardness in reading performance -which applied most to children in poor metabolic control (Gath et al., 1980)- and excessive school absence (Orr et al., 1983).

Social problems

The most consistent findings appear in studies on social functioning of IDDM children. Most researchers agree about the occurrence of social problems in relation with others (Ahnsjo et al., 1981; Simonds, 1977; Pennings-Van der Eerden, 1986), in relation with friends (Allen et al., 1984; Simonds, 1977; Swift et al., 1967), or refer to problems caused by isolation from healthy peers (Joslin, 1985; Kimball, 1971; Orr et al., 1983;

Groen et al., 1973).

In conclusion, many investigations have studied psychosocial differences between children with diabetes and controls, but yielded inconsistent results. Reviews suggested that methodological shortcomings and limitations in research design contributed to the diversity of results (Lavigne et al., 1982; Johnson, 1980; Court et al. 1988). For example, small sample sizes and/or diversity of measurement procedures caused conflicting results. Furthermore, studies did not reveal whether emotional, behavioral or intellectual problems already existed before diabetes onset or rather emerged after diagnosis (Johnson, 1980).

To sum up, existing clinical views about disturbances in several psychosocial domains have not been clearly confirmed mainly due to methodological shortcomings. The more reliable findings point to merely social problems in children with diabetes.

2.4.2 Psychosocial factors and metabolic control

The mixed data on psychological disturbances in children with diabetes mellitus compared to controls gave rise to studies that investigated disturbances *among* children with diabetes. The assumption being that subsets of children, e.g., children in poor metabolic control, run a higher risk of psychological disorders.

Emotional and behavioral disturbances

Simonds (1977) carried out a study to shed light on psychological characteristics of children with diabetes in good versus poor control. Forty poorly controlled children and 40 well controlled children were compared to a matched non-diabetic sample. Using interviews at the homes of children, individuals were classified in terms of psychiatric disorders and interpersonal conflicts. Simonds did not find significant differences between the 80 children with diabetes on the one hand and non-diabetic controls on the other hand, but revealed that patients in poor control showed more anxiety and depression than patients in good control. Pennings-Van der Eerden (1986) found symptoms of anxiety and a lower selfconcept in poorly controlled adolescents. Koski (1969) described that poorly controlled children were characterized by a "less integrated, less imaginative and less sensitive" personality compared to children in good control.

However, a number of studies did not support a significant relation between emotional/behavioral disturbances and metabolic control (Court et al., 1988; Close et al., 1986; Fonagy et al., 1987; Tiefengruber et al., 1987). Close and associates (1986) concluded that well controlled diabetes is not necessarily associated with psychological

well-being; they suggested that management methods to achieve good control might induce depression. In accordance with this suggestion Fonagy and associates (1987), confirmed by Smith and associates (1991), found an association between psychiatric disturbances and children in good control: anxious children showed better metabolic control, but were more dependent of their parents. It was obvious that parents played an important role in the execution of the regimen and protected their young child from the adverse effects of early self-care behavior (Fonagy et al., 1987).
Other studies on psychological attributes have underlined a diverse and inconsistent relation with metabolic control. For instance, Rovet and associates (1988) studied the relation between temperament and metabolic control and found that high scores on activity, predictability, regularity and distractibility were related to good control, and that high response intensity was related to poor control.

Knowledge of diabetes

Other investigations have explored the effect of knowledge about IDDM on metabolic control. Early studies established that knowledge was incomplete among IDDM children (Etzwiler et al., 1962; Miller et al., 1978). However, the improvement of knowledge about the disease -an important aim of many educational programs (see Chapter 3)- did not necessarily lead to better control and skills (Johnson et al., 1982; Hamburg et al., 1982; McCaul et al., 1987; Rubin et al., 1989). Surprisingly, it has even been found that better knowledge was associated with poor metabolic control. As an explanation for this result, Hamburg and associates (1982) have described that the acquisition of knowledge and information seeking can function as a coping strategy to reduce stress. Therefore, children in poor control might know a lot about their disease, because there is a need to reduce stress. The understanding of the relation between knowledge and metabolic control has been further complicated as a result of recent data which indicate that episodes of mild hypoglycaemia interfere with cognitive functioning of children with diabetes (Rovet et al. 1988; Reich et al., 1990; Ryan et al., 1990).

Locus of control

Some investigations into the relation between psychological and metabolic factors have included the potential importance of the personality dimension "locus of control". This expectancy variable refers to the extent by which a person perceives an event as dependent of personal action (internal locus of control) or dependent of chance or fate (external locus of control). Locus of control is said to be especially relevant in diabetes, since diabetes management procedures are highly under individual control. Schlenk and associates (1984) have argued that internally controlled persons seek more information and benefit more from information and care. In addition, locus of control is thought to be important to establish and maintain compliance to the treatment regimen. Several studies offer some support for these arguments and indicate a strong relation between locus of control and metabolic control (Jacobson et al., 1986). Nonetheless, others found a weak or no relation (Simonds et al., 1981; Evans et al., 1987). Sometimes children with diabetes appeared to be more internally oriented (Simonds et al., 1981), sometimes more externally (Jacobson et al., 1986; Evans et al., 1987). Evans and associates (1987) have suggested that good diabetic control can be achieved by external locus of control and a rigid family organization, because not the child but the rigid rules of the family are responsible for good control. Furthermore, they added that these family characteristics may function as a threat to the development of autonomy and independence of the child.

Age and gender

A relation between age on the one hand and psychological adaptation and metabolic control on the other hand should be expected (Eiser, 1985; Cerreto et al., 1984; Rovet et al., 1987b). In a recent study Grey and associates (1991) supported this assumption and found that adolescents were more depressed, more anxious, had adjustment problems and were in poorer metabolic control than pre-adolescents. Kovacs and associates (1990) found important differences between boys and girls and differences during the first six years after diagnosis of IDDM. That is, girls were more upset by the disease implications than boys and with time boys as well as girls regarded the regimen more difficult to cope with.

From the large number of studies about psychological and metabolic factors we may conclude that these complex variables strongly influence each other, but the directions of their relations are unclear. In addition to methodological shortcomings, the possibility of indirect relations between psychological and metabolic factors, mediated by intercurrent variables such as life stresses or regimen adherence, has been proposed as a cause for the inconsistencies described (Schafer et al., 1983; Hanson et al., 1987a).

2.4.3 The role of stress in metabolic control

Stress has been defined by Selye as "the sum of all nonspecific changes caused by different nocuous agents, the rate of wear and tear in the body that accompanies any vital activity and, in sense, parallels the intensity of life" (Selye, in Barglow et al., 1984). Barglow and associates (1984) have argued that stress is usually defined by the presence of psychopathology without consideration of individual response variability.

In health, it is known that stress influences metabolic control by directly increasing anxiety levels and thus causing higher production of stress hormones, i.e., catecholamines and corticosteroids, raising glucose levels (Barglow et al., 1984). Additionally, stressful events influence metabolic control indirectly. For instance, stress may interfere with regimen adherence and, consequently, will influence metabolic stability (Fisher et al., 1982; Chase et al., 1981; Barglow et al., 1984; Halford et al., 1990). In the light of the diverse ways in which psychological stress influences control, Minuchin and associates (1975) defined diabetes as a "psychosomatic illness". Another cause for confusion was described by Fisher and associates (1982): they concluded in their review that stressful stimuli sometimes might produce an increase in glucose levels, and sometimes a decrease. The different direction of glycaemic responses was explained in terms of different amounts of available free insulin in the blood circulation. Barglow and associates (1984) noted that the diversity of findings refers to the absence of a distinction between direct neurohormonal influence of stress and the indirect influence mediated by adherence. Furthermore, they have underlined the unclear definition of stress as a cause of the diversity.

In brief, several researchers have argued that stress and metabolic control relate directly and indirectly. Barglow and associates (1984) have summarized the existing data in the following way:" if stress does affect diabetic control, it exerts its action by altering the "internal milieu" (stress hormones), or the "external milieu", i.e., the patient's compliance".

2.4.4 Regimen adherence and metabolic control

Diabetes -in contrast to other chronic diseases- demands considerable responsibility for self-management and for a healthy physical condition of the patient. Children with IDDM are expected to adhere to a complex regimen involving timed insulin injections, regular blood-glucose monitoring, dietary rules and regular exercise. Adherence[1] to these life rules is a major determinant of optimal metabolic control, but clinical workers generally agree that adherence is often low. Reviewers have speculated that low adherence rates may be easily explained by the complexity of the regimen (Ary et al., 1986; Schafer et al., 1983; LaGreca, 1990). It is assumed that new technologies, e.g., home blood-

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[1] The term "adherence" has been used instead of "compliance", because adherence is less value-laden in its associations (Dunbar et al., 1979) and conveys more the self-regulatory requirements of the diabetes regimen (Brownlee-Duffeck et al., 1987).

glucose monitoring, have contributed to increased adherence problems (Wilson et al., 1986).

Traditionally, education programs which aim at increasing diabetes knowledge have been the favoured approach to improve regimen adherence (see Chapter 3). However, evidence that increased knowledge in children will influence adherence and subsequently metabolic control has been weak and inconsistent (Fisher et al., 1982; McCaul et al., 1987).

Several studies have highlighted the complex role of adherence in diabetes control and psychological well-being. Some results show that adherence is directly influenced by psychological and environmental variables, e.g., age, developmental stage, parental support and coping strategies (Fisher et al. 1982; Johnson, 1980; Glasgow et al., 1982; Hanson et al., 1987a, 1987b). The direct influence of health beliefs (predicting preventive health behaviors) on adherence has been considered as well, but has not been clearly established in children (Brownlee-Duffeck et al., 1987).

Furthermore, regimen-adherence behaviors appear to be mediators between psychological functioning and outcomes of metabolic control (e.g., Newbrough et al., 1985; Schafer et al., 1983; Tattersall et al., 1985; Hanson et al., 1987b; Bobrow et al., 1985). Studies revealed that knowledge, family relations and family conflicts are related to adherence on the one hand and that adherence influences metabolic control directly on the other hand (Newbrough et al., 1985; Schafer et al., 1983; Bobrow et al., 1985; Hauser et al., 1990). Alternatively, Hanson and associates (1987a, 1987b) found some evidence for a direct relation of stress with adolescents' metabolic control and the absence of an indirect relation via adherence. That is, high stress was linked with poor metabolic control, especially for adolescents with low social competence, but indications of high levels of stress were not associated with low adherence. Consistent with these results, Schafer and associates (1986) found only a weak relation between adherence to self-care management on the one hand and metabolic control on the other hand. These authors argued that their low correlation was due to differences in prescribed regimen rules.

In many studies the relations between adherence and other variables has been analyzed in a concurrent way. In a few studies, adherence at follow-up was predicted from variables reported at first measurement. It was assumed that if good predictors were identified, a better understanding of adherence problems would be achieved (McCaul et al., 1987). McCaul and associates (1987) concluded from their results that measures of expectancies and environmental support were related to regimen behaviors at follow-up. In another longitudinal study, Jacobson and associates (1990) found that coping-mechanisms established at diagnosis and initial adjustment to the diabetic state were predictive of the level of patient adherence over a period of four years.

Overall, the results from studies about regimen-adherence behaviors and their psychological correlates show diversity and inconsistency. The interdependency of psychological factors on the one hand and pathophysiologic factors on the other hand may have obscured results. Furthermore, differences in prescribed rules and differences in research designs have been held responsible for the inconsistencies (Kuttner et al., 1990). Some authors have commented upon the measurement of regimen-adherence behaviors. It has been argued that adherence measures are characterized by low reliability due to denial of patients and physician bias (Belmonte et al., 1988; LaGreca, 1990; Glasgow et al., 1986; Irvine et al., 1990).

In conclusion, substantial evidence suggests that psychological variables, metabolic control and regimen-adherence behaviors influence each other in a direct and indirect way. Research findings indicate complex relationships and suffer from methodological shortcomings which have undoubtedly contributed to the diversity of the results obtained. Even so, it is generally agreed that stimulation and motivation to better adherence needs more attention. It has been propagated that subgroups of non-adherence should be identified in order to tailor interventions to the needs of each of such subgroups (LaGreca, 1990).

2.5 Summary and discussion

Clinical views have argued that insulin-dependent diabetes mellitus often elicits psychosocial problems in the affected children and their families. In general, the reviewed studies underline the importance of psychosocial factors before and after disease onset. However, low agreement in research strategies and inconsistencies in results have prevented the identification of a clear pattern of psychological and social factors that affect children with diabetes. Furthermore, several studies have addressed the complex relation between psychological and metabolic factors. One of the problems in this area of research is the unclear direction of the relation, as psychological problems can be defined as cause as well as effect of poor metabolic regulation.

Early psychosocial research was focused on etiological factors in diabetes. In the 1950s, research aimed at the definition of a "diabetic personality", and second, the impact of life stresses on diabetic onset was examined. Both research lines did not clearly establish personality nor life stresses as precipitating factors. In the 1980s, biochemical evidence

showed that auto-immune factors play an important role several years prior to diabetes onset.
However, psychosocial factors may indirectly act upon this type of diabetes pathogenesis and may facilitate actual onset of diabetes symptoms (Dahlquist et al., 1991). Longitudinal and systematical studies, including pre-diabetes, will be needed to clarify the complex relationship between precipitating pathogenetic factors and clinical onset.

After diagnosis, many psychosocial problems result from and affect the complexity of the treatment and management procedures necessary to establish and maintain stable metabolic control.
In the 1960s and 1970s research was initially focused on psychological characteristics which distinguish children with diabetes from controls. The most reliable results show that children with diabetes experience social problems. Data concerning psychological factors per se are conflicting, explicable by methodological shortcomings, such as small sample sizes and the retrospective design of the studies. Along this line, Fisher and associates (1982) have added that research measures employed were often gathered from different settings and, consequently, were not tailored to the specific characteristics of IDDM in minors.

In the 1980s several researchers (e.g., Johnson, 1980) have supported a shift towards research that examines the differences between categories of children having IDDM instead of comparing affected children with healthy controls. A relatively new line in research was into categories of children defined as having diabetes onset at an early age (<5 years). In this subgroup several studies have confirmed that children with such early diabetes run a higher risk of neurocognitive impairment.
Other studies have focused on differences between children in good versus poor metabolic control, examining whether psychological disturbances affect metabolic stability. Again, the results of these studies were diverse and inconsistent. It can only be concluded that the relation between psychosocial variables and metabolic control is complex and presumably mediated by intervening variables as stressful life events and regimen adherence.

Studies about the influence of life stresses on metabolic control have indicated a direct neurohormonal relation and an indirect relation via changes in regimen behaviors. To add to the confusion, it has been found that stress might induce an increase as well as a decrease in blood-glucose levels.
The role of regimen adherence, the other presumed mediator, has been extensively

studied. The results are difficult to interpret due to methodological weaknesses and the complexity of the relation with metabolic control.

In all, most authors have agreed that psychosocial results are disappointing and that more systematical, longitudinal and prospective studies will be needed to clarify to some extent the complex relations between psychosocial factors and diabetes (Johnson, 1980; Newbrough et al., 1985; Ary et al., 1986; Cerreto et al., 1984). Specifically, Fisher and associates (1982) have recommended investigators to tailor psychological perspectives in association with medical treatment to the needs of children with diabetes and their families. The question remains how to treat but preferably to prevent psychological problems by anticipation. Clearly, research should focus on the development of treatment strategies which offer support for both the child and family. The implication and evaluation of comprehensive treatment programs will be helpful in optimizing treatment for IDDM patients.

CHAPTER 3

AIMS AND EFFECTS OF THERAPEUTIC STRATEGIES IN INSULIN-DEPENDENT DIABETES MELLITUS

3.1 Introduction

As a result of the multifaceted character of the disease and the unclear relation between physiological variables and psychosocial correlates (see Chapter 2), several investigators have recommended to shift the focus of research to the development of intervention strategies instead of further concentration on psychosocial problems (e.g. Anderson et al., 1980).

In general, the ultimate goal of all diabetes treatment strategies is defined by the establishment and maintenance of metabolic control. To achieve this, many treatment programs aim -more or less explicitly- at different subgoals such as the improvement of self-care behavior, management skills, disease-related knowledge, adherence behaviors, internalizing health locus of control, psychological well-being and/or quality of life. Moreover, programs include several subgoals at the same time and to some extent differ with respect to methods and setting.

In this chapter data-based evaluations of treatment strategies will be described, generated over the last decade.

First, the important changes in disease treatment strategies will be discussed: the technical innovations in IDDM treatment (paragraph 3.2) and changes in the physician-patient relationship resulting in the assignment of more responsibility to the patient (paragraph 3.3). These changes shaped the premises of IDDM treatment: self-care and self-control became cornerstones in diabetes management strategies (paragraph 3.4). Additionally, diabetes education has been recognized as a necessary tool in diabetes management (paragraph 3.5). Furthermore, the importance of psychosocial interventions incorporated in standard medical care will be outlined (paragraph 3.6). Finally, home-care services are discussed, a relatively new strategy in IDDM treatment (paragraph 3.7). Home-care services incorporate many of the goals of traditional treatment strategies, but effectuate these targets in the home environment of the child and, at the same time, integrate them in the medical-care system. Limited but promising exploratory studies have indicated that there is a need for further systematical research on the medical and psychosocial benefits of this approach. This reflects the principal aim of the study described in this thesis (see chapter 4-7).

3.2 New technologies in IDDM treatment

Since insulin availability, medical diabetes treatment has been excessively modified in many respects. Technical means for the disease treatment have been altered with the introduction of human insulin (Dankmeyer, 1985), insulin infusion pumps (Davies et al., 1988b; Hanas et al., 1990), and facilitated with innovations such as pen injectors (Gall et al., 1989).

Additionally, two developments appear to have exerted beneficial effects with regard to monitoring metabolic regulation, hence admissions to the hospital: the availability of blood glucose and urinary ketone strips, described later (see paragraph 3.4), and the measurement of haemoglobin A1% (HbA1%). HbA1% gives an adequate estimation about average blood glucose over 6-8 weeks before the blood test (Nathan et al., 1984). Normal HbA1-values in healthy children range from approximately 4 to 6%, if measured by high pressure liquid chromatography.

It should be clear that the application of new techniques in diabetes management requires intensive patient education, more attentive self-care and a balanced physician-patient relationship (Jacobson et al., 1984).

3.3 Physician-patient relation

During the last decades the relation of health-care professionals with IDDM patients has been modified. Among physicians the recognition has increased that patients should not be treated as passive recipients of medical care, but should be considered as individuals with their own responsibility for health and control (Eiser, 1985). Especially for the adolescent with IDDM, the physician-patient relation may be quite different from the traditional situation in which the physician provides directions and the patient follows the decisions of the physician (Jacobson et al., 1984). Szasz and associates (1956) have suggested the mutual-participation model as the most effective model for physician-patient relations in managing diabetes. According to this model physician and patient participate equally and share responsibilities for the patient's care. The physician often serves as an expert consultant and co-worker, he encourages the patient to make his own decisions, and stimulates independent and responsible functioning (Jacobson et al., 1984; Johnson et al., 1982). In addition, more control by patients and less control by physicians appears to be consistently related to better control of diabetes (Kaplan et al., 1989). It is clear that young children with IDDM will not be able to share responsibilities with the physician. With young children, the physician will perform a more active role and the child will be more compliant.

Following the mutual-participation model, self-care and self-control became important goals in diabetes management (Köhler et al., 1982). Strict regimen guidelines were loosened and some laxity in treatment and irregularity in adherence behaviors was accepted, particularly in adolescent patients (Greydanus et al., 1979).

3.4 Self-control strategies

Self-control became a corner-stone in diabetes management after the introduction of self-monitoring blood glucose (SMBG). SMBG enables patients to measure blood-glucose levels by themselves accurately without necessarily consulting a physician (Shapiro et al., 1981). Using monitoring procedures correctly, patients attain responsibility for self-interpretation of blood-glucose levels and achieve self-regulation of insulin dosages. Inclusion of SMBG in treatment was favoured, because of assumed beneficial effects on self-control, adherence and/or metabolic control. First, we will report about studies, which examined the effects of SMBG on metabolic control as measured by HbA1.

Self-monitoring blood glucose (SMBG)

In a longitudinal study, Delamater and associates (1990) examined the effects of self-management training on metabolic control during the first 2 years after diabetes onset. 36 Children (3-16 years of age) were randomized to self-management training directed at SMBG, to supportive counselling or to conventional follow-up without SMBG. The results show that self-management participants had lower HbA1-levels than the comparison groups and that self-management training helped to avoid deterioration in metabolic control often seen between 6 and 24 months after diagnosis.

Belmonte and associates (1988) observed SMBG in 219 youngsters during a period of three years. They concluded that patients benefit from SMBG for several reasons: first, SMBG provides security during intercurrent illnesses; second, it establishes or disproves the presence of hypoglycaemia when patients have symptoms suggesting this; third, a decrease in hospital admissions for ketoacidosis and severe hypoglycaemia was established. However, the results also indicated that no improvement in diabetic control had been achieved and that only 50% of the patients were strictly adhering to SMBG. Apparently, teaching how and when to monitor blood glucose is not sufficient to improve glycaemic control. Belmonte and associates suggested that an intensified insulin regimen (2 or more injections a day) should be added to SMBG in order to substantially improve glycaemic control.

SMBG and intensified insulin therapy

A combination of SMBG and intensified insulin therapy was examined by Geffner and associates (1983). This study introduced 63 patients (4-21 years of age) to the combined treatment during a period of 18 months. Afterwards, the investigators reported a significant decrease in HbA1% in their patients with apparently satisfying adherence after the study period.

SMBG and peergroup intervention

Other investigators supported the addition of a peer-group intervention to SMBG in order to prevent deterioration of metabolic control which frequently occurs during (early) adolescence. Anderson and associates (1989) assigned young adolescents to such a peer-group intervention based on problem-solving with SMBG integrated in standard outpatient care, or to outpatient care only, for a period of 18 months. The results showed that participation in the problem-solving groups prevented the expected deterioration in metabolic control.

SMBG and reinforcement procedures

In several studies SMBG was encouraged using reinforcement procedures derived from social learning theory. These approaches had been particularly used for improvement of self-care behaviors and adherence to the regimen (Fisher et al., 1982). Unfortunately, reports on these interventions in children have mainly included single case studies.

For example, Carney and associates (1983) designed a SMBG treatment program for 3 children (10, 11 and 14 years of age) to improve self-care. The program included contingent praise by parents and a point system as reinforcers for the completion of the monitoring procedure. The results showed that blood-glucose monitoring improved for all subjects and was maintained at 4-months follow-up.

Gross and associates (1982) assigned 4 IDDM boys (10-12 years) to self-management training and contracting training. The boys developed a contract to earn reinforcement from their parents for using self-management skills. This treatment procedure resulted in a large increase in adherence to the medical regimen.

Schafer and associates (1982) conducted a comprehensive behavioral approach with three adolescents. The treatment consisted of self-monitoring goalsetting and behavioral contracting procedures. Two of the subjects showed significant improvement on adherence and on metabolic control measures. The third subject did not participate reliably due to family problems.

In conclusion, SMBG appears to have beneficial effects on metabolic control, self-control and adherence behaviors, particularly when SMBG was combined with behavioral strategies.

However, the above-mentioned studies are of limited value due to their small samples; larger and systematical studies will be needed to confirm these preliminary results. Even so, Stark and associates (1987) have argued that reinforcement procedures may not be successful for all subjects. These programs also involve the child's parents, and their cooperation and/or compliance can not always be expected.

3.5 Education strategies

In recent years patient education strategies have become an important part of diabetes treatment. Traditional education programs for children and adults emphasize factual knowledge about the disease and management, and aim at improved metabolic control as a result of increased knowledge (Etzwiler, 1970; Hamburg et al., 1982; Harkavy et al., 1983; Kaplan et al., 1985). Several reviews on educational programs designed for adults have revealed the effects to be mixed and weak due to programmatic and methodological shortcomings (De Weerdt, 1989; Schut, 1990; Rubin et al., 1989). Evaluation of knowledge acquisition during summer camps designed for children with IDDM revealed that knowledge, skills and metabolic control are not necessarily related (Harkavy et al., 1983) or even inversely related (Hamburg et al., 1982). Well-informed individuals may not translate their knowledge into improved self-care behavior (Kaplan et al., 1985). Consequently, a program directed only at knowledge cannot improve glycaemic control nor adherence behaviors (Rubin et al., 1989; De Weerdt, 1989; Schut, 1990; Jager et al., 1989; McCaul et al., 1987).

In contrast to traditional education programs, recent programs derived from social learning theory have produced promising results. These programs emphasize peer modelling, peer communication and aim at improvement of social skills (Kaplan et al., 1985; Rubin et al., 1989). Such programs are originally designed for adolescents who have difficulties with the diabetic regimen because they can not resist the influence of peers (Kaplan et al., 1985).

Education programs ranging from more traditionally oriented strategies to education programs directed at social skills are reviewed next.

Rudolf and associates (1982) provided to 7 adolescents an intensive education and management program, including either multiple insulin doses or a portable infusion pump combined with home glucose monitoring. The education part of the program consisted of intensive instruction concerning diabetes self-management skills. This program resulted in improved metabolic control (HbA1%) in all subjects and a sense of more internal control of life events at 6-months follow-up. The demanding program did not adversely affect scores on depression, self-esteem, social adjustment and diabetic adjustment.

Bloomfield and associates (1990) conducted a study to determine whether participation in an informal diabetes club could improve diabetic control. The results show that metabolic control (HbA1%) was stabilized on short term, but the effect was not sustained after 2 years. The main benefit of the program was an increased sense of support caused by increased social contacts with families of other diabetic children.

Van der Steen and associates (1992) evaluated an education program using videotapes composed by Dutch paediatricians (Insulientje). This program aimed at emotional well-being of the child and improvement of metabolic control. The results showed favourable effects in participating children compared with controls: participants discussed diabetes more openly and accepted more responsibility for management behaviors. Again, no significant effects were found on metabolic control.

McCaul and associates (1987) aimed at better adherence to the diabetic regimen emphasizing self-efficacy and outcome expectations. They concluded that patients adhere better if they expect execution of regimen behavior (self-efficacy expectancy) to be successful and if they expect a strong ratio of positive versus negative outcomes of their behavior (outcome expectancy). The authors argued that vicarious learning and modelling strategies would be an effective way to change efficacy expectancies, and therefore should be incorporated in education programs.

Kaplan and associates (1985) provided a social skills training for 11 adolescents aged 13 to 18 years and taught them to generate solutions to social situations which would cause them to deviate from the required regimen. After completing the training adolescents appeared to have significant lower HbA1 indicating better control compared to a matched control group.

In conclusion, education programs with diverse aims and inconsistent effects have been reported. Again, the programs used diverse measurement outcomes and showed methodological shortcomings such as small samples and the lack of a control group. Some authors have suggested that education programs should be integrated into medical care in order to establish positive and on-going results (Jager et al.,1989; Van der Steen et al., 1992; De Weerdt, 1989). Furthermore, group discussion and peer support have been mentioned as important elements in optimizing the effects of education programs (Tattersall et al., 1985; Jager et al., 1989; De Weerdt, 1989).

3.6 Comprehensive and psychosocial strategies

Increasing research evidence suggests that treatment-approaches that emphasize medical care and formal information transfer only may be less effective than those incorporating psychosocial interventions (Jacobson et al., 1984). Ludvigsson (1989) emphasized that psychosocial care is probably the most important part of the management of diabetes in children and adolescents. More comprehensive education programs have been developed in order to influence metabolic as well as psychological well-being (Hanson et al., 1987b). Group therapy (Tattersall et al, 1985; Marrero et al., 1982), anxiety management training (Rose et al., 1983), multidisciplinary psychosocial programs (Laron et al., 1979), crisis intervention (Galatzer et al., 1982) and family therapy (Orr et al., 1983; Minuchin et al., 1975) have been applied in order to support children with IDDM and their families in a comprehensive fashion. These programs will be reported on in the next section.

Marrero and associates (1982) randomly assigned 10 adolescents to a group therapy intervention which addressed coping strategies for diabetes-related problems. The results after 8 group sessions indicated a reduction in depression and an increase in self-esteem and social support compared to controls.

Tattersall and associates (1985) have supported group therapy led by a trained professional as a way of helping patients to express their feelings effectively. They concluded that group participants showed general improvement in psychological well-being and social functioning and that diabetes control remained unchanged. Furthermore, they noted that group therapy is a very time consuming strategy which might be most profitable for definite groups of children having similar problems such as teenagers, obese patients, etc.

Summer camps especially designed for IDDM children may be as effective as group therapy, because they use group dynamics (Tattersall et al., 1985). Results show that summer-camp participation contributed to an increase in self-esteem (McCraw et al., 1973),-although this study was methodologically criticized- and led to improvement in problem solving and diabetes adjustment (Herskowitz, 1990).

Rose and associates (1983) studied the effects of anxiety management training and muscle relaxation on psychological functioning and metabolic control as measured by urine testing. Five poorly controlled adolescents were assigned to the program. The outcome after a six-month period suggested that metabolic regulation had been improved, but anxiety and tension scores had not been reduced.

Laron and associates (1979) found that the introduction of a psychosocially oriented program decreased the frequency of diabetic ketoacidosis and hospital visits, improved understanding of the disease and its requirements, and improved motivation for adherence. 262 children and their parents were treated during a period of 10 years. Treatment included frequent contacts with a multidisciplinary team of mental-health professionals available on a 24-hour basis, counselling by a psychologist at every outpatient visit, education groups, discussion groups and parents participating as volunteers.

Galatzer and associates (1982) presented a crisis intervention program for 223 patients (7-24 years of age). This program consisted of intensive treatment by a multidisciplinary team of clinical workers, included home visits and contacts with school or work, and provided supportive contacts with families having a long history of diabetes. The results show that patients, who participated in the program directly after diagnosis, were better adjusted to IDDM than controls.

Orr and associates (1983) provided family or group counselling for poorly controlled adolescents. During 12-18 months of group participation no hospital admissions occurred, improved psychosocial functioning was established, but HbA1% remained on the same high level indicating poor metabolic control.

Minuchin and associates (1975) found family psychotherapy effective in reducing emotional instability in a child with diabetes which led to better control. They viewed a child's symptoms as part of the family stress and underlined that symptoms have a role in stabilizing the family.

In conclusion, in some studies the impact of comprehensive psychosocial strategies on psychosocial functioning and metabolic control have been evaluated. Again, the programs are diverse and hardly comparable. Psychosocially oriented treatments should be addressed more frequently in research in order to establish their potential benefits.

3.7 Home care

In earlier days insulin treatment after diagnosis of diabetes was commonly started during hospital admission. Nowadays, the availability of home blood-glucose monitoring and of specially trained nurses who can visit the child at home allows the setting up of insulin treatment on an outpatient basis (Bruining, 1984; Van Ballegooie et al., 1990). The introduction of self-care has already emphasized the important role of the family environment in implementing diabetes treatment (e.g. Anderson et al., 1980; Shapiro, 1983).

As a result, a new trend in health-care delivery for children with IDDM was started recently, extending the influence of multidisciplinary treatment into the home environment. Specifically, home care programs incorporate education and self-care strategies applied in the home environment. It was assumed that metabolic and psychosocial problems could be more easily identified and more successfully addressed by visiting the homes of children with IDDM.

Rettig and associates (1986) provided a diabetes education program for adults administered by "home health nurses", who provided individual instruction at the patient's home. At six-month follow-up increased knowledge about self-care behaviors and better skills compared to controls were reported. However, the program did not show significant effects on hospital admission rate and physician visits.

Nerup and associates (1983) introduced home care for 109 children and adults with newly-diagnosed diabetes, and compared them with control patients not enroled in home care. The home-care program consisted of re-information and instruction provided by a specialized nurse-practitioner. The home-care group received 5 visits during the first year of diabetes. The results showed a decrease in hospital admissions and outpatient visits, an increase in telephone calls for advice and an improvement in HbA1.

In Berlin, Germany, a "Pediatric Home-Care Service" (PHCS) was introduced, including home visits by a pediatric nurse-practitioner. PHCS aimed at better understanding of the disease, improvement of management skills, self-control and self-regulation. Schlier and associates (1983) reported a reduction in hospital admission rate for children with newly-diagnosed diabetes. Weber and associates (1983) described effects of PHCS on adherence rates in 9 adolescents. In only 4 patients adherence to diet and urine testing was achieved. The remaining 5 subjects refused further participation in the program.

In the Netherlands, Bruining and associates (1983, 1984) compared hospital-based care versus home care during a period of three years. In the home-care group of 41 children, a nurse-practitioner provided education and evaluated knowledge and self-care management. Other tasks involved evaluation of adherence to clinical advice, home visits in case of near-disregulation, ensurance of medical and social adjustment at school, and detection of long-term complications. With home care compared to hospital-based care, a thirty-fold decrease in both admission rates as a result of disregulation and acute outpatient visits was brought about. Furthermore, home care appeared to be twice less costly as hospital-based care.

In conclusion, the home-care programs provide education and support extended into the home environment. Until now, the results of the few studies appear promising but have a preliminary outcome as the measurements were global and designs were exploratory. Controlled, prospective and longitudinal evaluation is needed using objective measurements of glucose control and psychological functioning in order to establish the specific benefits of these programs.

3.8 Summary and discussion

A large variety of therapeutical strategies in managing IDDM was available from the literature. Technological improvements and increased responsibility of the patient for diabetes management provided the fundamentals of modern diabetes treatment. Self-care became a central theme in diabetes management encouraged by the introduction of self-monitoring blood glucose. Self-control strategies and education programs were developed in order to improve metabolic control and self-care behaviors. However, evaluation studies showed inconsistent results due to programmatic and methodological shortcomings.

More comprehensive and psychosocially oriented programs were directed at improvement of metabolic and psychosocial functioning of the child with IDDM. The large variety of programs directed at different aims and using different outcome measures made results, however, hardly comparable, requiring further exploration in a systematical fashion.

A relatively new approach involved home care, including extension of comprehensive care into the family environment. This approach may provide a productive direction aiming at optimizing diabetes management. However, studies in this area are still scarce and incomplete. Systematical evaluation of home-care services using objective measures and appropriate control-groups is clearly necessary to establish the effects of such programs on metabolic and psychosocial functioning. Therefore, a prospective evaluation study was started directed at systematical medical and behavioral evaluation of home care. The design and methods of this study will be described in the next chapter.

CHAPTER 4

HOME CARE IN CHILDHOOD DIABETES, DESIGN AND METHODS OF A CONTROLLED EVALUATION STUDY

4.1 Introduction

Inconsistent and weak results about the role of psychosocial factors in IDDM (see Chapter 2) have elicited research into the development of treatment strategies which support and maintain psychosocial well-being and metabolic control of the IDDM child and the family.
However, evaluation of conventional treatment approaches, e.g., education strategies, showed weak and mixed results (see Chapter 3). In recent years more comprehensive home-care strategies were developed, which include education and self-care guidelines. Home care has introduced an extension of treatment to the broader milieu of the family, thereby providing support for the child as well as the family.

In the Netherlands, home care was introduced by Bruining and associates (1983, 1984) to a subset of children with IDDM visiting the outpatient's clinic of Sophia's Children Hospital in Rotterdam. A preliminary evaluation of a home-care program after a period of three years indicated that children had benefitted from the program showing a decrease in hospital-admission rates (see Chapter 3). Due to its preliminary and exploratory character, the study addressed a limited number of outcome measures and did not focus on psychological functioning before and after home care. In order to evaluate the metabolic and psychological effects of home care, a controlled prospective multicentred evaluation study was started. In this thesis the results of this study will be presented and discussed.

In this chapter, the design and methods of the study are described. Paragraph 4.2 comprises the aims and main questions of the study. In paragraph 4.3 the home care and traditional hospital-based care are discussed. Paragraph 4.4 presents the study design and measurement procedures. Paragraph 4.5 deals with the outcome variables, followed by a description of the intervening variables in paragraph 4.6. In paragraph 4.7 descriptive measures of the intervention will be presented and in paragraph 4.8 variables are mentioned which were excluded from further statistical analyses. A summary of the statistical methods which were used in this study are presented in paragraph 4.9. Finally, in paragraph 4.10 the issues of this chapter are summarized.

4.2 Aims of the study

Home care was aimed at the improvement of hospital-based care. Therefore, the main focus of our study was the description of psychosocial functioning of IDDM children and their parents before and after a period of home care, compared to a controlgroup of

IDDM children and their parents receiving traditional hospital-based care. At the same time, the study was directed at the evaluation of medical functioning of IDDM children before and after home-care treatment compared to controls. In addition to psychological and medical evaluation, we were interested in the subjective treatment satisfaction of participants and interviewed subjects about this aspect after participating in the home-care program. In the home-care group, characteristics of and effects in participants with a high number of home visits were examined. Furthermore, characteristics predicting improved or deteriorated functioning after home-care participation were explored. Summarizing, the main questions of the study were:

1. Does a home-care program have favourable effects on psychosocial functioning of IDDM children and their parents compared to children who receive traditional hospital-based care?
2. Does a home-care program have favourable effects on medical functioning of IDDM children compared to controls?
3. Do IDDM children and their parents show treatment satisfaction after participating in the home-care program?
4. Do unfavourable baseline characteristics of IDDM children induce a higher number of home visits and do frequent home visits positively affect outcomes at the end of the study?

4.3 The intervention: home care versus traditional hospital-based care

Traditional hospital-based care

In the Netherlands, hospital-based care is the traditional mode of treatment of IDDM. Paediatricians and dieticians provide integrated care, education and evaluation of self-care on an outpatient basis, including regular outpatient visits to the clinic. Sometimes, a specialized nurse is present during the outpatient visits to the clinic in order to enhance paediatric services. In case of metabolic disregulation IDDM patients are admitted to hospital in order to stabilize metabolic functioning. In our study three hospitals, all situated in the urban western part of the Netherlands, namely Sint Franciscus Gasthuis in Rotterdam, Reinier de Graaf Gasthuis in Delft and Merwede Ziekenhuis in Dordrecht, provided hospital-based care and thus participated as control-hospitals.

Home-care

In the home-care program, home visits were added to hospital-based care. Home care was provided by one well-trained experienced nurse-practitioner, who visited IDDM children and their parents on a regular basis guided by the needs of the participants. The tasks of the nurse-practitioner were described as follows:

1. education of knowledge about IDDM and (re-)instruction of self-care behaviors,
2. enforcement of adjustment of insulin dosages and dietary prescriptions to the individual circumstances of the child,
3. stimulation and motivation of children to improve or maintain adherence to regimen prescriptions,
4. prevention of hospital admission due to metabolic disregulation,
5. signal psychosocial and metabolic problems perceived in the home environment to the medical team,
6. social support for children and parents,
7. guidance and instruction during outpatient clinic visits, during hospital admissions, and advice by telephone,
8. support of social adjustment of IDDM children by means of information supply at schools of participating children.

Furthermore, the availability of outpatient care on a 24-hour basis and special clinics for IDDM children were incorporated in the home-care program. In addition, diabetes-team workers (i.e., paediatricians, dieticians and nurse-practitioner) met monthly to discuss treatment management of IDDM patients, supported by child psychiatrist consultation. Three hospitals situated in Rotterdam, Sint Clara Ziekenhuis, Ikazia Ziekenhuis and Zuider Ziekenhuis, agreed to participate in the home-care program.

4.4 Methods

4.4.1 Study sample

Included in this study were all children with IDDM who visited the outpatients clinics of six participating hospitals in spring 1986 and who were between 5 and 16 years of age at the start of the study. Parents and teachers of selected children were also enroled in the study. All selected children were beyond the remission phase of their diabetes and were treated with short and/or long acting human insulins.

Newly-diagnosed IDDM children were excluded from the study, as well as patients and parents who were not able to understand the Dutch language sufficiently.

4.4.2 Procedure

Pilot-study
Before the start of the investigation a pilot-study was carried out with six participating IDDM children derived from Sophia's Children Hospital to prepare medical and psychological measures and to adapt measurement instruments to the purpose and conditions of the investigation.

Study design
The study was based on a multicentred controlled design. IDDM children of 3 hospitals, denoted hospital 1, 2 and 3, comprised the home-care group, whereas IDDM children from 3 *other* hospitals, denoted hospital 4, 5 and 6, served as controls. Logistical and organizational considerations caused that individual children were not randomized to experimental and control groups. Three hospitals had an appropriate organizational structure to embed home care within their diabetes care strategies, whereas in three other hospital organizations the traditional hospital-based care was more appropriate. In addition to these organizational aspects, ethical concerns would have advised against randomization. If it had been possible to allocate patients randomly to the home-care program, it was to be expected that control patients would become aware of home-care availability; they might experience negative feelings of discrimination and would attempt to share the benefits of home care. To verify whether the control-group participants served as a comparable sample of IDDM children, a comparison was made between the first measurement results of the hospital samples.
After completion of informed consent procedures IDDM children and their parents were evaluated medically and psychologically several times during a period of 27 months. The study design and measurement points are schematically presented in figure 4.1.

medical measurements at (during outpatient visits)	0	3	6	9	12	15	18	21	24	27	months
psychological measurements at (at home)	0			9			18			27	months

home care : children in hospitals 1, 2 and 3.
no home care : children in hospitals 4, 5 and 6.

Figure 4.1: Study design and measurement points

Psychological measurements

The psychological variables were measured four times. At the start of the study -i.e., before the initiation of home care- and at three follow-up measurements; that is (planned at) 9, 18 and 27 months after the start of the study respectively, patients and parents were visited in their home environment by an interviewer/psychologist. A semi-structured interview and standardized questionnaires were offered to children and parents separately. A short questionnaire for the school teacher was left behind at the homes of participating families, and children were instructed to take the questionnaire to school. A reply envelope was included for the teacher.

Home care was started after the first psychological measurement, generally within four weeks. After every psychological measurement the participating families were visited at least once by the nurse-practitioner. The number and frequency of additional home visits were guided by the needs of patients and their families or initiated by the nurse-practitioner.

Due to the time-consuming aspect of psychological evaluation at the homes of participants, three well-trained interviewers were added to the research team, after the first psychological measurement. In table 4.1 the random assignment of patients to interviewers, matched for patients' age, gender and hospital, is presented.

Table 4.1: Random assignment of patients to interviewers A, B, C and D, respectively, at the psychological measurement points

psychological measurement	50% of patients interviewed by	50% of patients interviewed by
1	A	A
2	A	B
3	A	C
4	A	D

At first measurement, all patients were evaluated by interviewer A. A random subset of 50% of patients were also interviewed by interviewer A at the next three psychological measurement points. At second measurement, 50% of the patients were randomly allocated to interviewer B. At third and fourth measurement the same 50% of patients were assigned to interviewer C and D, respectively.

At the start of the psychological follow-up period two interviewers visited at least 10 families in turn and scored the responses of parents or child simultaneously. After this training period the interrater-reliability turned out to be 90% or higher. Subsequently, interviewers performed standardized interviews on their own, according to the assignment schedule.

Medical measurements

The medical evaluations took place during regular outpatient visits and were obtained by a physician. In order to standardize the medical data collection, patients and parents came to the outpatients clinic every three months (see figure 4.1). If the condition of the child required extra medical care, e.g., in case of metabolic disregulation, additional outpatient visits to the clinic took place. In five participating hospitals one physician obtained the medical data. In one control-hospital three physicians participated in the data collection.
At all medical measurement points physicians collected blood samples to measure HbA1% and filled in the data on a medical form. The data on hospital admission rate and the frequency of outpatient visits were documented in each hospital in a standardized fashion; these data were verified and added up at 9, 18 and 27 months after the start of the study. The variables representing the number of hypoglycaemias and quality of injection sites were gathered by the psychologist/interviewer at 9, 18 and 27 months.

4.5 Outcome variables

In the following paragraphs 4.5.1 and 4.5.2 psychosocial and medical outcome variables are described.

4.5.1 Psychosocial outcome variables

The selection of adequate measurement instruments to evaluate the usefulness of a home-care program compared to traditional care appeared to be complicated by the following factors.
Psychological measurement methods for home-care evaluation specifically were not available. Consequently, we had to decide to either use standardized measurement methods from other fields of research or to design new instruments for the purpose of this study. Bearing in mind that disappointing results in psychological research in IDDM children may have been caused by using measurement instruments which were untailored to IDDM (Fisher et al., 1982; see paragraph 2.4), we aimed at the selection and design of appropriate instruments.

In our study sample, a broad age-range of 5-16 years was considered, whereas many measurement methods are designed for a more limited age-range. From a developmental point of view it would be desirable to apply different measures for different ages, since IDDM and its treatment may influence different cohorts in different ways (see paragraph 1.6). However, using different measures for subsequent ages would split our study sample in (too) small subgroups. Therefore, we searched for instruments covering the total age-range of our sample, or for measurement items which could be easily adjusted to different ages.

Considering these limitations a standardized checklist of behavior problems was chosen for children of 4 to 16 years old (see paragraph 4.5.1.1 to 4.5.1.3). Furthermore, evaluation measures were designed which are tailored to the special characteristics of IDDM and which reflect the goals and expected outcomes of home care. As home-care goals primarily address behavioral effects in the child and parents, e.g., self-care behaviors, we primarily chose behavioral measurement items instead of items assessing emotions (see paragraphs 4.5.1.4, 4.5.1.5, 4.5.1.8 to 4.5.1.11). Finally, existing and well-defined questionnaires were used, adjusted to the purpose of the study (paragraph 4.5.1.6 and 4.5.1.7).

4.5.1.1 Behavior problems

To assess behavior problems the Dutch version of the Child Behavior Checklist (CBCL) for ages 4-16 (Achenbach et al., 1983: Verhulst et al., 1985a; Verhulst et al., 1985b) was used. The CBCL is a normed and validated questionnaire designed to collect data on a wide variety of behavior problems. The CBCL contains 118 behavioral items scored on a 0, 1, 2-scale by the parents of a child (see Appendix A.1). The checklist is self-explanatory enabling the parents to fill it out independently within 15-17 minutes. A total score is obtained by the summation of separate scores on all 118 items. The CBCL has standardized norms gathered from a sample of 2076 Dutch children, selected from the general population.

4.5.1.2 Social competence

A second part of the Child Behavior Checklist (see paragraph 4.5.1.1 and Appendix A.1) consists of 20 social competence items designed to measure positive social behaviors of children aged 4-16 years. Parents were asked to indicate the number of sports, hobbies, organizations, jobs, chores and friendships their child is used to participating in, as well as the intensity and the quality of participation in each activity. Furthermore, parents were asked to rate the school performance of their child. The social competence items are scored according to the scoring rules provided by Achenbach and associates (1983) and complete 4 subscales.

The activity scale includes scores for the number of sports and non-sports activities, plus the mean scores for parents' ratings of amount and quality of participation in each activity. The social scale includes scores for the number of organizations, the level of participation in organizations, the number of friends, contacts with friends, how well the child gets along with siblings, parents and other children and how well the child plays alone. The school scale includes parents' ratings of performance in academic subjects, plus reports of special class placements, grade repetition and other academic problems. The total social competence scale includes all the items of the subscales.

4.5.1.3 School absence

In addition to the school-performance items of the Child Behavior Checklist, parents were asked to fill in a question on school absence including the reasons for absence (as a result of IDDM or otherwise). Moreover, the teacher or mentor of the child was asked to report concerning school absence (see Appendix A.2).

4.5.1.4 Self-care

Parents

Parents were asked in a semi-structured interview to estimate their child's level of self-care and self-control with regard to specific diabetes management behaviors. The ability of children to inject insulin themselves and to monitor blood glucose at home was scored on a two-point-scale, indicating either complete mastery of self-injection or self-monitoring or indicating the child's dependence on others. The scored behavior described the child within the past three months (Appendix A.3, items 1 and 2).

In addition, parents were asked if their child was able to execute diet guidelines, extra food intake, insulin injections and blood glucose control at right points of time (Appendix A.3, items 3, 4, 5 and 6). These items were also scored on a two-point-scale and were added up and combined to a total score.

Furthermore, parents were asked to estimate their own level of advised self-care in case of near-disregulation or hypoglycaemia (Appendix A.3, item 7 and 8). The response categories ranged from dependent reactions, i.e., calling upon physician or hospital care, to independent reactions, i.e., being able independently to solve the problem situation.

Children

IDDM children themselves were also asked about their level of self-care concerning insulin injections and their reactions to symptoms of hypoglycaemia, in a semi-structured interview separately from their parents (Appendix A.3, items 9 and 10). Response categories ranged from dependent to independent handling of self-care behaviors.

4.5.1.5 Regimen adherence

In the semi-structured interview parents reported the level of adherence of their child to specific self-care behaviors, such as insulin injections, home blood-glucose monitoring, diet guidelines and extra food intake (see Appendix A.4). Responses were scored on a 3-point scale: always adhering, sometimes adhering, scarcely adhering. These item scores were also added up to a total score.

4.5.1.6 Child adjustment to IDDM

The child was asked to fill in a 23-item-questionnaire designed to measure adjustment to IDDM and scored on a yes, ?, no-scale (Appendix A.5, items 1-23). The items were derived from the Diabetic Adjustment Scale (Sullivan, 1979a) and obtained from research instruments of Beaufort and associates (1985) and Laron and associates (1981). The items refer to physical and psychological adjustment to IDDM, social restrictions, problems in peer relations, family relations and school adjustment, dependency-independency conflicts and problems concerning body image and self-discipline. An oral form of the questionnaire was designed for young children. Again, the total score was used as a psychological outcome measure.

Furthermore, in the semi-structured interview referred to above, parents were asked to estimate the impact of the overall psychological strain of IDDM upon their child and their child's ability to adjust (Appendix A.5, items 24-27). Parents described adjustment behavior patterns of their child in terms of aggressiveness and moodiness, in terms of withdrawal or depression, or described no adversive but well-adjusted behaviors.

4.5.1.7 Parental adjustment to IDDM

The adjustment of parents to IDDM was assessed by a questionnaire comprising 40 items derived from the Parent's Diabetes Opinion Survey (Johnson, 1985). The items concern several areas of adjustment: physical limitations, social contacts and constraints, diet problems, treatment beliefs, emotional adjustment, educational attitude (e.g., overprotection, overindulgence) and future expectations (see Appendix A.6, items 1-40). The scores on this scale were summarized to a total score.

4.5.1.8 Child knowledge about IDDM

An important aim of home care addresses the improvement of knowledge. In cooperation with two paediatricians and two nurse-practitioners, who were trained professionals in the field of home care, a questionnaire was designed to assess knowledge about IDDM and self-care behaviors. Ten open-ended items were selected from a pool of items. These items reflected the endeavour of the nurse-practitioner during home visits. The knowledge questionnaire was presented to the child in an interview. The formulation of the items was adjusted to the intellectual level and age of the child. The responses of the children were categorized and added up to a total knowledge score (see Appendix A.7).

4.5.1.9 Parental knowledge about IDDM

The parents were asked to fill in a multiple-choice questionnaire derived from the same pool of items as the child version of the knowledge questionnaire (see 4.5.1.8) and based on the same issues concerning knowledge about IDDM and self-care behaviors (see Appendix A.8). The item scores were added up to a total score.

4.5.1.10 Parental concerns about the future

In the semi-structured interview parents were asked about their concerns about future functioning of their child. An open-ended item addressed the specific contents of their concerns. The responses to this open-ended question were categorized as follows: concerns about future complications, about future choice of a partner and pregnancy problems; about future profession; about self-discipline and independent management of IDDM; and a category with remaining individual concerns (see Appendix A.9).

4.5.1.11 Treatment satisfaction

During the follow-up measurements the home-care participants, both parents and children, were asked if they had benefitted from the home-care program. Furthermore, they were asked which aspects of the program were mostly valued. As the interviewers were not associated with home care nor hospital-based care, participants felt free to express their feelings about the program provided (see Appendix A.10).

4.5.2 Medical outcome variables

4.5.2.1 Metabolic control

As a parameter for long-term metabolic control we used glycosylated haemoglobin (HbA1%). This gives an established estimate of the metabolic control in the 6-8 weeks period before the blood test (Nathan et al., 1984; Bruining, 1984). In four hospitals, three participating in the home-care program and one control hospital, HbA1% was measured by the column-chromatography method using Pierce-columns. In the remaining two control hospitals column-chromatography was used according to the micro-column-Isolab-system and the Biorad absorption-chromatography, respectively. Consequently, the ranges of reference values indicating "normal" HbA1-percentages were not the same at the start of the study. Because the error in HbA1-values was considered to be random, the initial unstandardized values were used in the statistical analyses.
In addition, it was assumed that the differences in HbA1-values could also be explained by scale-dependent shifts. Therefore, it was decided to establish new reference values for the study sample to correct scale-dependent shifts and to allow comparison of changes of HbA1% between hospital samples in the long term. After the data collection of the study had been completed, blood samples were gathered from non-IDDM children in each hospital (the number of children ranged from 4 to 14 per hospital). These samples were sent to the other hospitals and were analyzed by means of the procedures of every participating hospital. The HbA1-percentages of each hospital sample were transformed by means of linear regression to the values of hospital 1 (see Appendix B). Disadvantages of this transformation procedure were the possible inducement of extra-bias within HbA1% measurements and the arbitrary choice of reference hospital 1.

4.5.2.2 Insulin dosage

The total daily dosage of insulin was expressed per kg body weight of each child and recorded by the physician at every outpatient visit (see Appendix A.11). Physicians adjust dosages of insulin in accordance with the level of metabolic control, physical maturation and other prevailing individual conditions of each child.

4.5.2.3 Ratio weight/height

In essence, the weight/height ratio represents body seize, i.e., an obese child will have a high ratio, a lean child a low one.

The Dutch growth-curve database was used in order to standardize the percentile of the ratio weight/height for all children of our IDDM sample, allowing for variation of the ratio with age and puberty. The procedures used for calculating the weight/height percentiles of the general population were adapted to the evaluation goals of our study; by that means we were able to compute changes in percentile values of IDDM children between subsequent outpatient visits.

The weight/height ratio of a particular IDDM child was related to the median level of the normal Dutch population, the 50th percentile or P50. If the ratio equalled the P50 exactly, it was scored as 100%. If the ratio corresponded to a lower percentile, e.g., P40, this indicated a lower weight/height ratio, which was scored as 80% representing a relatively lightweighted child. Similarly, a higher percentile than P50, e.g., P60, was scored as 120% and indicated a relatively heavyweighted child.

The ratio weight/height can be used as an objective measure to evaluate medical management of IDDM. For example, from one clinic visit to the next, a decreased weight/height ratio may be associated with a lower insulin-effect and an increased HbA1%. Thus, variability in weight for height over time may serve as another objective measure of instability of IDDM.

4.5.2.4 Frequency of outpatient clinic visits

The frequency of regular or planned outpatient visits as well as acute or non-planned clinic visits, e.g., caused by metabolic disregulation, were recorded retrospectively at 9, 18 and 27 months (see Appendix A.12). Due to the small diversity in responses (see paragraph 5.2.5), response categories of regular visits were dichotomised: 1. one visit per three months or less frequently and 2. more frequently than one visit per three months. The non-planned visits were also retrospectively counted and recorded as 1. no visits and 2. one or more visits.

4.5.2.5 Hospital admission rate

Hospital admission rate was recorded every nine months. Hospital admissions appeared to be relatively exceptional (see paragraph 5.2.5) and, therefore, response categories were defined as: 1. no admissions and 2. one or more admissions (see Appendix A.13).

4.5.2.6 Hypoglycaemias

The number of hypoglycaemias was retrospectively documented at 9, 18 and 27 months.

In the semi-structured interview parents estimated the number of "hypos" characterized by (a combination of) symptoms such as paleness, headache, dizziness and ultimately faintness. The responses of parents were classified as 0-5 hypos and 6 or more hypos (see Appendix A.14).

4.5.2.7 Quality of injection sites

The quality of injection sites is a subjective measure. Lumps at injection sites are generally associated with reduced resorption of insulin which is felt to affect metabolic control in a negative way. In order to improve metabolic control, the nurse-practitioner visiting the "home-care children" stressed the importance of variation of injection sites to avoid the generation of lumps. The quality of the injection sites was assessed every nine months in the semi-structured interview with the child, classifying responses as 1. bad or moderate quality of the injection site and 2. acceptable quality (see Appendix A.15).

4.6 Intervening variables

In the statistical analyses, intervening variables were incorporated which will be described in the next paragraphs.

4.6.1 Life events

Important life events in the year prior to the study and during the years thereafter were assessed with an open-ended question in the interview with the parents. The maximum number of life events mentioned was two. The responses were categorized and the number of events (0, 1, or 2) was recorded (see Appendix A.16).

4.6.2 Extra-education

In the semi-structured interview the parents were retrospectively asked if they had participated in extra-curricular programs, information courses, self-care training programs, in addition to those received in the home-care or traditional care setting. (see Appendix A.17).

4.6.3 Membership of DVN

Membership of the Dutch diabetes patient organization (DVN) was assessed in the semi-structured interview with the parents, every nine months (see Appendix A.18).

4.6.4 Interviewer

As we have explained in paragraph 4.4.2, four interviewers participated in the psychological part of the study. In our analyses "interviewer" was added as an intervening variable (see Appendix A.19).

4.6.5 Socio-demographic data

Gender, age and school of the IDDM children were documented. Socio-economic status of the parents was assessed by using the classification of Westerlaak and associates (1975) (see Appendix A.20).

4.6.6 IDDM-related initial data

The age at diabetes onset and the duration of the disease were measured at the first measurement. The general health status of the child (in good health or suffering from physical illnesses in addition to IDDM), the frequency of insulin injections per day (one or two injections) and the hospital executing IDDM treatment (total 6 hospitals) were documented as disease-related variables (see Appendix A.21).

4.7 Descriptive measures of home care

During the treatment period the number of home visits and contacts by telephone were recorded in three periods: 0-9 months, 9-18 months, and 18-27 months. Furthermore, we examined who initiated most home visits in each period, the nurse-practitioner or physician on the one hand, the parents, child or family on the other hand (Appendix A.22).

4.8 Exclusion of variables

After completing the data collection the data were thoroughly checked to reduce collection or processing errors. Each measurement item and response category was reviewed. A few items had to be excluded from further statistical analyzes due to low response frequency, insufficient variability in responses or response bias. These items are summarized in Appendix C.

4.9 Statistics

Due to the non-randomized design of the study, effects of home care versus traditional hospital-based care had to be analyzed on a hospital-sample basis. First, the comparability of the six hospital samples at baseline was examined using Kruskal-Wallis non-parametric tests for quantitative data and chi-square tests for categorical data (see chapter 5). All differences between hospital samples with $p<.10$ are presented, whereas results with $p<.05$ are considered as significant outcomes.

The long-term effects of home care versus traditional care on quantitative psychological and medical variables were analyzed with analyses of covariance (see chapter 6). Dichotomous outcome variables were evaluated using a logistic model for regression analyses with random effects. In all analyses, relevant intervening variables (socio-demographic and IDDM-related variables) were incorporated as covariates.

The relation between the number of home visits and patient characteristics were examined with Mann-Whitney U-tests for dichotomous data, Kruskal-Wallis tests for ordinal data and Spearman rank-order correlation analyses for quantitative data (see chapter 7).

4.10 Summary

In this chapter the aims and design of this longitudinal, multicentred and controlled study are described.

The study was primarily designed to evaluate the usefulness of a home-care program for IDDM children and their parents compared to traditional hospital-based care. Psychological measures were assessed by interviewers/psychologists in the home environment of all participants, before initiation of the home-care program and at 3 follow-up measurements, i.e., (planned at) 9, 18, and 27 months thereafter. Medical outcomes were measured by paediatricians during regular outpatient visits, mostly 3-monthly. All outcome measures and relevant intervening variables were described in this chapter. Finally, the statistics used in the study were summarized.

CHAPTER 5

PSYCHOLOGICAL AND MEDICAL CHARACTERISTICS OF THE STUDY SAMPLE AT THE START OF THE STUDY

5.1 Introduction

Before the start of home care the IDDM children, their parents and teachers participated in a baseline psychological and medical measurement in order to obtain characteristics of the study sample at entry of the treatment intervention. In this chapter the results of the baseline measurement are described.

As described in chapter 4, the design of the study did not include randomization of children within hospitals. Three hospitals and their patients agreed to participate in the home-care program, whereas patients of three other hospitals were willing to serve as controls. Consequently, we were particularly interested in the comparability of the samples of children in the different hospitals. In paragraph 5.2 the baseline characteristics are described for the total study sample and for each hospital sample separately. In addition, differences between hospitals are reported. Furthermore, the outcomes of the IDDM sample at baseline were compared to those of a Dutch general population sample with respect to behavior problems and social competence (paragraph 5.3).

Earlier research showed unclear and inconsistent results about the relation between metabolic control and psychological variables (see Chapter 2). The exploration of this relation between variables in the present study is described in paragraph 5.4. Finally, in paragraph 5.5 the baseline results are summarized and discussed.

5.2 Baseline characteristics of the study sample

5.2.1 Study sample

In the spring of 1986 the study sample initially consisted of 110 IDDM children and their parents, meeting the inclusion criteria of the study. Of this eligible group 4 parents refused participation in the study, one family could not be reached and one family moved to another province of the Netherlands. The remaining 104 IDDM children and their parents agreed to participate in the first measurement.

All participants were treated on an outpatient basis in one of six participating hospitals. The distribution of patients between hospitals is presented in table 5.1.

All 104 IDDM children and their parents participated in the first psychological and in the first medical measurement. During the course of the follow-up period 5 children withdrew from participation in both the psychological measurements and medical measurements; 6 other children dropped out from the psychological measurements only and 3 children did not undergo medical measurements, leaving 90 children who participated in all measurements.

Table 5.1: Number of IDDM patients of each hospital at baseline measurement

Hospitals with home care Number of patients		Hospitals with traditional care Number of patients	
Hospital 1:	18	Hospital 4:	8
Hospital 2:	16	Hospital 5:	19
Hospital 3:	17	Hospital 6:	26
Total:	51		53

Reasons for ending participation were: refusal of participation (1 home-care participant[1] and 4 controls), removal to another town (2 home-care participants), shift to another hospital for IDDM treatment (1 home-care participant and 1 control) or admission to a special IDDM-care centre (2 home-care participants).

At the end of the study, 93 participants were assessed by psychological measures, 45 in the home-care group and 48 controls, respectively. 96 children participated in the medical measurements at the end of the study, 46 IDDM children in the home-care group and 50 controls, respectively.

The three psychological follow-up measurements were executed on average at 9 months, 19 months and 31 months after the first measurement, respectively. The 9 medical follow-up measurements were carried out on average at each 3 months after the previous measurement.

5.2.2 Socio-demographic characteristics

The socio-demographic characteristics of the IDDM sample at the start of the study are outlined in table 5.2.

At entry into the study 50 IDDM boys and 54 IDDM girls were measured. The mean age of the children was 11 years and 9 months and ranged from 5 years and 8 months to 15 years and 6 months.

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[1] Children and parents of hospital 1, 2 and 3 are sometimes denoted "home-care participants" at baseline measurement, although the home-care program started *after* baseline measurement. Participants of hospital 4, 5 and 6 are sometimes denoted "controls".

Table 5.2: Socio-demographic characteristics at baseline measurement (N=104)

Socio-demographic variables	hospitals H1 N=18	 H2 N=16	 H3 N=17	 H4 N=8	 H5 N=19	 H6 N=26	 total N=104
Male	7	11	10	5	7	10	50
Socio-economic status							
low	9	6	5	4	4	6	34
middle	3	4	5	1	7	9	29
high	6	6	7	3	8	11	41
Age in years, M	11.9	11.3	11.8	11.8	12.6	11.8	11.9
School							
kindergarten	1	0	0	0	0	1	2
elementary school	7	8	9	5	7	14	50
secondary school	8	6	7	3	11	9	44
special class	2	2	1	0	1	2	8

Note. H1, H2 and H3: home-care hospitals; H4, H5, and H6: control hospitals. Kruskal-Wallis non-parametric tests and Chi-square tests showed no significant statistical differences between hospital samples.

The two youngest children attended kindergarten, 50 children attended elementary school and 44 went to secondary school. 8 Children attended a special class.

Socio-economic status was scored on a six-step scale of occupation (Westerlaak et al., 1975). Some occupational levels were grouped together, because of the relatively small number of subjects. The first and second occupational level (e.g., unskilled employees and skilled manual employees) were combined, indicating "low" socio-economic status. The third and fourth occupational level (e.g., minor professionals and owners of small businesses) were combined to a "middle" socio-economic status. Finally, the fifth and sixth level (e.g., supervisory professionals and owners of large businesses) comprised "high" socio-economic status. 34 Parents of IDDM children were characterized by a low socio-economic status, 29 had a middle socio-economic status and 41 were classified as having a high socio-economic status. As mentioned in table 5.2 the socio-demographic characteristics did not reveal any significant differences between hospital samples.

5.2.3 IDDM-related initial characteristics

The IDDM-related characteristics of the study sample at baseline measurement are presented in table 5.3.

Table 5.3: IDDM-related characteristics at baseline measurement (N=104)

IDDM-related	hospitals						
variables	H1 N=18	H2 N=16	H3 N=17	H4 N=8	H5 N=19	H6 N=26	total N=104
Age at IDDM onset in years, M	7.0	7.8	6.0	7.6	7.4	7.9	7.3
Duration IDDM in years, M	4.8	3.4	5.8	4.3	5.3	3.8	4.6
Frequency insulin injections							
one per day	1	2	0	2	2	0	7
two or more	17	14	17	6	17	25	96
pump	0	0	0	0	0	1	1
Admission to IDDM care centres	2	0	4	1	1	2	10
Other disease	0	1	0	1	1	1	4

Note. H1, H2 and H3: home-care hospitals; H4, H5, H6: control hospitals. Kruskal-Wallis non-parametric tests and Chi-square tests showed no significant statistical differences between hospital samples.

The average age at diabetes onset was 7 years and 3 months and ranged from 9 months of age to 13 years and 10 months. The average duration of the disease at entry into the study was 4 years and 6 months; the duration ranged from 6 months to 10 years. Three children aged 7, 8 and 10 years, had diabetes for a period of 6-12 months.

A meaningful result, although statistically insignificant, can be the early age of IDDM onset in the sample of hospital 3 and their relatively long duration of the disease, compared to the other hospital samples. As we explained earlier in paragraph 2.3, early IDDM onset might have implications for cognitive and psychological functioning of the child. Seven children injected insulin once a day, 96 children applied two or more

injections per day. One child used a subcutaneous infusion pump at the entry of the study. Ten children had been admitted to a special care centre for IDDM children prior to the study.
Four participating children were characterized by a physical handicap in addition to IDDM. Two children were diagnosed for having epilepsy, one child received treatment for cystic fybrosis and one child for cardiac dysfunctioning. On face value, these children did not show any divergent characteristics on the first measurement resulting from their additional physical handicap, compared to other IDDM children. After reviewing their first measurement results, they were accepted as participants in the follow-up measurements of the study.

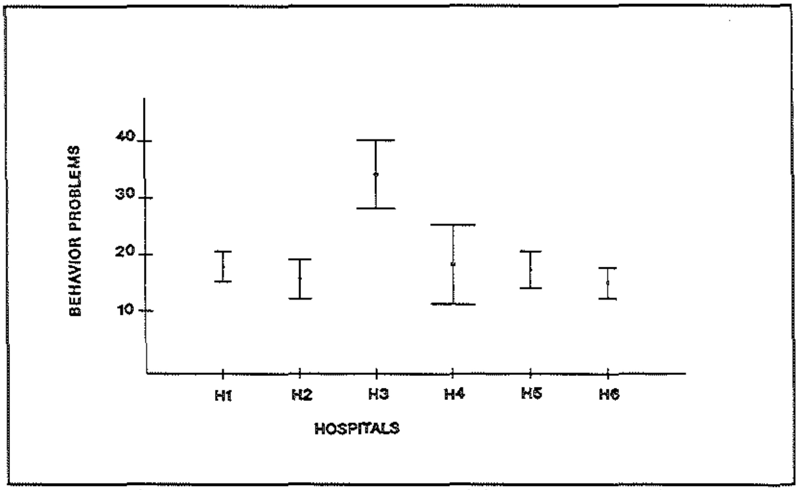
5.2.4 Quantitative psychological and medical outcomes at baseline measurement

Baseline scores concerning quantitative psychological and medical outcome variables are represented in figures 5.1 to 5.14 for each hospital sample. Details about the distribution of scores for each psychological and medical variable are described in Appendix D.

In general, the figures show differences between hospital samples at the start of the study, often indicating less favourable scores in the home-care group compared to controls. Particularly, the baseline scores of hospital 3 appear to be unfavourable in comparison with the other hospitals with respect to behavior problems, regimen adherence and child knowledge. The differences between treatment groups were statistically examined; the results of these analyses are presented in table 5.4. In accordance with the presented figures 5.1 to 5.14, table 5.4 shows a number of significant differences between hospitals at the start of the study.

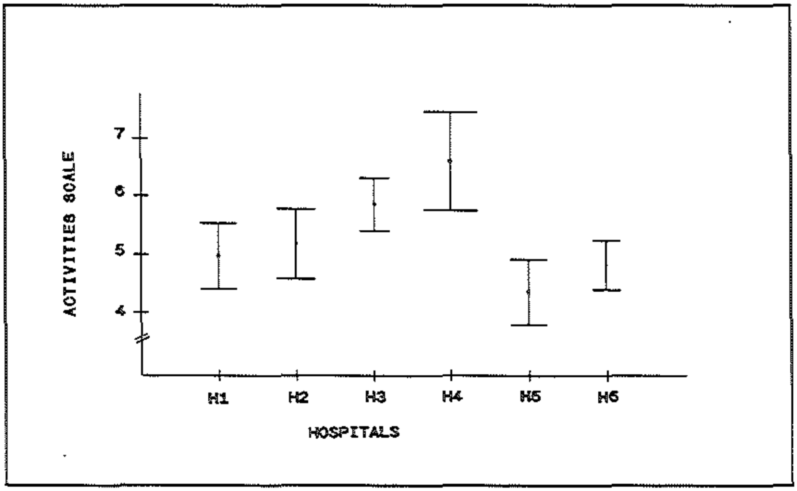
The differences found at baseline are assumed to complicate the comparison of treatment effects of home care versus traditional care during the course of the study. Therefore, long-term effects of treatment are considered for each hospital sample separately instead of grouping hospital 1, 2 and 3 as one experimental group and hospital 4, 5 and 6 as one control group.

Figure 5.1 Behavior problems: unadjusted mean scores for each hospital sample at baseline measurement (± standard error)



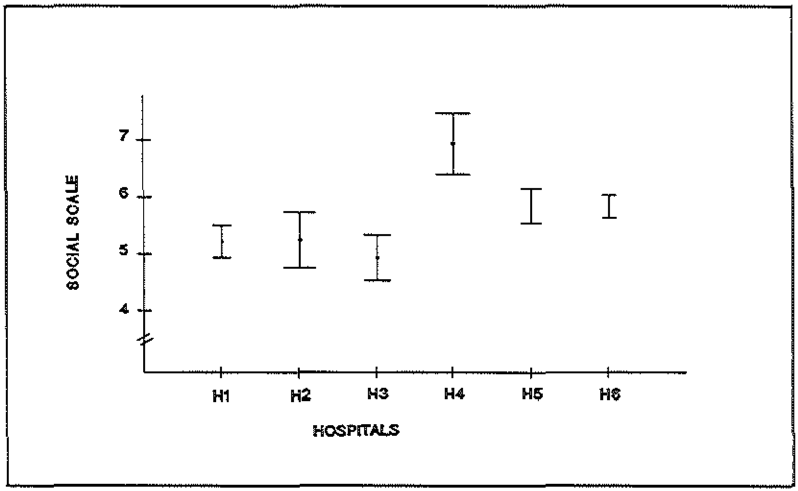
Note. High scores represent a high level of behavior problems.

Figure 5.2 Activities scale: unadjusted mean scores for each hospital sample at baseline measurement (± standard error)



Note. High scores represent favourable activities scores.

Figure 5.3 Social scale: unadjusted mean scores for each hospital sample at baseline measurement (± standard error)



Note. High scores represent favourable social scores.

Figure 5.4 School scale: unadjusted mean scores for each hospital sample at baseline measurement (± standard error)

Note. High scores represent favourable school scores.

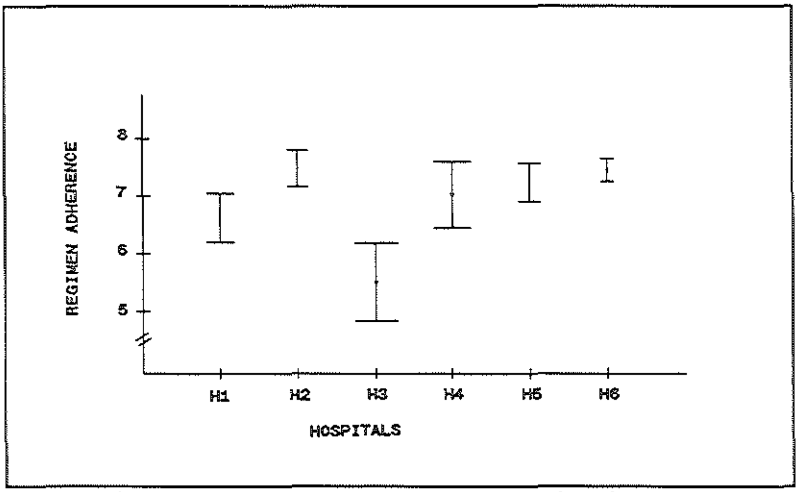
Figure 5.5 Social competence scale: unadjusted mean scores for each hospital sample at baseline measurement (± standard error)

Note. High scores represent favourable social competence scores.

Figure 5.6 Self-care: unadjusted mean scores for each hospital sample at baseline measurement (± standard error)

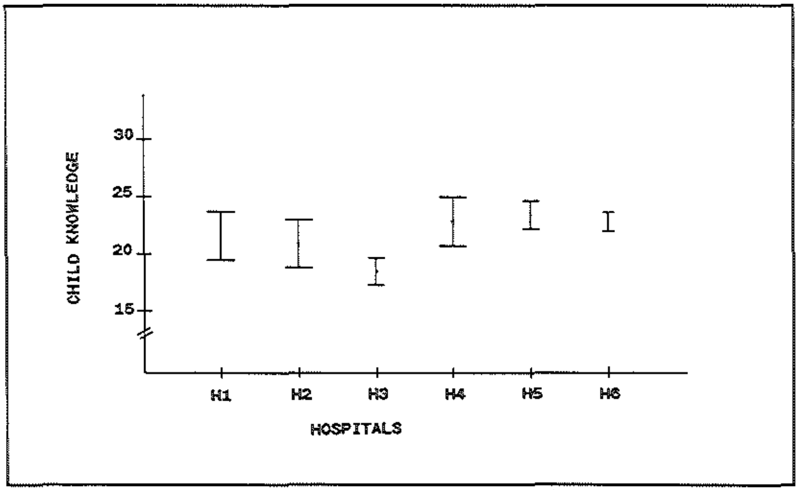
Note. High scores represent a high level of self-care.

Figure 5.7 Regimen adherence: unadjusted mean scores for each hospital sample at baseline measurement (± standard error)



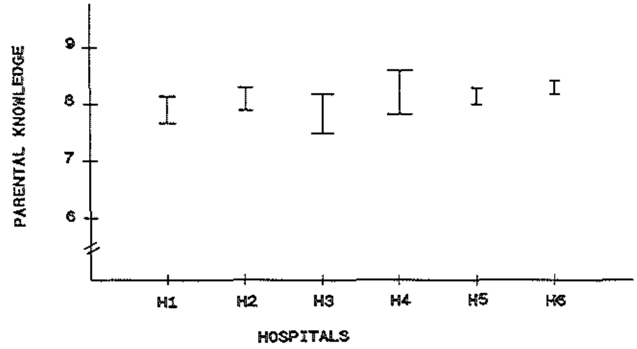
Note. High scores represent a high level of regimen adherence.

Figure 5.8 Child knowledge: unadjusted mean scores for each hospital sample at baseline measurement (± standard error)



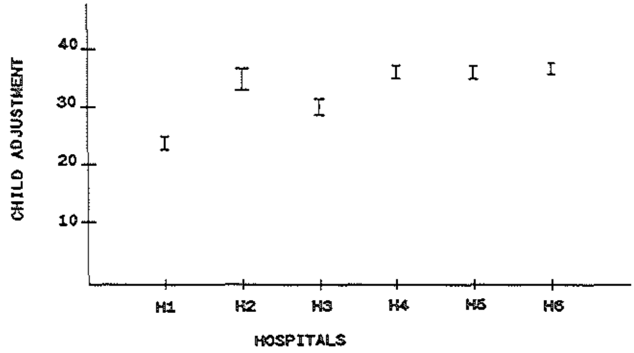
Note. High scores represent a high level of child knowledge.

Figure 5.9 Parental knowledge: unadjusted mean scores for each hospital sample at baseline measurement (± standard error)



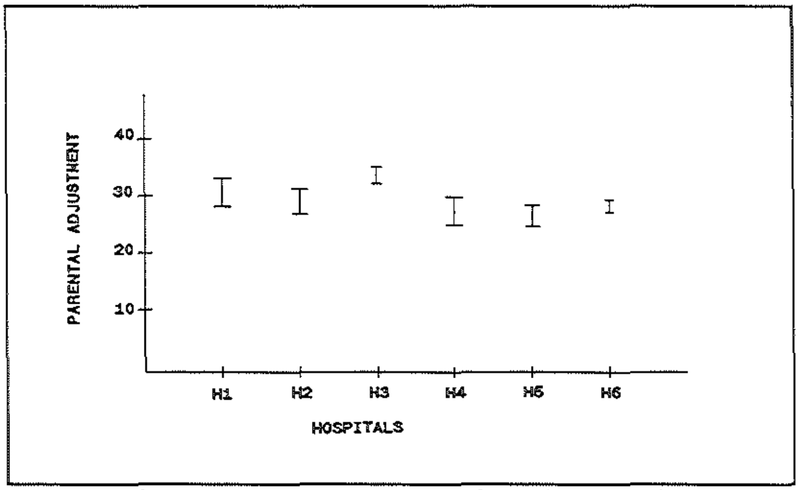
Note. High scores represent a high level of parental knowledge.

Figure 5.10 Child adjustment: unadjusted mean scores for each hospital sample at baseline measurement (± standard error)



Note. High scores represent a high level of child adjustment.

Figure 5.11 Parental adjustment: unadjusted mean scores for each hospital sample at baseline measurement (± standard error)

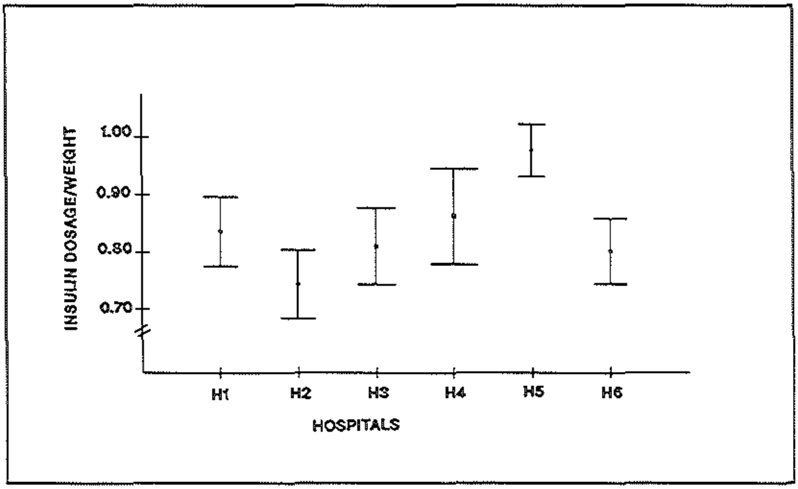


Note. High scores represent a low level of parental adjustment.

Figure 5.12 HbA1%: unadjusted mean scores for each hospital sample at baseline measurement (± standard error)

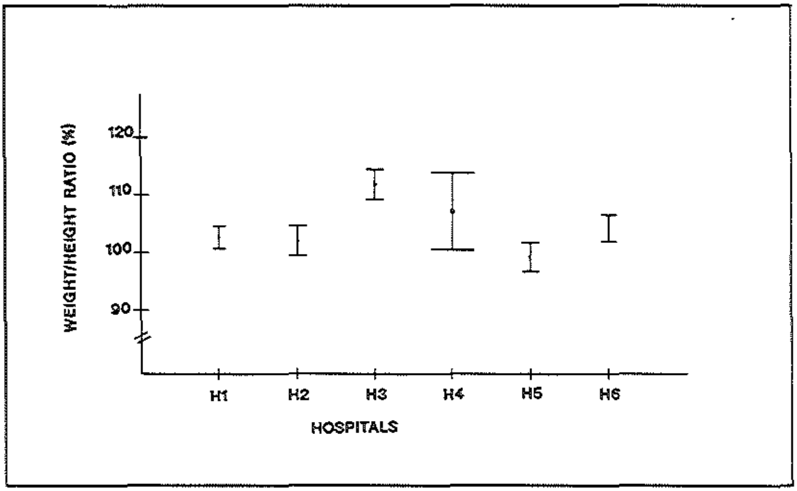
Note. High scores represent high HbA1%.

Figure 5.13 Insulin dosage/weight: unadjusted mean scores for each hospital sample at baseline measurement (± standard error)



Note. High scores represent high insulin dosages.

Figure 5.14 Ratio weight/height: unadjusted mean scores for each hospital sample at baseline measurement (± standard error)



Note. A ratio of 100% represents a favourable outcome.

Table 5.4: Quantitative psychological and medical outcome scores: differences between hospital samples at baseline ($p<.10$, $N=104$)

	H1 H2 H3 p^1	H4 H5 H6 p^2	H1-H6 p^3
Behavior problems	.0124		.0315
Activities scale			
Social scale		.0957	.0504
School scale			
Social competence scale			
Self-care			
Regimen adherence	.0618		.0516
Child knowledge			
Parental knowledge			
Child adjustment			.0477
Parental adjustment			.0669
HbA1%			.0000
Insulin dosage			
Weight/height ratio			.0389

Note. All comparisons were tested with Kruskal-Wallis non-parametric tests.
p^1: differences between home-care samples (H1-H3)
p^2: differences between control-hospital samples (H4-H6)
p^3: differences between six hospital samples

The results at baseline with respect to quantitative psychological and medical outcomes are described in more detail in the next section. The distribution of outcome variables is presented in Appendix D.

Quantitative baseline scores

The baseline behavior problem score showed significantly unfavourable scores in children of hospital 3 (see figure 5.1, table 5.4 and Appendix D). The social scale revealed significant lower scores in all three home-care hospitals compared to controls.

In addition, parental reports about the level of adherence to specific management behaviors, such as insulin injections, home blood-glucose monitoring, diet guidelines and extra food intake indicated low adherence rates in hospitals 1 and 3.

The adjustment of the child to IDDM was measured with a special questionnaire for the child. High scores indicate better adjustment. Again, the baseline results showed that home care-children of hospitals 1 and 3 were less adjusted to IDDM.

Parental adjustment was measured by a 40-item questionnaire. High scores indicate low adjustment which is discordant with the scores of the child adjustment scale. In agreement with the child scores, parents of home-care children indicated a lower level of adjustment compared to control parents. Spearman correlation analysis showed a significant correlation, rho= -.36 (p=.000), between parental and child adjustment scale. The correlation is negative, as a result of opposite coding of the parental and child adjustment scores.

Child knowledge was measured by a specially designed questionnaire. A higher score on the child knowledge scale implies better knowledge. Children received a mark for each answer dependent on the exactness of the answer. The results indicated a lower level of knowledge about IDDM in home-care children. Parental knowledge was measured by a 9-item questionnaire. Parents received one point for each correct response. The results showed that the average parent reported 8 correct responses and one wrong response. Spearman correlation analysis revealed a significant correlation, rho=.25 (p=.006), between parental and child knowledge.

By contrast, the self-care scale including items about diet guidelines, extra food intake, insulin injections and blood glucose control at right points of time, showed a slightly higher level of self-care in the home-care children of hospitals 1 and 3 compared to other participants in the study.

As described earlier, metabolic control was measured by means of HbA1%. HbA1% scores were higher in the samples of hospital 3 and 6. The transformed HbA1% (see paragraph 4.5.2.1) showed also significant differences. In accordance with high HbA1%, the same set of participants received lower dosages of insulin and showed a higher ratio weight/height. In particular, the children of hospital 3 showed high weight for height values compared to children of other samples.

5.2.5 Dichotomous psychological and medical outcomes at baseline measurement

After describing quantitative variables at baseline, the dichotomous outcome variables, including psychological, medical and intervening variables, are presented here. Again, several dichotomous variables revealed significant differences between hospitals (see table 5.5).

Table 5.5: Dichotomous variables at baseline measurement ($p<.10$)

Dichotomous variables		hospitals							p
		H1	H2	H3	H4	H5	H6	total	
Psychological outcome variables									
School absence,	parental report	11	8	8	2	6	10	45	.0477
	teacher report	7	5	12	2	11	12	49	.0726
Self-care									
Self-injection,	parental report	7	6	10	5	13	9	50	
	child report	8	7	12	5	16	11	59	.0581
Self-monitoring blood glucose		8	5	6	4	7	14	44	
Hypoglycaemias,	parental report	1	3	2	5	9	6	26	.0148
Hypo symptoms,	parental report	4	1	4	3	3	4	19	
	child report	6	4	4	0	3	1	18	.0529
Child adjustment,	parental report								
aggression		5	4	7	3	7	8	34	
withdrawal		4	5	4	1	7	7	28	
depression		3	1	2	1	1	4	12	
adjustment		6	6	4	3	4	7	30	
Future concerns, yes		16	12	12	7	16	19	82	
about	IDDM complications	4	8	5	3	8	4	32	
	partner choice	6	2	2	0	0	6	16	.0764
	profession	3	2	0	2	5	5	17	
	self-discipline	1	0	3	1	3	3	11	
	remaining concerns	2	0	2	1	0	1	6	
Medical outcome variables									
Regular outpatient visits									.0001
high frequency		8	2	4	3	2	19	38	
low frequency		10	14	12	5	17	7	65	
Non-planned outpatient visits									
one or more		6	5	6	4	9	10	40	
Hospital admission, one or more		11	6	7	1	13	6	44	.0109
Hypoglycaemias, five or more		4	2	6	3	6	6	27	
Injection site, acceptable		10	9	10	4	10	13	56	
Intervening variables									
Life events, 1		13	12	15	6	15	19	80	
2		5	4	2	2	4	7	24	
Extra-education		7	4	10	3	15	18	57	.0133
DVN-membership		14	14	16	6	19	26	95	.0289

Note. H1, H2, and H3: home-care hospitals; H4, H5 and H6: control hospitals. All comparisons were tested with Chi-square tests.

The results presented in table 5.5 are illustrated in the next sections.

School absence

At baseline psychological measurement 45 parents reported frequent school absence of their children. Twelve parents mentioned IDDM as the main cause of school absence (6 home care, 6 controls). More home-care parents mentioned school absence compared to controls.

Teachers reported frequent school absence in 49 children. Their reports did not significantly differ from parental reports (Chi-square, p=0.225). Teachers noted that 24 children (11 home care, 13 controls) absented from school as a result of IDDM.

Self-care

Self-care was measured by a number of items in a semi-structured interview with the parents and, separately, with the child. Table 5.5 presents the number of children with an adequate level of self-care.

Almost half of the parents (50) reported that their children were themselves able to inject insulin, dependent on the age of the child. More than half of the children (59) reported self-injection. The higher number of children that reported self-injection is possibly biased by the childrens feelings of shame for non-self-injection. The agreement rate between parental and child report of self-injection was 84%.

26 Parents reported adequate self-care when near-disregulation or hypoglycaemias occurred; most of these parents were controls. Adequate handling in case of mild hypoglycaemic symptoms was reported by 19 parents and 18 children (70% agreement).

Child adjustment to IDDM

In addition to the standardized questionnaire filled in by children, parents were interviewed about their child's adjustment.

About one third of the parents (34) reported agressive reactions and moodiness in their child as a result of having IDDM. 28 parents reported withdrawal and 12 mentioned depressive reactions. The remaining 30 parents reported well-adjusted behaviors.

Parental reports about their child's adjustment behavior showed similar results in the home-care group and controls.

Parental concerns about the future

In the semi-structured interview parents were asked about their future concerns about their child. 82 parents expressed concerns about the future. Most frequent concerns (32 parents) involved the long-term chronic complications as a result of IDDM.

Medical outcome variables

38 children visited the outpatient clinic once per three months or more frequently; 65 children showed a lower frequency of regular visits ranging from 4 to 6 months. The results in table 5.5 show that IDDM children of hospital 6 visited the outpatient clinic more frequently than children of other hospitals.

Almost half of the children (44) had been admitted to the hospital once or more in the period of five years prior to the study (median: one admission; range: 0-5 admissions). A higher number of children of the hospitals 1 and 5 were admitted.

One third of the children (27) retrospectively reported more than five hypos in the three months prior to the study. More than half of the children (56) described their injection sites as acceptable.

Intervening variables

The intervening variables comprised the number of life events, participation in education programs prior to the study and the membership of patient organization DVN.

The results show that all parents reported one or more life events. 80 Of the parents described one life event during the year prior to the study; 24 parents described two life events. Reported life events included severe illnesses or death of a family member reported by 23 parents (13 home care, 10 controls); 23 parents (9 home care, 14 controls) described removal of the family to another home as a major event. 25 Parents (15 home care, 10 controls) stressed the impact of daily life events on the child's functioning. According to the parents these "minor" events (e.g., the child having influenza or falling off bike) were valued as major events for an IDDM child.

During the year prior to the study significantly more families of hospitals 5 and 6 received extra-education, compared to families in the home-care group. Finally, the results indicate that 95 of the parents are members of the patient organization DVN.

5.3 Behavior problems and social competence in the IDDM sample compared to the general population

The baseline characteristics of the IDDM sample were further explored by comparing behavior problems and social competence scores derived from the Child Behavior Checklist to those of a Dutch general population sample of children (Verhulst et al., 1985a).

Total behavior scores were calculated for each child within its appropriate age-sex group (6-11 and 12-16 years) and were corrected for socio-economic differences in accordance with the scoring rules of Achenbach and associates (1983). From the general population sample, a matched set of 936 children was selected by using the matching variables: gender, age (6-11 and 12-16 years) and socio-economic status (low, middle and high status). The scores of the selected set of 936 children, i.e., the maximum number of children that matched the IDDM sample, were compared to the scores of the IDDM sample. The total scores on behavior problems for the four age-sex groups are summarized in table 5.6.

Table 5.6: Total behavior problems scores for IDDM children and the general population sample

Behavior problems	IDDM sample			General population sample		
Sex-age group	Mean (Sd)	Range	N	Mean (Sd)	Range	N
boys 6-11	18.1 (16.4)	2-62	22	25.5 (19.7)	1-109	198
boys 12-16	20.2 (12.3)	0-41	28	18.4 (15.3)	0-93	252
girls 6-11	19.6 (18.4)	2-78	26	20.0 (14.6)	0-85	243
girls 12-16	17.2 (18.8)	0-86	27	16.0 (14.4)	0-92	243
total sample	18.8 (16.4)	0-86	103	19.7 (16.4)	0-109	936

Note. One IDDM girl of 5 years and 8 months of age was added to the 6-11 years group. Differences between IDDM children and the general population sample were analyzed by means of Student's t-tests and Mann-Whitney U-tests.

Table 5.6 shows that teenaged IDDM children and control children reported almost similar behavior problem scores. At most, IDDM boys aged 6-11 scored lower with respect to behavior problems than young boys from the general population sample, but this difference did not reach statistical significance ($p > .05$).

The social competence scores were calculated in accordance with the scoring program for the social competence scales (Achenbach et al., 1983; Verhulst et al., 1985a). The results of the activities scale, social scale, school scale, and the total social competence scale of the IDDM sample and the general population sample are presented in table 5.7.

Table 5.7: Social competence scale scores for IDDM children and the general population sample

Social competence	IDDM sample (N=104)			General population sample (N=936)			
	Mean	(Sd)	range	Mean	(Sd)	range	p
activities scale	4.16	(1.73)	0 -7.5	4.26	(1.57)	0- 7.8	
social scale	5.54	(1.49)	1.5-8.5	6.21	(1.79)	1-11.5	.0004
school scale	4.77	(1.16)	1 -6	4.87	(0.99)	1- 6	
social competence	14.54	(3.22)	3.5-21	15.37	(3.05)	5-24.3	.0204

Note. Differences between IDDM children and the general population sample were analyzed by means of Student's t-tests and Mann-Whitney U-tests.

The social scale scores and the total social competence scores showed significantly lower scores in the IDDM sample, indicating lower social functioning, compared to the general sample of children.

5.4 Relation of metabolic control to baseline characteristics

As explained in chapter 2, the relation of metabolic control with psychological functioning is unclear and inconsistent. In the present study, it was decided to explore this relation by means of correlation coefficients (table 5.8). Consistent with earlier findings, the results indicate low correlations of HbA1% with psychological variables in all cases ($r_s < .21$). Correlation of HbA1% with duration of IDDM was moderate, namely .51.

To find an explanation for the low correlation coefficients, the time intervals between the baseline psychological and medical measurements were examined. The average time interval appeared to be 59 days, which might explain the low correlation coefficients. When scores with a time interval less than 10 days were selected, correlation coefficients increased, although, due to a smaller number of children, statistical significance did not. As expected, these results support simultaneous measurement of psychological and medical variables. Therefore, in research aiming at the relation between metabolic control and psychological functioning the time interval between measurements should be considered carefully.

Table 5.8: Correlations of HbA1% with baseline characteristics

	Time interval between psychological and medical baseline measurement			
Variables	59 days (N=104)		< 10 days (N=34)	
	r_s	p	r_s	p
Behavior problems	.1760	.048		
Activities scale			.5493	.032
Social scale				
School scale				
Social competence scale				
Self-care scale	-.2946	.006	-.6393	.013
Regimen adherence	-.1963	.066	-.6093	.018
Parental knowledge				
Child knowledge				
Parental adjustment	.2062	.040	.4595	.066
Child adjustment				
Duration IDDM	.5125	.000	.7182	.006

Note. Average time interval between psychological and medical baseline measurement: 59 days (range 1-188 days), N=104. Selected data with a time interval less than 10 days, N=34. r_s*= Spearman rank-order correlation coefficient.*

5.5 Summary and discussion

104 IDDM children and their parents participated in a baseline psychological and medical measurement before the start of the home-care program. In this chapter the baseline characteristics of the study sample were described.

Due to the non-randomized character of the study, baseline differences between the six hospital samples were thoroughly investigated. No significant differences were found with respect to socio-demographic and IDDM-related characteristics. However, a number of significant differences between hospital samples were established in psychological functioning, which generally indicated less favourable psychological baseline scores in children and parents of the home-care sample, compared to controls. Furthermore, hospital samples differed significantly with regard to medical variables, showing relatively high HbA1% in the samples of hospitals 3 and 6, and a high weight/height ratio in hospital 3.

Explanations for differences between hospital samples are only suggestive. Socio-demographic and IDDM-related variables could not be held reponsible for these differences. In this context, other researchers have stressed the increase in paediatric practice of behaviorally and emotionally disturbed children, contributing to changes and diversity in paediatric treatment (Oberklaid, 1991; Dugdale et al., 1977; Burnett et al., 1978; Dworkin et al., 1979). To investigate possible differences among paediatric practice provided by paediatricians in the six hospitals, an independent interviewer was employed. The results of the interviews with the paediatricians (a summary of the interviews can be found in Appendix E) showed several differences in treatment attitude and practice: e.g., some paediatricians appeared to underline the importance of strict metabolic control, whereas others stimulated a more lenient regimen. Furthermore, some tried to identify behavior problems or family disturbances in their IDDM sample and attempted to solve these problems, whereas others referred problematic patients to other specialists. In agreement with other authors' views (e.g., Kaplan et al, 1989; Linn et al., 1982: Dugdale et al., 1977) it is suggested that these differences in treatment attitude and paediatric practice might be reflected in the psychological and medical characteristics of each hospital sample.

Earlier research showed that the relation between metabolic control and psychological measures is inconsistent and divergent.
Correlation of metabolic control and other baseline measures in the present study supported earlier findings and appeared to be low. However, correlation coefficients improved when a subset of scores was selected with a time interval of 10 days or less between psychological and medical measurement. As expected, in research aiming at the relation between metabolic control and psychological factors the simultaneous measurement of medical and psychological variables is needed to explore their relation.

Finally, the baseline outcomes of the total IDDM group were compared to a sex-age-matched sample of the Dutch general population with respect to behavior problems and social competence. The total behavior problem scores revealed almost similar results in the IDDM sample compared to the general population sample. However, social activities scores and total social competence scale scores showed significantly lower scores in IDDM children. These outcomes correspond with earlier reseach findings (e.g., Ahnsjo et al., 1981; Allen et al., 1984; Orr et al., 1983; see chapter 2.4), indicating social problems in relation with peers or significant others.

CHAPTER 6

LONGITUDINAL EFFECTS OF HOME-CARE COMPARED TO TRADITIONAL HOSPITAL-BASED CARE

6.1 Introduction

The principal question of this study concerns the evaluation of long-term effects of the home-care program compared to traditional hospital-based care. To evaluate treatment effects several methods of analyses were performed, described in this chapter. Each paragraph outlines the method of analysis and presents the results coming from the analyses.

In all analyses, effects of treatment were distinguished for each hospital sample separately. This strategy was necessary as a result of significant differences between hospital samples at baseline measurement (see Chapter 5). Socio-demographic and IDDM-related covariates were included in the analyses to correct baseline differences of the study samples, due to non-randomization of patients. Additionally, other relevant intervening variables were included possibly influencing treatment effects during the course of the study (31 months).

First, in paragraph 6.2, different findings are described on the operation of the home-care program during the study. Second, the impact of using four interviewers on psychosocial outcome variables is examined to exclude the influence of doing so on outcomes (paragraph 6.3).

Third, in paragraph 6.4, the long-term results on quantitative outcome variables are presented. Analyses of covariance were used for quantitative variables, whereas dichotomous outcome variables were analyzed with a logistic model for regression analyses with random effects. Fourth, in paragraph 6.5, the results of inquiring into treatment satisfaction among home-care participants is reported. Finally, in paragraph 6.6 the findings will be summarized and discussed.

6.2 Operation of the home-care program

Characteristics of execution of the home-care program during the study are described here, the data being collected by the nurse-practitioner during three follow-up periods.

The first follow-up period covers a period of 9 months after the actual initiation of the study, that is between the baseline psychological measurement and the first follow-up. The second period represents the actual period of 10 months between first and second psychological follow-up. The third period corresponds to the interval of 12 months between the second and third psychological follow-up.

6.2.1 Home visits

During each follow-up period the nurse-practitioner planned one home visit to check for unnoticed metabolic disregulation of the child and the general functioning of the family. These visits were designated as check-up visits. Additional home visits aimed for re-instruction, education and social support, were called upon a few times because of acute disregulation. In table 6.1 the number of home visits for the three follow-up periods is given, including planned, requested or nurse-initiated visits.

Table 6.1: Distribution of number of home visits per family in three follow-up periods

	Home visits per family (total home-care group)			
Period	Mean	(Sd)	range	Number of families
0- <9 months	6.75	(7.95)	1-44	51
9- <19 months	2.87	(3.36)	0-16	47
19- <31 months	2.33	(2.64)	0-12	46

	Home visits per family (per hospital)		
Period	Mean H1	Mean H2	Mean H3
0- <9 months	4.22	8.81	7.47
9- <19 months	3.41	2.38	2.79
19- <31 months	1.82	2.63	2.62

Note. H1 (=hospital 1) with 18, 17 and 17 families in three follow-up periods, respectively, H2 (=hospital 2) with 16 families in all three periods and H3 (=hospital 3) with 17, 14 and 13 families, respectively.

Table 6.1 shows that IDDM children and their parents were most frequently visited during the first nine months of the study, which applied especially for participants of hospital 2 and 3. In the subsequent follow-up periods the average number of home visits lowered. The number of home visits did not show significant differences between hospital samples (Kruskal-Wallis test, $p > .05$).

In the first period, the nurse-practitioner visited 51 families at least once. One particular family was visited 44 times due to a need for intensive re-instruction and support. In the second period the highest number of visits to a single family was 16; 8 families were not visited by the nurse-practitioner. In the final period of the study the highest number of visits was 12 per family, whereas no visits were reported in 4 families.

Further analyses were into the number of home visits requested by parents, the child or family, compared to the number of visits initiated by the nurse-practitioner or paediatrician. Table 6.2 presents the distribution of home visits requested by home-care participants or health-care professionals in each period of the study.

Table 6.2: Number of family requests for home visits, or visits initiated by the nurse-practitioner, paediatrician, medical team, in three follow-up periods (total home-care group)

Period	0- <9 months		9- <19 months		19- <31 months	
Number of home visits per family	Family requests	Medical requests	Family requests	Medical requests	Family requests	Medical requests
1	1	14	1	7	1	5
2-4	2	7	8	9	6	17
> 4	16	8	11	5	6	3

In all three periods of the study, families with relatively many home visits, i.e., more than 4 visits per period, were the ones requesting most frequently therefor. By contrast, families with only one visit per period were more often visited at the initiative of the nurse-practitioner. These differences reached significance in all three periods (Kruskal-Wallis test; $p=.001$ in the first period, $p=.006$ in the second period and $p=.018$ in the third period).

Home visits were initiated for a variety of reasons; sometimes a particular home visit was brought about by more than one reason. In table 6.3 the most important reason for home visits during a particular follow-up period, as reported by the nurse-practitioner, is presented. The need of re-instruction of insulin injections, of education about IDDM mangement and check-up visits were most often documented as causes for home visits.

In conclusion, the results presented in this paragraph indicate that the number of home visits was the highest during the first follow-up period. Families with a high number of visits were most often visited at their own request. The main reasons for home visits were re-instruction of insulin injection, education and check-up visits.

Table 6.3: Percentage of families indicating prominent reasons for home visits during three follow-up periods

Reasons	0- <9 months % of families	9- <19 months % of families	19- <31 months % of families
Routine visit	32	14	39
Re-instruction of injections	30	21	22
Education about IDDM management	17	12	15
Adaptation of management regimen	7	7	6
Social support	6	13	4
Re-instruction of SMBG	4	1	2
Acute metabolic disregulation	3	2	4
Education at school	2	1	1
Reason unknown	0	12	0
No visits	0	17	7

Note. SMBG= self-monitoring of blood glucose

6.2.2 Telephone calls

Parents, children and other caretakers, e.g., school teachers of IDDM children, were enabled to consult the nurse-practitioner by telephone. The number of telephone calls are presented in table 6.4.

Whereas the number of home visits per family decreased during the course of the study, the number of telephone calls increased (see table 6.4). In the first follow-up period 31 individuals called the nurse-practitioner once or more; 20 families or associated caretakers did not make any calls to the nurse-practitioner. In the second and third period, 24 and 27 individuals, respectively, made one or more phone calls, leaving almost half of the home-care group who did not apply for the telephone service. In the third follow-up period more home-care participants of hospital sample 3 consulted the nurse-practitioner by phone compared to the other hospital samples (Kruskal-Wallis test, p=.0812).
In general, most telephone calls (about 50%) were made because of acute metabolic disregulation and for advice for handling the disregulation. During the first period many parents expressed by telephone their need of social support (35%). In the second and third period the need of social support diminished (15% and 2% respectively).

Table 6.4: Distribution of number of telephone calls per family in three follow-up periods

	Telephone calls per family (total home-care group)			
Period	Mean	(Sd)	range	Number of families
0- <9 months	1.85	(3.43)	0-17	51
9- <19 months	1.96	(3.78)	0-21	47
19- <31 months	2.96	(5.38)	0-25	46

	Telephone calls per family (per hospital)		
Period	Mean H1	Mean H2	Mean H3
0- <9 months	0.94	2.06	2.65
9- <19 months	1.59	2.19	2.14
19- <31 months	2.53	1.75	5.00

Note. H1 (=hospital 1) with 18, 17 and 17 families in three follow-up periods, respectively, H2 (=hospital 2) with 16 families in all three periods and H3 (=hospital 3) with 17, 14 and 13 families, respectively.

The nurse-practitioner was most often called by the parents of the child: 83% of the calls were made by parents in the first period; 99% and 97% in the second and third period, respectively. During the first period about 11% of the telephone calls were made by teachers or school nurses of the child.

In all, most telephone calls (per family) were made during the third measurement period, possibly associated with a lowered number of home visits. In most cases parents needed advice with respect to acute metabolic disregulation or, particularly during the first measurement period, asked for social support.

6.3 Interviewer agreement

Outlined in paragraph 4.4.2, four interviewers were employed in the psychosocial interviews. Half the total study sample was interviewed by interviewer A at all psychosocial measurement points. During the second measurement, the other half of the study sample was examined by interviewer B; interviewer C and D interviewed the same half of participants during the third and fourth measurement, respectively.

The interviewers B, C and D were thoroughly trained and reached at least a 90% interrater-reliability with interviewer A before the execution of the interviews on their own. After completion of the data collection of all psychosocial interviews the results of the four interviewers were compared. The results of each interview item measured at the second measurement were subtracted from those measured at baseline. The difference scores in subset A, i.e., the subset of participants who were all interviewed by interviewer A, were compared to the difference scores of subset B, i.e., the participants who were interviewed by A during baseline and by B during the second measurement, respectively. The same strategy was used for the comparison of results of interviewer C with A and D with A, respectively. The difference scores of the two obtained subsets were analyzed by using Chi-square tests or Mann-Whitney U-tests. Of 140 items, 6 items were found with significant differences between difference scores of two defined subgroups ($p<.05$). These 6 items were excluded from further analyses due to their extremely interviewer-dependent character. To correct (insignificant) interviewer bias in the remaining items the interviewer remained an intervening variable in the repeated measurements analyses.

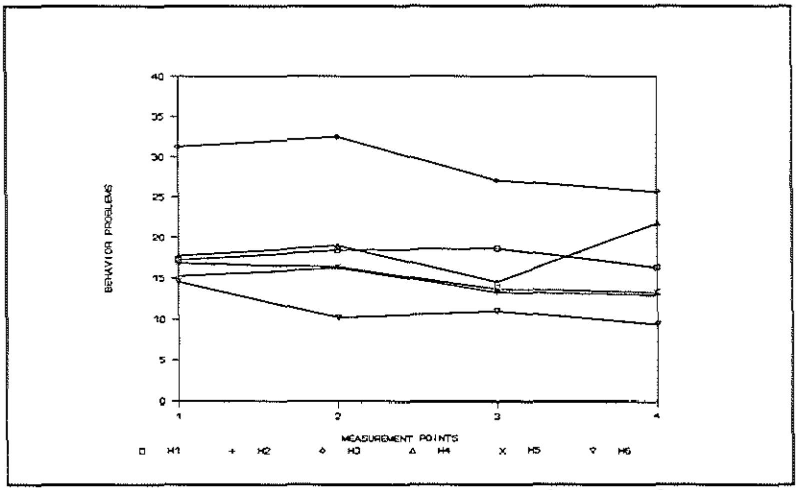
6.4 Statistics and longitudinal results

6.4.1 Results at 4 psychological and at 10 medical measurement points

The results of quantitative psychological and medical variables at each measurement point are presented in figures 6.1 to 6.14, for each hospital sample. The distribution of frequencies of each psychosocial and medical variable at each measurement point are summarized in Appendix D.

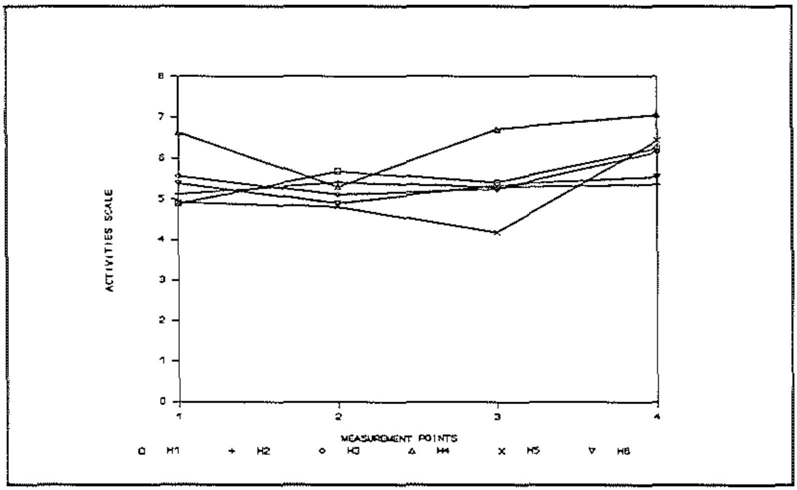
Figures 6.1 to 6.14 show that some variables, i.e., child knowledge and child adjustment, increase in terms of mean scores at subsequent measurements. Statistical analysis of the overall changes in the total study group revealed a significant improvement in functioning during the study with respect to behavior problems (Friedman test, $X^2(3)=18.90$, $p=.0003$), child knowledge (Friedman test, $X^2(3)=55.41$, $p=.0000$), child adjustment (Friedman test, $X^2(3)=16.28$, $p=.0010$) and parental adjustment (Friedman test, $X^2(3)=35.04$, $p=.0000$). In addition, figures representing medical variables, indicate fluctuations in functioning during the course of the study.

Figure 6.1 Behavior problems: unadjusted means for each hospital sample at 4 measurement points



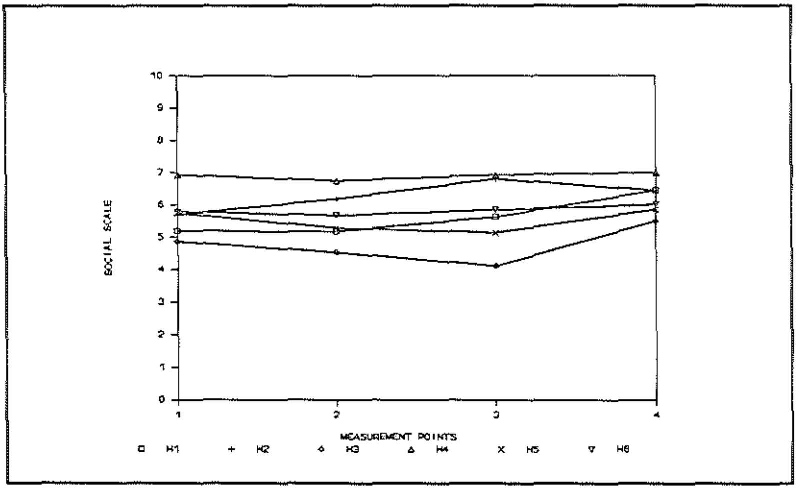
Note. High scores represent a high level of behavior problems.

Figure 6.2 Activities scale: unadjusted means for each hospital sample at 4 measurement points



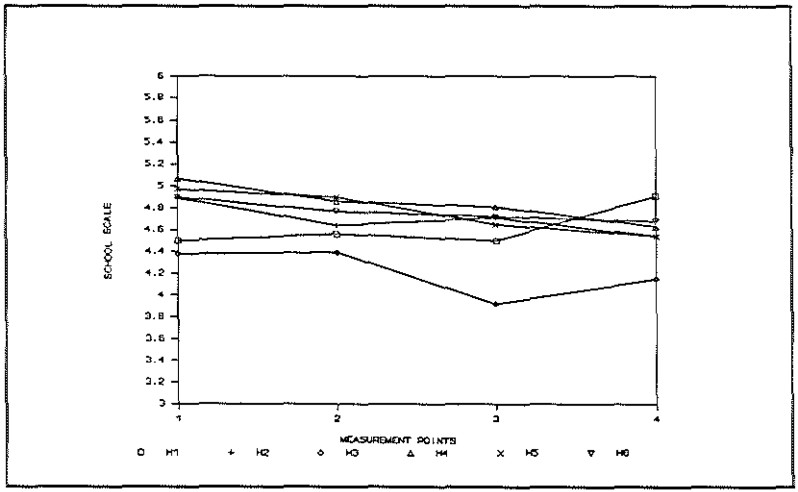
Note. High scores represent favourable activities scores.

Figure 6.3 Social scale: unadjusted means for each hospital sample at 4 measurement points



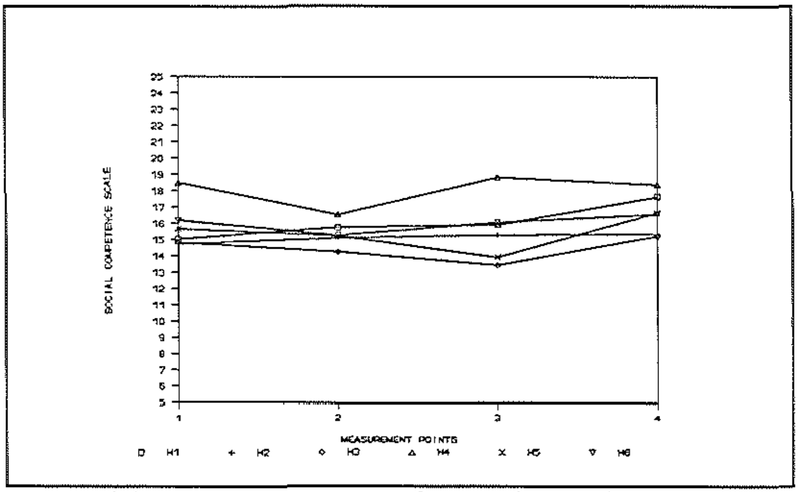
Note. High scores represent favourable social scores.

Figure 6.4 School scale: unadjusted means for each hospital sample at 4 measurement points



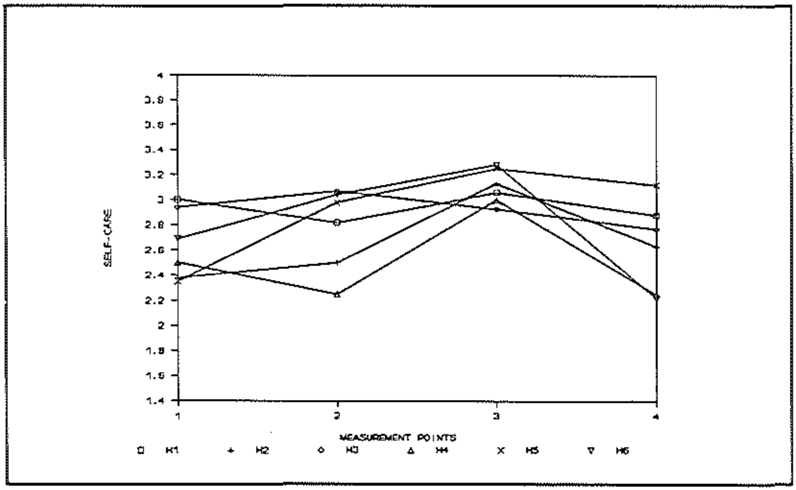
Note. High scores represent favourable school scores.

Figure 6.5 Social competence scale: unadjusted means for each hospital sample at measurement points



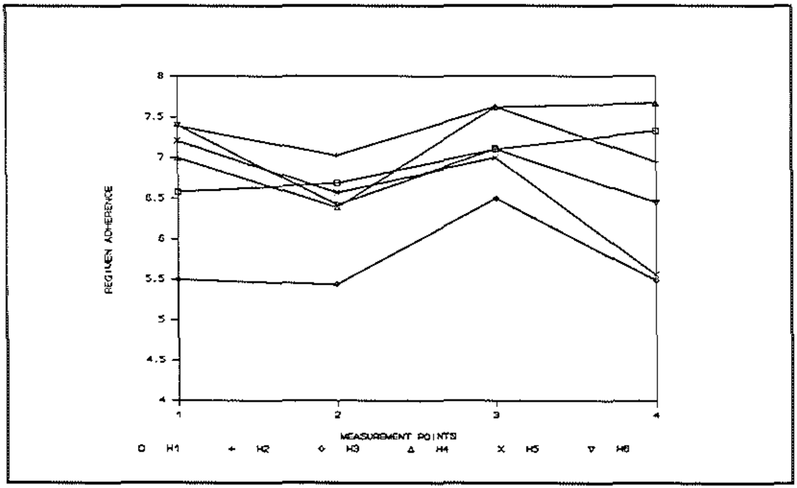
Note. High scores represent favourable social competence scores.

Figure 6.6 Self-care: unadjusted means for each hospital sample at 4 measurement points



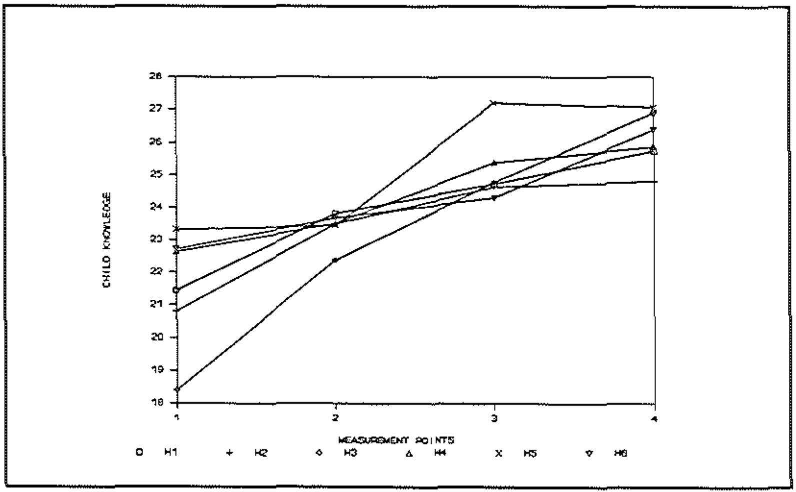
Note. High scores represent a high level of self-care.

Figure 6.7 Regimen adherence: unadjusted means for each hospital sample at 4 measurement points



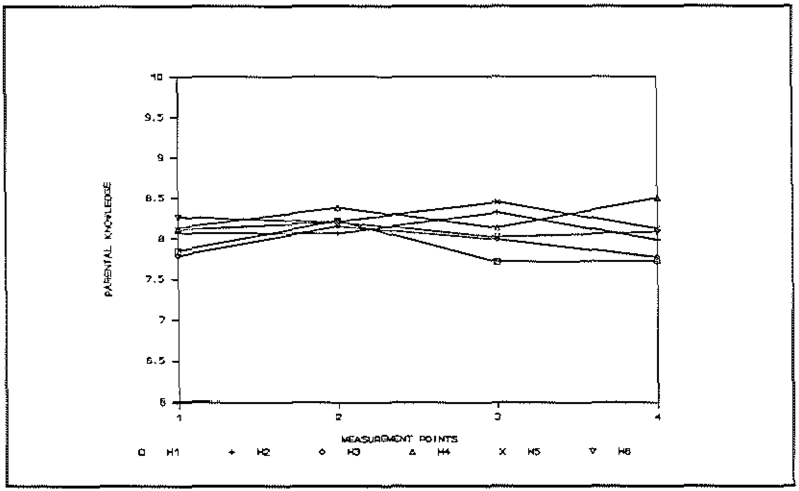
Note. High scores represent a high level of regimen adherence.

Figure 6.8 Child knowledge: unadjusted means for each hospital sample at 4 measurement points



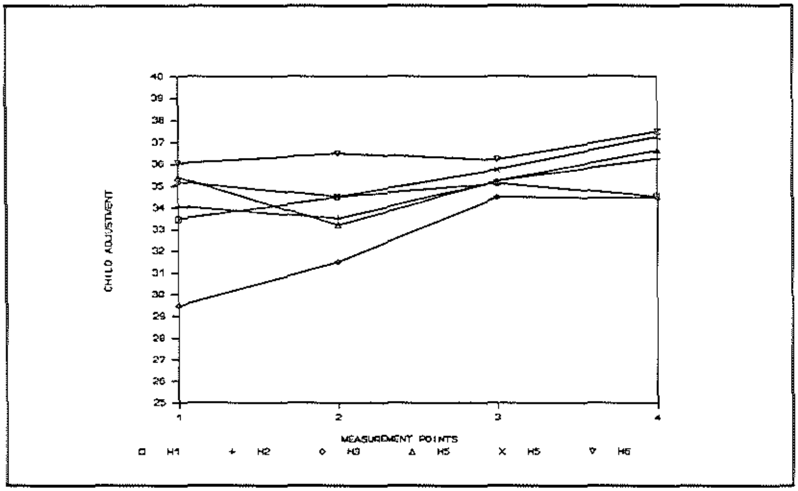
Note. High scores represent a high level of child knowledge.

Figure 6.9 Parental knowledge: unadjusted means for each hospital sample at 4 measurement points



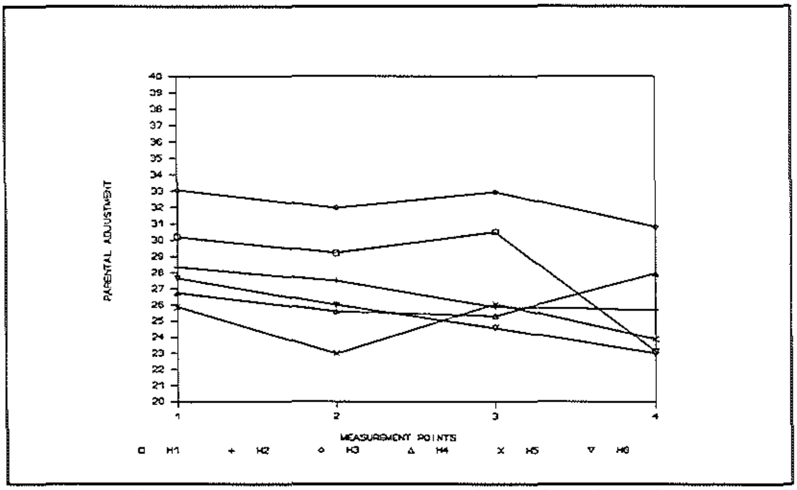
Note. High scores represent a high level of parental knowledge.

Figure 6.10 Child adjustment: unadjusted means for each hospital sample at 4 measurement points



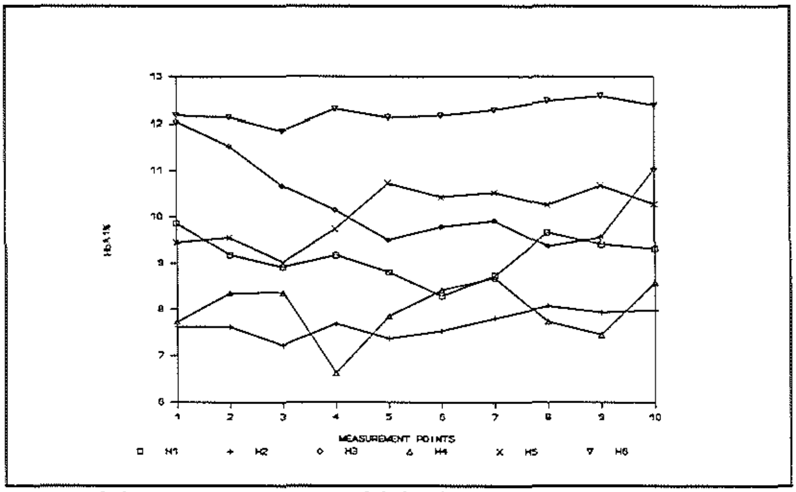
Note. High scores represent a high level of child adjustment.

Figure 6.11 Parental adjustment: unadjusted means for each hospital sample at 4 measurement points



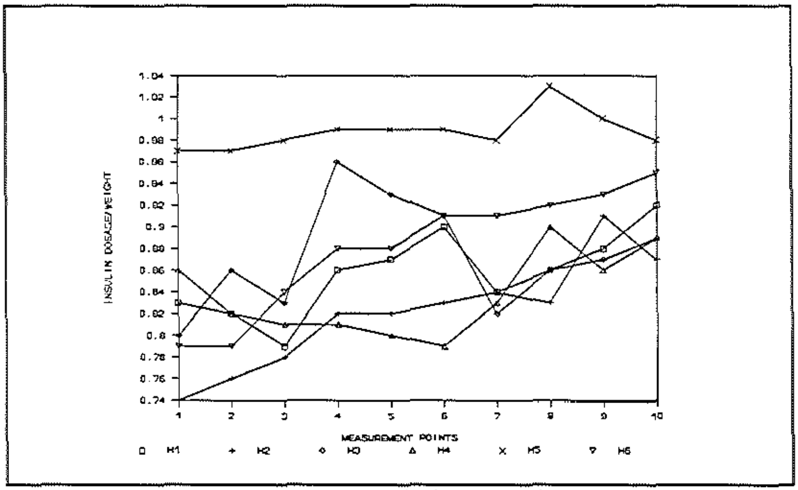
Note. High scores represent a low level of parental adjustment.

Figure 6.12 HbA1%: unadjusted means for each hospital sample at 10 measurement points



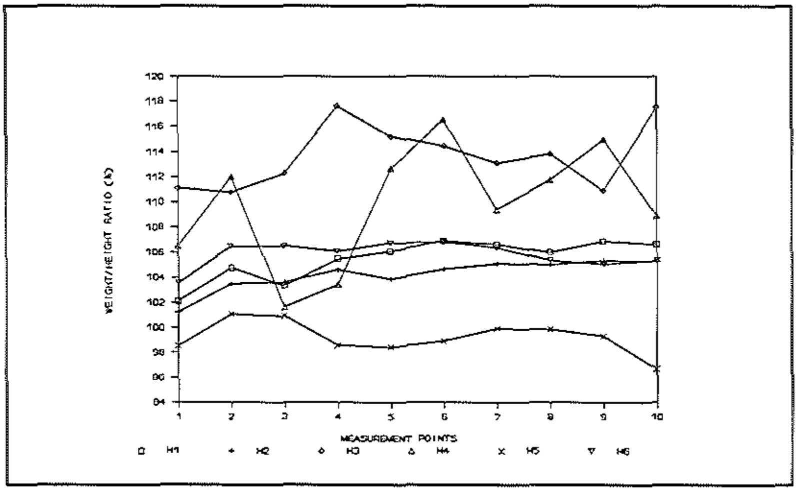
Note. High scores represent high HbA1%.

Figure 6.13 Insulin dosage/weight: unadjusted means for each hospital sample at 10 measurement points



Note. High scores represent high insulin dosages.

Figure 6.14 Weight/height ratio: unadjusted means for each hospital sample at 10 measurement points



Note. A ratio of 100% represents a favourable outcome.

6.4.2 Evaluation of trend by analyses of covariance

Longitudinal evaluation required several statistical strategies depending on the scale of the outcome variables considered.
Quantitative psychological and medical variables were analyzed by determining the slope of their regression line with time in each individual child. Additionally, analyses of covariance were performed to answer the question whether IDDM children and their parents of the home-care group showed different slopes, compared to the control children and their parents, given the covariates that may be related to the outcomes being investigated. The following set of covariates was included in all analyses: the outcome score on the baseline measurement, IDDM duration, age at IDDM onset (all quantitative covariates); socio-economic status (ordinal covariate); gender, member of the patient organization DVN, extra-education, life events, and interviewer (all binary covariates). Of both the covariates IDDM duration and age at IDDM onset linear and quadratic terms were incorporated. All analyses were conducted with BMDP statistical software (Dixon et al., 1985).

The adjusted group means of the slopes, resulting from the analyses of covariance, are presented in table 6.5 for the psychological and in table 6.6 for the medical outcome variables considered (see the column "adjusted means" in the tables 6.5 and 6.6). As three of the hospitals were allocated to the home care program, they constitute the experimental treatment group. The adjusted means of the slopes concerning these three hospital samples are indicated in the left column of the tables 6.5 and 6.6. The control group consisted of the other three hospitals; the adjusted means of their slopes are presented in the right column of the tables.

Statistical testing was performed by comparing the adjusted mean slopes for the two groups of three hospitals by means of Student's t-test for variables with homogeneous standard errors and by means of Mann-Whitney U-tests for variables with diverging standard errors. A statistically significant result with the latter test was obtained at the 5% level (one-sided), when the ranges of the two sets of three means were disjoint.
The results of table 6.5 indicate that with respect to self-care the adjusted means assessed in the home-care group were significantly improved compared to those of the control group ($p < .05$).

Table 6.5: Mean slope values adjusted by covariance analyses of quantitative longitudinal psychological outcomes

Home-care hospitals	adjusted means	se	N	Control hospitals	adjusted means	se	N
Behavior problems							
1	.022	.124	10	4	-.102	.139	8
2	-.069	.125	11	5	-.187	.101	15
3	-.158	.125	10	6	-.211	.086	21
Activities scale							
1	.032	.023	8	4	.034	.027	6
2	-.024	.022	8	5	.032	.021	9
3	.016	.021	8	6	.010	.014	20
Social scale							
1	.034	.016	10	4	.038	.019	8
2	.015	.019	8	5	-.004	.015	12
3	-.017	.018	8	6	.008	.012	20
School scale							
1	.027	.013	5	4	.009	.012	6
2	.006	.011	8	5	.002	.009	11
3	.003	.010	8	6	.004	.007	19
Social competence scale							
1	.111	.036	5	4	.070	.037	5
2	.017	.034	6	5	.032	.029	7
3	-.016	.029	7	6	.016	.018	17
self-care							
1	.013	.009	13	4	-.003	.011	8
2	.009	.009	11	5	.005	.008	15
3	.006	.009	11	6	-.012	.007	22
Regimen adherence							
1	.018	.020	11	4	-.003	.029	5
2	.016	.024	7	5	-.041	.017	12
3	-.015	.026	7	6	-.033	.018	14
Parental knowledge							
1	-.020	.006	13	4	.013	.008	8
2	.011	.007	11	5	.003	.006	15
3	-.006	.007	11	6	-.005	.005	22
Child knowledge							
1	.118	.025	13	4	.133	.031	8
2	.084	.029	10	5	.131	.023	15
3	.179	.028	10	6	.105	.020	20
Parental adjustment							
1	-.184	.048	10	4	-.015	.054	8
2	-.121	.048	11	5	-.017	.039	15
3	.002	.046	10	6	-.143	.033	21
Child adjustment							
1	.021	.047	13	4	.081	.058	8
2	.046	.054	10	5	.087	.044	14
3	.127	.055	10	6	.086	.038	19

Note. 1, 2, 3= home-care hospitals; 4, 5, 6= control-hospitals
se= standard error; N=number of children/parents

Table 6.6: Mean slope values adjusted by covariance analyses of quantitative longitudinal medical outcomes.

Home-care hospitals	adjusted means	se	N	Control hospitals	adjusted means	se	N
HbA1%							
1	-.305	.328	17	4	-.836	.518	7
2	-.426	.380	14	5	.609	.366	13
3	-.653	.337	15	6	.954	.294	25
Insulin dosage/weight							
1	.039	.024	18	4	.028	.034	8
2	.046	.025	15	5	.019	.023	18
3	.047	.024	16	6	.040	.019	26
Ratio weight/height							
1	.154	1.054	17	4	1.212	1.593	7
2	1.497	1.114	15	5	-1.391	1.026	18
3	1.909	1.124	15	6	-.572	.864	24

Note. 1, 2, 3= home-care hospitals; 4, 5, 6= control-hospitals
se= standard error; N=number of children

With regard to the remaining psychological and medical variables no significant differences were observed (see table 6.5 and 6.6). Analysis of the HbA1-percentages as well as the transformed HbA1-values (see paragraph 4.5.2.1 for the transformation procedure) did neither reveal significant differences between the experimental and control group.

6.4.3 Evaluation of final follow-up measurement by using analyses of covariance adjusting for baseline measurement

To further evaluate the findings from analyses of covariance in the previous section, a narrower approach was applied. Experimental and control group differences at the fourth psychological measurement (or, correspondingly, the tenth medical measurement) were analyzed for each dependent quantitative psychological and medical variable, including the first measurement as a covariate, by means of analyses of covariance. If the score of the tenth medical measurement was missing, the score of the ninth measurement was used. The results of the analyses are presented in table 6.7 and 6.8.

In the tables 6.7 and 6.8, the mean scores at final measurement, adjusted for baseline measurement, are presented for each hospital. Again, statistical testing was performed by comparing the adjusted mean scores for the two groups of three hospitals by means of Student's t-test for variables with homogeneous standard errors and by means of Mann-Whitney U-tests for variables with diverging standard errors.

Table 6.7: Mean final psychological scores adjusted for baseline variables by analyses of covariance.

Home-care hospitals	adjusted mean final scores	se	N	Control hospitals	adjusted mean final scores	se	N
Behavior problems							
1	20.712	3.878	10	4	23.057	4.360	8
2	16.916	3.931	11	5	13.119	3.183	15
3	13.489	3.907	10	6	10.794	2.693	21
Activities scale							
1	6.712	.799	8	4	6.530	.922	6
2	5.025	.773	8	5	6.687	.709	9
3	6.182	.728	8	6	5.764	.487	20
Social scale							
1	6.914	.511	10	4	6.924	.610	8
2	6.245	.601	8	5	5.803	.466	12
3	5.156	.566	8	6	5.982	.364	20
School scale							
1	6.089	.400	5	4	5.491	.357	6
2	5.370	.324	8	5	5.164	.274	11
3	5.171	.298	8	6	5.183	.196	19
Social competence scale							
1	20.183	1.247	5	4	18.277	1.280	5
2	16.795	1.158	6	5	17.421	.990	7
3	15.931	.981	7	6	16.675	.629	17
self-care							
1	3.030	.278	13	4	2.462	.333	8
2	2.672	.303	11	5	2.950	.257	15
3	2.821	.286	11	6	2.330	.207	22
Regimen adherence							
1	7.181	.598	11	4	6.523	.882	5
2	7.042	.739	7	5	5.421	.534	12
3	6.265	.786	7	6	5.514	.546	14
Parental knowledge							
1	7.630	.216	13	4	8.578	.264	8
2	8.274	.240	11	5	8.107	.196	15
3	7.903	.227	11	6	7.893	.166	22
Child knowledge							
1	26.124	.716	13	4	26.432	.878	8
2	25.252	.832	10	5	25.720	.651	15
3	27.884	.797	10	6	25.849	.561	20
Parental adjustment							
1	21.440	1.546	10	4	27.129	1.743	8
2	24.531	1.563	11	5	26.315	1.265	15
3	27.660	1.508	10	6	23.686	1.970	21
Child adjustment							
1	34.342	1.476	13	4	35.614	1.847	8
2	35.037	1.721	10	5	36.374	1.406	14
3	38.045	1.749	10	6	36.923	1.199	19

Note. 1, 2, 3= home-care hospitals; 4, 5, 6= control-hospitals
se= standard error; N=number of children/parents

Table 6.8: Mean final medical scores adjusted for baseline variables by analyses of covariance.

Home-care hospitals	adjusted mean final scores	se	N	Control hospitals	adjusted mean final scores	se	N
HbA1%							
1	-.734	.492	16	4	-2.128	.761	7
2	-1.150	.578	13	5	.351	.565	12
3	-.352	.545	12	6	1.650	.446	24
Insulin dosage/weight							
1	.094	.049	17	4	.061	.068	8
2	.125	.051	15	5	.060	.049	17
3	.070	.053	13	6	.111	.039	25
Ratio weight/height							
1	2.973	2.241	16	4	3.106	3.282	7
2	4.629	2.589	14	5	-.140	2.204	17
3	6.252	2.406	12	6	1.830	1.817	23

Note. 1, 2, 3= home-care hospitals; 4, 5, 6= control-hospitals
se= standard error; N=number of children

The results show that the conclusions from the previous analyses based on mean slopes (see paragraph 6.4.2) are confirmed here. No significant differences were found between experimental and control groups. Again, both analysis of HbA1% and transformed HbA1% (see paragraph 4.5.2.1 for the transformation procedure) showed comparable insignificant differences between the two groups of hospitals.

6.4.4 Evaluation of dichotomous outcome variables by using logistic regression analyses with random effects

With respect to dichotomous outcome variables for psychological and medical assessments logistic regression analyses were performed. As before, each individual contributes a set of four measurements of the psychological outcome variables as well as of the time-varying covariates, and a set of ten measurements of the medical outcome variables. A logistic model for regression analyses with random effects was therefore used. This means that in the analyses for each individual a random intercept is introduced in the logistic regression model, with the observations within an individual being assumed to be independent (local independency). The same covariates as before were incorporated into the model: hospital, time, hospital x time, gender, socio-economic status, IDDM duration, age at IDDM onset, extra-education, membership DVN and interviewer. Statistical testing concerned the differences of the coefficients, representing the hospital x time interaction-term, between the two groups of experimental and control groups, using

Mann-Whitney U-test, $p<.05$ one-sided. Hospital 1 was arbitrarily taken to represent the reference in the hospital coding. If the two sets of coefficients were disjoint, it was concluded that the home-care group behaved differently in time compared to the control group. The described coefficients (see the column "effect" in table 6.9) denote the change in the log odds per time unit in each hospital sample with respect to this change in hospital 1, which is therefore set as 0. All 22 dichotomous psychological and medical variables were analyzed in this way. The results are presented in table 6.9 and 6.10.

Table 6.9: Significant differences in effects between treatment groups (experimental versus control groups) on dichotomous outcome variables with logistic regression analyses with random effects ($p<.05$)

Home-care hospitals	effect	se	Control hospitals	effect	se
Self-care, hypo symptoms, child report					
1	0		4	.604	.788
2	.019	.483	5	.409	.437
3	.105	.436	6	.387	.469
Self-care, hypoglycaemia, parental report					
1	0		4	-1.868	.577
2	-.058	.573	5	-1.502	.497
3	-.370	.562	6	-.972	.477
Quality of injection sites, child report					
1	0		4	.297	.485
2	-.507	.402	5	.346	.383
3	.009	.391	6	.023	.348
Frequency of regular outpatient visits					
1	0		4	1.152	.535
2	.237	.551	5	.622	.512
3	-.429	.567	6	.339	.409
Frequency of non-planned outpatient visits					
1	0		4	-.172	.427
2	.220	.372	5	-.405	.363
3	-.031	.368	6	-.209	.328

Note. 1, 2, 3= home-care hospitals; 4, 5, 6= control-hospitals
se= standard error

Table 6.10: Dichotomous outcome variables showing insignificant effects between experimental and control groups by logistic regression analyses with random effects, $p>.05$

School absence	parental report	
School absence	teacher report	
Self-injection	parental report	
Self-injection	child report	
Self-monitoring blood glucose		
Self-care, hypo symptoms	parental report	
Child adjustment	parental report	aggression
		withdrawal
		depression
		adjusted behaviors
Parental concerns about the future		chronic complications
		partner choice
		occupation
		self-discipline
		remaining concerns
Frequency of hypoglycaemias		
Hospital admission rate		

Table 6.9 shows the outcome variables with significant differences in effects between two groups indicating different functioning in home-care participants compared to controls.

The level of self-care when the child experiences hypoglycaemia (parental report) shows a favourable trend in the home-care group compared to the control group. Furthermore, the frequency of regular outpatient visits shows a decreasing trend in the home-care group compared to controls. However, the non-planned outpatient visits had increased in the home-care group during the study, compared to controls.

The remaining outcome variables with significant effects indicate less favourable results in the home-care group compared to controls. The level of self-care in case of hypoglycaemic symptoms, reported by children, indicated a substantial decrease in the

home-care group compared to a smaller decrease in the control group. Furthermore, the quality of injection sites reported by children shows an increase of quality in the control group and less favourable results in the home-care group. It should be noted that variables with unfavourable outcomes in home-care participants were assessed in the child interview, whereas the earlier described variables with favourable outcomes were measured by interviewing the parents of the child.
The remaining dichotomous outcome variables are presented in table 6.10; these variables did not show significant effects between experimental and control groups.

In conclusion, according to a logistic regression model with random effects some significant differences between hospital samples were found during the course of the study. Parents of the home-care group reported improved functioning with respect to self-care and outpatient visits to the clinic compared to controls. On the other hand, children in the home-care group were less positive about their self-care behavior and injection sites compared with controls.

6.5 Treatment satisfaction

In addition to the objective outcome variables evaluated in previous sections we included the subjective opinion of parents and children about home care. Parents and children in the control group were of course not asked about this issue.
At the three psychosocial follow-up measurements the home-care parents and children were asked to express their feelings about the treatment program and, if they appreciated the program, which aspects they valued most. It is important to underline that the interviewers treated the answers of parents and children with discretion and maintained their independent functioning, i.e., they operated strictly independent from the nurse and paediatricians. As a result, parents and children felt free to express both positive and negative feelings about the home-care program.
Table 6.11 presents the results about treatment satisfaction, reported by parents.

The results of table 6.11 indicate that the majority of parents valued the home-care program provided and that the number of satisfied parents remained almost stable during the course of the study. The small increase in percentages is due to dropouts during the home-care program. A number of parents expressed their discontent about home care which will be discussed later in more detail (see also table 6.13).

Table 6.11: The number of parents reporting treatment satisfaction in three follow-up periods

Follow-up period		hospital 1 N (%)	hospital 2 N (%)	hospital 3 N (%)	Total N (%)
0 -	<9 months	8 (44)	13 (81)	10 (71)	31 (65)
9 -	<19 months	10 (71)	11 (73)	10 (77)	31 (73)
19-	<31 months	12 (86)	12 (80)	9 (90)	33 (84)

In addition, we asked children if they appreciated the home-care program. Their reports are presented in table 6.12.

The results about treatment satisfaction among IDDM children show similar findings compared with those of their parents: most children expressed their satisfaction with home care. There were no significant differences found in treatment satisfaction between hospital samples.

Table 6.12: The number of children reporting treatment satisfaction in three follow-up periods

Follow-up period		hospital 1 N (%)	hospital 2 N (%)	hospital 3 N (%)	Total N (%)
0 -	<9 months	9 (50)	12 (75)	9 (64)	30 (62)
9 -	<19 months	10 (71)	9 (60)	8 (62)	27 (64)
19-	<31 months	10 (77)	10 (67)	8 (80)	28 (73)

Furthermore, the interviewers asked home-care participants which aspects of the treatment were valued most. Participants who showed discontent were asked to explain their objections. In the tables 6.13 and 6.14 the beneficial and unfavourable aspects of home care are summarized, reported by parents and children, respectively.

Table 6.13: Beneficial and unfavourable aspects of home care which were reported by parents in three follow-up periods

Benefits of home care	Number of parents N (%) 0-<9	 9-<19	 19-<31	 Total
Instruction about management skills	13 (30)	9 (25)	18 (49)	40 (34)
Social support	6 (14)	8 (22)	3 (8)	17 (15)
Extra control and supervision	4 (9)	4 (14)	6 (16)	14 (16)
Information about new treatment procedures	0	5 (14)	1 (3)	6 (5)
Feelings of security	4 (9)	1 (3)	3 (8)	8 (6)
Low threshold for information and care	0	1 (3)	3 (8)	4 (3)
Increased independent IDDM management	3 (7)	0	0	3 (2)
Unfavourable aspects of home care	**Number of parents N (%) 0-<9**	**9-<19**	**19-<31**	**Total**
Home care unnecessary, long acquaintance with IDDM, violation of privacy, disagreement with the nurse's guidelines	4 (11)	13(30)	9 (24)	26 (21)

Note. The percentages do not add up to 100%, because parents had the opportunity to mention more than one benefit or objection about home care.
0-<9, 9-<19, 19-<31: three follow-up periods.

The results in table 6.13 and 6.14 indicate that both the majority of parents and children valued the information and instruction about IDDM management skills provided by the nurse-practitioner. Furthermore, parents appreciated the social support from the nurse-practitioner, particularly during measurement period 1 and 2. IDDM children, and to some extent their parents, valued the control and supervisory tasks of the nurse.

The results also show the objections which were mentioned by a number of parents and children. They told the interviewer that home care was unnecessary, that they were acquainted with IDDM for a long time already, that they objected to the violation of privacy associated with the home visits of the nurse, or that they disagreed with the guidelines of the nurse. Many of these parents and children explained that they preferred to manage IDDM on their own without interference of a nurse. Additional exploratory analyses did not reveal a clear pattern of characteristics identifying families with objections to home care.

Table 6.14: Beneficial and unfavourable aspects of home care reported by children in three follow-up periods

Valued aspects of home care	Number of children N (%)			
	0- <9	9- <19	19- <31	Total
Instruction about management skills	18 (43)	12 (32)	15 (45)	45 (40)
Social support	4 (10)	2 (5)	5 (15)	11 (10)
Extra control and supervision	6 (15)	9 (24)	6 (18)	21 (19)
Awareness of IDDM implications	3 (7)	4 (11)	2 (6)	11 (8)
Unfavourable aspects of home care	**Number of children N (%)**			
	0- <9	9- <19	19- <31	Total
Home care unnecessary, long acquaintance with IDDM, violation of privacy, disagreement with the nurse's guidelines	10 (25)	10 (27)	5 (15)	25 (22)

Note. The percentages do not add up to 100%, because children had the opportunity to mention more than one benefit or objection about home care.
0-<9, 9-<19, 19-<31: three follow-up periods.

In conclusion, parents and children expressed freely their opinion about home care, indicating satisfaction with the treatment for the majority of individuals. In general, the information and instruction about management skills were valued most, whereas a number of individuals mentioned objections to the program.

6.6 Summary and discussion

In this chapter the longitudinal effects of home care were compared to traditional hospital

based care, followed over a period of 31 months.
First, details of home care were specified, to shed more light on the home-care-versus-traditional-care comparisons. The number of home visits was found to decrease during the course of the study, whereas the number of telephone calls to the nurse-practitioner increased. Apparently, the actual appearance of the nurse within the home environment was most needed during the first nine months of the study. Later, the transfer of information and support was achieved more and more by telephone.
The most home visits focused on reinstruction of insulin injection and general management information or were executed as check-up visits.

Preparing for longitudinal analyses the interrater reliability between 4 interviewers was examined in the four consecutive psychological measurements. A high level of interrater agreement was found. Socio-demographic, IDDM-related and intervening variables were incorporated in the analyses as a consequence of non-randomization at the onset of the study. As a result of the baseline differences found between hospital samples, analyses were directed at treatment effects within each hospital sample and subsequently, treatment effects within home-care samples were compared to those within control samples.

Longitudinal results concerning (unadjusted) quantitative psychosocial and medical variables showed a significant improvement of scores across time in the total study sample with respect to behavior problems, knowledge scores and adjustment scores. The decrease of problem scores was in agreement with findings in the general population of children aged 4-14 years over a two-year follow-up period (Verhulst et al., 1988). Verhulst and associates have argued that there is no satisfactory explanation available for this apparent improvement of mental health. In the present study, improvement could have been an effect of time or a consequence of participation in a health-care program, in this instance either home care or hospital-based care.
Furthermore, the longitudinal follow-up results revealed fluctuations in medical functioning. These variables represent intermittent measures, highly affected by the developmental stage of the child and by daily life influences. Therefore, the instability of these variables was to be expected.

The long-term effects of the treatment program on quantitative outcome variables were examined by means of analyses of covariance. However, these analyses did not reveal systematic differences in treatment effects of the home-care group on the one hand and the control group on the other hand. The analyses of covariance showed improved self-care behavior in home-care participants compared to controls. This outcome may, however, represent a chance finding and should therefore be considered with caution.

A narrower method directed at evaluation of final follow-up measurement with first measurement as a covariate showed corresponding results. At the same time this approach implies that the home-care group did not behave differently compared to controls.

Dichotomous outcome scores were analyzed by means of logistic regression analyses with random effects. Of 22 analyses, 5 analyses were found with significant results, indicating different treatment effects in the home-care group compared to controls. Parents of home-care children reported improved functioning in self-care behavior of their child and a lower frequency of planned outpatient visits to the clinic. However, non-planned outpatient visits increased in the home-care samples and home-care children reported less favourable scores concerning self-care behavior and the quality of injection sites. It seems as if home care reduced the need of regular outpatient clinic visits, but lowered the threshold to visit the outpatient clinic intermittently, thereby explaining the decrease in regular (planned) visits and the increase in non-planned visits. The unfavourable results in home-care children, namely lower self-care and lower quality of injection sites, may be explained by the influence of the nurse-practitioner during home visits. Children were exposed to the emphasis she laid upon self-care and acceptable injection sites. As a result, home-care children might become more aware of their behavior and their regimen shortcomings and consequently, value their behavior as less favourable.

Finally, home-care participants were interviewed about the benefits of or objections to the home-care program as perceived by them. The results show that the majority of the participants appreciated the care provided via home care, the instruction on IDDM management skills valued most. However, some parents and children objected to the program and explained that they preferred to manage IDDM in their own way. It should be noted that the home-program was provided by one nurse-practitioner, contributing inevitably to individual preferences and objections in the nurse-patient relations.

Reviewing the longitudinal results we may conclude that objective psychosocial measures revealed a few significant effects in the home-care group compared to the traditional hospital-based group. No significant differences were found on medico-physiological functioning between the two samples. There are several possible explanations for the absence of clear favourable differences in effects of the treatment programs. These involve methodological issues, others are associated with the design of the home-care program.

As mentioned previously, a serious drawback was the impossibility of prior randomization, in view of the baseline differences between the home-care group and the control group in this study. Such methodological limitations induced to focus on analyses of treatment effects of the three home-care samples versus the three control samples, instead of examining one experimental group versus one control group. This strategy, inevitably associated with six relatively small sample sizes, may have obscured treatment effects. Furthermore, overall improvement in some areas of psychosocial and medical functioning or instability of behavior might have hampered the finding of beneficial effects in home-care participants versus controls.

The home-care program was intentionally included in the study as a relatively undefined program. Home visits were guided by the needs of the family or initiated by the nurse. Therefore, the comparison of the results of the present study with other corresponding programs can not be validly made and the generalization of the present results is fairly limited.

Furthermore, the contents of the home-care program were filled in by the nurse and by the participants. As a result, home care became a diversified program which may have different effects on different children and parents. This consideration corresponds with the finding that many home-care participants appreciated the program, but that some of the participants indicated objections. Perhaps, a home-care program might be suitable for subgroups of children or parents. In the next chapter, characteristics within the home-care group are examined to identify whether patients benefitted from a higher frequency of home visits.

CHAPTER 7

THE RELATION OF HOME VISITS TO PSYCHOLOGICAL AND MEDICAL OUTCOMES

7.1 Introduction

Long-term effects on 36 psychological and medical outcome variables in hospital samples with home care as compared to traditional hospital-based care revealed minor differences (see chapter 6). In the analyses so far, home care was regarded as a fixed program without considering individual differences in the actual number of home visits between participants.
It was hypothesized that unfavourable scores at the start of the study would induce a higher frequency of home visits which would positively influence the final outcome scores at the end of the study. To examine these hypotheses, exploratory analyses were performed within the home-care group. The results of these analyses are described and discussed in this chapter.

First, in paragraph 7.2, the relation of home visits with the characteristics of home care participants (N=51) was identified, by studying the correlation of baseline characteristics with the number of home visits during the first period of the study (0-9 months). In addition, correlation analyses were performed to identify the relations of final outcomes with the number of home visits during the total period of the study.
In paragraph 7.3, the impact of the number of home visits on changes of outcome scores was examined by means of stepwise regression analyses. In paragraph 7.4 the results of this chapter are summarized.

7.2 Relation of home visits to characteristics of home-care participants

It was decided to first examine whether the baseline profile of children and parents was a determinant of the number of home visits. The examination of baseline characteristics might shed more light on the motives of the nurse-practitioner for executing these frequent home visits. Furthermore, the findings might reveal which type of participants asked for or accepted a higher number of home visits. Correlation coefficients between baseline characteristics and the number of home visits during the first nine months are presented in table 7.1 for those cases with $p<.10$.

Table 7.1 indicates that 5 out of 46 baseline characteristics were associated significantly ($p<.01$) with the number of home visits during the first period of the study. Number of behavior problems, level of self-care, child and parental knowledge scores were most significantly associated with number of home visits in the first period of nine months of the study.

Table 7.1: Relations between baseline scores, parental satisfaction and the number of home visits during the first nine months of home care

Baseline scores	p
Quantitative variables	
Behavior problems	.000 (r_s=.46)
Activities scale	.073 (r_s=.22)
Social scale	.056 (r_s=-.24)
Self-care	.008 (r_s=-.34)
Child knowledge	.003 (r_s=-.38)
Parental knowledge	.004 (r_s=-.37)
Parental adjustment	.019 (r_s=.30)
Child adjustment	.017 (r_s=-.31)
HbA1%	.091 (r_s=-.20)
Ordinal variable	
Socio-economic status	.089
Dichotomous variables	
Self-injection, parental report	.073
Child adjustment, parental report: depression	.077
Home visits at parental request	.001
Parental satisfaction about home care (2nd measurement)	.001

Note. Relations with home visits were analyzed with Mann-Whitney U-tests for dichotomous variables, Kruskal-Wallis tests for ordinal data and Spearman rank-order correlation analyses for quantitative data (only presented for relations with $p<.10$, $N=50$; underlined: $p<.01$)

Apparently, unfavourable behavior baseline scores prompted a higher number of home visits. In addition to the 5 baseline characteristics with a relatively strong association with number of home visits, it was found that parental satisfaction after nine months of home care correlated significantly with number of home visits, i.e., the higher the number of home visits, the more treatment satisfaction was observed.

Given the relations of baseline characteristics with number of home visits during the *first* period of the study, it was hypothesized that number of home visits during the *total* study period was related to outcome scores measured at the end of the study. The more home visits during 31 months, the more favourable outcome scores were assumed to be found at the end of the study. The results are presented in table 7.2.

Table 7.2: Relations between outcome scores and the number of home visits during the total study period

Outcome score	p
Quantitative variables	
Behavior problems	.072 (r_s=.22)
Activities	.011 (r_s=.40)
Social competence	.090 (r_s=.26)
Self-care	.044 (r_s=-.26)
Child knowledge	.057 (r_s=-.24)
Parental adjustment	.061 (r_s=.23)
Child adjustment	.017 (r_s=-.31)
Dichotomous variables	
Self-care, hypo symptoms, child report	.005
Quality injection sites	.069
Special class	.051
Hospital admission	.042
Parental treatment satisfaction	.098

Note. Relations with home visits were analyzed with Mann-Whitney U-tests for dichotomous variables and Spearman rank-order correlation analyses for quantitative data (only presented for relations with $p<.10$, $N=46$; underlined: $p<.01$)

In contrast with the forementioned expectations, only one variable, i.e. the activities score, showed a favourable outcome at the end of the study associated with a higher number of home visits. Furthermore, an *un*favourable outcome score, i.e., lower level of self-care, was significantly related to a higher number of home visits. All other relations presented in table 7.2 did not reach a significant p-value of .01, but they support a tendency of higher number of home visits associated with unfavourable outcomes at the end of the study. For instance, a higher level of behavior problems, lower child knowledge, and lower adjustment scores were associated with higher number of home visits. Apparently, children and parents characterized by behavioral disturbances at the end of the study had received a higher number of home visits, without causing expected favourable outcomes over time. In addition to these variables, children attending a special class and children with hospital admissions during the study were visited more frequently.

In conclusion, exploratory analyses revealed that low behavioral scores at baseline measurement triggered a higher number of home visits. In contrast with the expectations, relations were found between lower outcome scores at the end of the study and a higher number of home visits.
It appears that the nurse-practitioner was readily able to detect families with problems in psychosocial domains and with a need of extra support on the basis of baseline characteristics. Consequently, these families were visited more frequently. However, at the end of the study, the analyses indicate that frequent home visits did not yield improved outcomes.

7.3 Relation of home visits to change in outcome scores

The results described in the previous paragraph show that unfavourable outcomes at the end of the study were related to a higher number of home visits. These outcomes gave rise to the question whether favourable *changes* in quantitative outcome scores during the study were associated with the number of home visits, after adjusting for hospital and other relevant confounding variables. In order to answer this question regression analyses were performed predicting change in outcomes. Change was defined as the final outcome scores minus baseline scores. In the analyses a selected set of intervening variables was used: sex, socio-economic status, age at IDDM onset and duration of IDDM, because including all intervening variables would have produced an unfavourable variables-to-subjects ratio (Cohen et al., 1983). After hospital and the total number of home visits were put into the equation, intervening variables were then allowed to enter stepwise, in each step selecting one additional variable with the lowest p-value ($p<.05$). Table 7.3 shows the results of the 14 stepwise regression analyses. In this table only the outcome with respect to number of home visits is reported.

The results of table 7.3 suggest that home visits contribute to a change in parental adjustment, indicating that improvement of parental adjustment resulted from a high number of home visits. The other dependent variables were not significantly affected by the number of home visits.

Table 7.3: Results of stepwise multiple regression analyses relating before-after changes in 14 outcome scores to number of home visits adjusted for intervening variables

Dependent variable change in	Effect of number of home visits (se)		p total model	Adjusted R^2	N
Behavior problems	-.045	(.266)	.87	.04	41
Activities	.071	(.048)	.15	.25	33
Social scale	-.013	(.037)	.72	.15	35
School scale	-.004	(.013)	.76	-.02	31
Social competence	.009	(.076)	.90	.21	24
Regimen adherence	.033	(.063)	.59	.11	37
Self-care	-.015	(.018)	.39	.31	46
Child knowledge	.003	(.063)	.97	.51	43
Parental knowledge	.017	(.014)	.24	.35	42
Parental adjustment	.303	(.082)	.00	.39	41
Child adjustment	-.131	(.081)	.11	.29	42
HbA1%	.421	(.270)	.13	.49	34
Insulin dosage	.288	(.240)	.24	.38	42
Weight/height ratio	-.144	(.086)	.10	.05	36

Note. se=standard error

7.4 Summary and discussion

In this chapter exploratory analyses are described within the group of home-care participants in order to examine whether children and parents benefitted from a higher number of home visits. Instead of considering home care as a fixed treatment, the impact of the number of home visits was explored. It was hypothesized that a higher number of home visits resulted from unfavourable baseline scores and would positively affect outcomes after participation in the home-care program. Correlation analyses supported the first part of the hypothesis. Unfavourable scores at the start of the study, i.e., higher behavior problems, lower self-care, lower child and parental knowledge, appeared to be associated with a higher number of home visits during the first nine months of the study. These results indicate that the nurse-practitioner primarily visited children and parents showing problems in psychosocial areas; medical indicators were not found to be associated with number of home visits.

However, a higher number of home visits turned out to be associated with *low* outcome scores at the end of the study, i.e., a high level of behavior problems, low child knowledge, low adjustment and low quality of injection sites. Additionally, children characterized by hospital admissions during the study or attending a special class were visited more frequently. In an area of social competence, i.e., the level of leisure activities, a high number of home visits appeared to be related to the intended favourable scores at the end of the study.

Apparently, the nurse-practitioner made home visits when problems were evident, but the achievement of favourable scores could not sufficiently be reached despite the nurse's efforts. It should be emphasized that the tasks of the nurse-practitioner were not primarily fitted to solve psychological problems. Additional training in psychological areas is required for the home-visiting nurse to optimize the effects of a home-care program.

Further, it may be argued that some children, parents or individual problems need other, additional or specialized care to reach significant improvement.

A next step in the analyses was the exploration as to whether home care visits contributed significantly to *change* in outcomes. In accordance with findings mentioned above the contribution of home visits to change appeared to be marginal.

Finally, it should be noted that number of home visits is merely a general indicator of the home-care program. As reported in chapter 6, home visits differed with respect to initiator of the visits (parental request or nurse-initiated), were planned, or were prompted by acute circumstances. These (and possibly other) characteristics of the home-care program need further examination to identify those features of home care which relate most significantly to favourable outcomes. The relation between number of home visits and outcome scores described in this chapter should be considered as a preliminary exploration of the impact of home visits on children and parents.

CHAPTER 8

SUMMARY AND CONCLUSIONS

Summary

During the last decades extensive research has revealed the complex character of insulin-dependent diabetes mellitus (IDDM) involving acute and chronic physical complications and far-reaching psychological consequences resulting from disease and treatment. Recently, investigations have focused on the optimization of medical treatment for the affected children and for their parents. Home care has been introduced as a relatively new strategy of treatment characterized by the extension of care into the home environment of the child. Until now, limited studies and preliminary results have indicated promising effects of home care. The present study concerned the evaluation of a home-care program in comparison with traditional hospital-based care for children with IDDM and for their parents in a systematical way. It was hypothesized that the implementation of home care would optimize diabetes care and thus would improve "medical" and psychological functioning of participants.

To understand the need for and the implementation of home care, it is necessary to understand the nature of IDDM, its treatment implications and its psychological consequences. Therefore, the first part of this thesis describes the characteristics of IDDM, of treatment strategies and associated issues in research.

In Chapter 1 the clinical picture and lifelong implications of childhood diabetes were summarized. IDDM is a chronic metabolic disorder associated with temporary acute complications and with life-threatening chronic complications in the long term. IDDM treatment involves complex self-care behaviors, aiming at the establishment and maintenance of the vulnerable balance of insulin dosages, diet and physical exercise, thriving for near-normoglycaemia. Nowadays, clinical workers acknowledge a variety of psychological and social problems in IDDM children and their parents, interfering with the disease-course and its treatment.

Chapter 2 shows the multitude of studies examining psychosocial prerequisites and consequences of IDDM. Despite clinical impressions, the majority of the studies did not support the expected higher prevalence of general psychological disturbances in IDDM children compared to "healthy" controls. The more convincing indices, however, showed that IDDM children suffer from social problems in their relationships with peers or significant others. The focus of psychosocial research shifted to subgroups of children, for example, indicating that IDDM children diagnosed before age 5 run an increased risk for neurocognitive impairment.

Inconsistent results of studies on psychosocial disturbances were primarily caused by methodological shortcomings, such as small sample sizes and the retrospective character of many. Another problem in this area of research appeared to be the complex relation between psychosocial and metabolic factors indicating that psychosocial problems can be defined as cause but also as effect of poor metabolic regulation. In addition, it was suggested that psychosocial problems and metabolic factors are mediated by interfering variables such as regimen adherence and life stresses. Many authors have concluded that longitudinal, prospective and systematical studies were needed to delineate psychosocial consequences of IDDM.

In Chapter 3 a number of therapeutical strategies in managing IDDM were reviewed. Technical improvements, increased responsibility of the patient for diabetes management and self-care became the basis of diabetes care nowadays. Self-care strategies, education programs and psychosocially oriented programs were implemented to optimize medical care. However, the studies performed to examine effects of such strategies showed diverging results.

A relatively new approach involves home care. In this treatment strategy a nurse-practitioner provides education and support to IDDM children and their parents in the home environment. Preliminary and incomplete findings showed that home care might be a promising approach. Systematical evaluation was required to evaluate the effects of home care on metabolic and psychosocial functioning.

In Chapter 4 the aims and design of a longitudinal, multicentred and controlled study were explained. The main question of the study concerned the evaluation of home care compared to traditional hospital-based care. Three hospitals agreed to participate in the home-care program as experimental group, and three other hospitals with hospital-based care comprised the control group. Only patients with a history of IDDM were included, aged 5-16 years; newly-diagnosed patients were excluded from the study. Psychological measures were assessed at baseline and after 9, 19 and 31 months follow-up. Medical outcomes were measured every three months during outpatients visits to the clinic, at 10 measurement points in total.

In Chapter 5 the baseline characteristics of the study sample were described. 104 IDDM children and their parents were enroled in the study. Due to the non-randomized design of the study, differences between hospital samples at baseline were thoroughly studied. No significant differences were found between hospital samples with respect to socio-demographic and IDDM-related characteristics. However, psychological and medical functioning showed a number of significant differences, generally indicating less favourable scores in the home-care group compared to the control group. Comparing the scores of all participating IDDM children to those of a sex-age-matched sample of the general population, significant social competence deficiencies in the IDDM sample were found.

In Chapter 6 the long-term results of home-care participants compared to controls were reported. Long-term results from all hospitals taken together indicated improved behavior scores, higher knowledge about IDDM and improved adjustment to IDDM across time. Other outcome variables, such as regimen adherence, self-care, HbA1% and insulin dosages, showed fluctuating scores during the study.
Further analyses were directed at the main goal of the study: i.e., differences in long-term medical and psychological effects between home-care hospital samples and control-hospital samples. Due to the non-randomized character of the study, effects of treatment had to be analyzed on hospital sample basis. Quantitative outcome variables were examined by means of analyses of covariance. The results indicated significant differences with respect to only one variable, i.e., self-care behavior. Home-care children showed improved self-care behavior (reported by their parents) in comparison with control-children at the end of the study.
Dichotomous outcome variables were analyzed using a logistic regression model with random effects. Of 22 variables, 5 showed significant results indicating different effects in home-care samples compared to controls. Parents of home-care children reported improved self-care behavior and a lower frequency of planned outpatient visits to the clinic. On the other hand, non-planned outpatient visits increased in the home-care samples. Children reported less favourable scores concerning self-care behavior and the quality of injection sites, compared to controls. This latter finding may reflect that the home-visiting nurse considered checking the quality of injection sites as one of her main tasks.
Within the home-care group it was apparent that the number of actual home visits had decreased during the follow-up period, whereas telephone calls for help had increased.

In Chapter 7 exploratory analyses were reported directed at the impact of the variable frequency of home visits instead of considering home care as a fixed treatment. It was hypothesized that unfavourable baseline scores would induce a higher number of home visits and that frequent home visits requested by parents or deemed necessary by the nurse-practitioner would positively affect outcomes after participating in the program. Correlation analyses only partially confirmed this hypothesis. The results revealed indeed that serious behavior problems, lower self-care, lower child and parental knowledge about IDDM were associated with a higher number of home visits. However, outcome scores at the end of the study showed that frequent home visits turned out to be related to low scores, because, in particular, lower self-care (reported by children themselves) was still found. On the other hand, leisure-activities scores indicated that a higher number of home visits was associated with favourable outcomes in this single respect at the end of the study. Exploratory analyses on the contribution of the frequency of home visits as such to change in outcome scores revealed insignificant findings. In the context of these findings the role of the home-visiting nurse-practitioner was discussed.

Conclusions

Here the overall-results of the study are discussed and put in a wider perspective. In addition, methodological limitations of the study are commented upon. Finally, implications for future research and directions for optimal IDDM treatment are suggested.

In spite of the efforts put in the home-care program the results on psychological and medical variables for IDDM patients and their parents showed only a low number of significant differences as compared to a traditional-care group on follow-up over 31 months. This outcome will be explained and commented upon from several points of view.

The low number of significant differences between experimental and control group suggest that both the home-care program and traditional hospital-based care provided sufficient care to achieve and maintain a particular (adequate) level of functioning in both groups of patients. This does not imply, however, that either treatment strategy will be suitable for all IDDM patients. It is obvious that treatment strategies must be of sufficient quality and need particular prerequisites, e.g., expert medical care, attention and support, to serve as the basis of appropriate strategies for IDDM children and their parents. Apparently, both strategies evaluated in the present study met such conditions sufficiently to secure comparable levels of functioning. It should be noted that the participating children already had IDDM for four years, on average. The present comparison dealt therefore with patients already accustomed, one way or another, to diabetes self-care.
In addition, the outcomes of the study raise the question whether the two treatment strategies investigated differed sufficiently from each other to establish contrasting effects in relatively small groups and small numbers of hospitals. Both treatment strategies aimed at near-normoglycaemia and psychological well-being and both included education about

self-control and self-regulation. The level of similarity between the goals of the two strategies may have precluded significant differences in effects on follow-up.
These considerations imply that, in addition to treatment aspects, features and qualities of health care professionals are of the utmost importance when it comes to metabolic and psychological well-being of IDDM children.

The results of this study clearly revealed differences between the samples of children in different hospitals at the start of the study. Apparently, hospital-dependent factors have a major impact on psychological and medical functioning of patients. It has been suggested before that treatment attitude and individual paediatric practice may be held responsible for differences between hospital samples (Kaplan et al., 1989; Linn et al., 1982; Dugdale et al., 1977). In addition, the broader perspective of hospital policies and organizations may have influenced treatment strategies and outcomes.
At any rate, the differences between hospital samples, observed at the start of the study, explain some of the inconsistencies in psychological and metabolic functioning of IDDM children. To our knowledge, research into psychological and medical characteristics has not taken into account explicitly so far the impact of different hospital or treatment policies.
Next to the hospital-dependent character of the results, it must be noted that the results are very possibly related to the attitude and other characteristics of the single nurse-practitioner involved. Therefore, the comparison of the present results with those of other corresponding programs can not be validly made, precluding generalization of the present data.

Although forementioned results indicate that significant psychological and medical benefits of home care compared to traditional care were minimal, it is important to note that a large number of home care participants highly valued the care provided and reported important advantages of the home-care program. It is conceivable that the implementation of home care generated satisfaction and unexpected psychological or medical outcomes at the same time. For instance, it was presumed that home care would reduce non-planned outpatient clinic visits. However, the results indicate an increase of non-planned outpatient visits to the clinic among home-care participants compared to controls. This "unfavourable" outcome may reflect an unforeseen effect, namely the lowering of the threshold for visits to the hospital. In this way, the concurrence of treatment satisfaction and the absence of "favourable" outcomes can be understood. This outcome also indicates that the aims of home care should be defined in agreement with patients, parents, physicians and other health care providers. Evidently, the goals of those involved do not always agree

(Schut, 1990).

The observed differences concerning treatment satisfaction or objection among participants should be considered as a signal that home care may be more desirable for a subgroup of patients and parents. Preliminary analyses did not reveal a clear pattern of characteristics which identify families appreciating or objecting to the home-care program. Since a minority of home-care participants indicated objections to the treatment, the notion is supported that home care is not suitable for all IDDM participants. The conclusion that a special program does not elicit beneficial effects in a group of participants as a whole has been supported by findings in other areas of psychological research, e.g., concerning evaluation of education programs for adult diabetics (Schut, 1990) and that of cardiac rehabilitation programs (Uniken Venema-Van Uden, 1990; Zoeteweij et al., 1991).

In addition, the absence of clear effects of home care compared to traditional care may be associated with the complex character of the disease and treatment. As explained in chapter 2, metabolic and psychological characteristics of IDDM patients interact in a complex fashion. Despite the present inclusion of intervening variables in the evaluation of home care versus traditional care, it is conceivable that unknown and individual causes obscured otherwise evident treatment effects in either treatment modality.

Limitations in design and methods of the study

The evaluation of home care versus traditional care in this study has not been without methodological limitations, several of which deserve to be mentioned. First, the study can be criticized for its absence of randomization of patients within hospitals. As explained earlier, such randomization was not considered feasible mainly due to organizational factors. Somewhat unexpectedly, the baseline measurement outcomes revealed that hospital samples differed significantly with respect to psychological and medical functioning. As a consequence for the present study, the analyses concerning effects of home care versus traditional care had to be based on the hospital samples as such. This may have hampered findings of clear treatment effects since the number of hospitals in each treatment program was small.

The measurement instruments employed in this study require comment as well. After completion of the data collection, the HbA1% measurements in the different hospitals appeared not to be fully standardized. HbA1% was assessed in participating hospital laboratories using different procedures. To facilitate comparison of long-term results between hospital samples, it was considered necessary that HbA1-outcomes were standardized by means of a transformation procedure and that these transformed data were evaluated in addition to analyses of original unstandardized HbA1-values. It is evident that the precision of the results was weakened by these measurement shortcomings and that the transformation procedure introduced some bias.

The psychological outcome measures should also be commented upon. The use of the Child Behavior Checklist (CBCL) for measuring behavior problems and social competence can be criticized for being untailored to the evaluation of home care versus traditional care. Consequently, the checklist may have been insensitive to the subtle differences between the treatment strategies. Still, it can be argued that specially designed instruments, e.g., for measuring diabetes knowledge and diabetes adjustment, neither revealed significant differences.

Other measurement instruments, e.g., for measuring self-care and regimen adherence, showed fluctuations in outcomes during the study, revealing that these instruments were appreciably sensitive, apparently identifying short-term shifts of functioning. Possibly, using these instruments the measurement intervals in this study were too wide.

The lack of standardization with respect to implementation of the home-care program into the study design may be criticized. Home visits were guided by the needs of participants and on the initiatives of the nurse-practitioner or paediatricians. This strategy had been deliberately defined in this way to accommodate home care to the individual patient.

Obviously, a disadvantage of this strategy concerns the variable intensity of home care between patients which may unintendedly have influenced responses of participants. Distinct standardization of home care may contribute to more uniformity and to the manifestation of differences.

Despite the above-mentioned limitations, the present differences observed between home-care and traditional care in this study should be considered as mainly insignificant, since important overall-effects of home care itself should have become manifest anyway.

Implications for future research and for IDDM treatment

It would be a mistake if, from this study, the final conclusion would emerge that home care was of no benefit. During the course of the study interviews with many participants showed benefits that should encourage further exploration. In particular, the intriguing question whether home care might be valuable for a subgroup of IDDM patients and their parents, needs further clarification. Future research should focus on the tailoring of clearly defined treatment strategies to patients and vice versa.

Future research into IDDM treatment will gain from methodological improvements and developments in research design. Aims and contents of the treatment program should be defined explicitly. When comparing effects of treatment strategies, strict randomization of patients within hospitals is necessary to establish clearcut presence or absence of effects. Furthermore, the participation of a fairly large number of hospitals, the enrolment of sufficient numbers of patients and the incorporation of sufficient standardization for repeated measurements will be needed to measure the size of treatment effects with sufficient precision. Improved measures of behaviors as well as standardization of metabolic outcomes will further contribute to detailed knowledge of treatment effects.

The results of the present study have particularly indicated that the impact of hospital-dependent variables, such as physician attitude and IDDM paediatric practice, on effects of treatment strategies should be considered carefully in future research.
In addition, the characteristics of participants in a home-care program should be examined. The present study included children with a history of IDDM. It is possible that home care is more effective to newly-diagnosed patients. For those patients, the implementation of home care can prevent hospital admissions necessary to stabilize initial metabolic disregulation. Newly-diagnosed patients and their parents can be educated and supported in the home environment by means of frequent visits of the nurse-practitioner.
For this patient group home care would have major advantages compared to traditional hospital-based care. Therefore, it would be important to focus future research on the effects of home care on newly-diagnosed patients.

In order to optimize IDDM treatment the role of the nurse-practitioner in diabetes care should be considered. The results of this study revealed that behavioral disturbances in IDDM children had not improved at the end of the study as a consequence of a high frequency of home visits by the nurse. Evidently, the nurse's tasks and capacities were not tailored to solving severe psychosocial problems. Additional training for home-visiting nurses is required to optimize the psychosocial effects of a treatment program. In particular, the detection and management of social problems in IDDM children, which are often observed in these children as shown in this study, can be considered as an important task for the home-visiting nurse.

In general, paediatricians consider referral for psychiatric consultation when psychological problems are lasting and threaten the child's health and metabolic stability. As a result, the traditional role of the psychiatrist or psychologist is limited. Further integration of a behavioral specialist into the diabetes health care team has been recommended by several authors (e.g., Johnson, 1980; Van Swet, 1987) to establish effective treatment of psychological problems or, more importantly, to prevent future psychological problems. This, of course, does not imply that every patient should visit a psychiatrist. Instead, the expertise of a behavioral specialist concerning, e.g., developmental issues or physician-patient attitudes, can be integrated in training and education programs of medical staff members and other health care providers (Johnson, 1980; Perrin et al., 1984; Jacobson et al., 1984).

In conclusion, it may be stated that health care providers should consider previously defined patient characteristics and examine the qualities of treatment strategies before referring patients to treatments such as home care, hospital-based care, psychiatric consultation, etc. The tailoring of quality treatments to individual patients will contribute to optimal physical and psychological well-being of IDDM patients.

SAMENVATTING EN CONCLUSIES

Samenvatting

Gedurende de laatste decennia hebben vele studies het complexe beeld van insuline-afhankelijke diabetes mellitus beschreven, dat onder meer gekenmerkt wordt door acute en chronische lichamelijke complicaties en verstrekkende psychologische consequenties als gevolg van zowel de ziekte als van de behandeling. Meer recent wordt er onderzoek verricht naar het optimaliseren van de medische behandeling voor kinderen met diabetes en hun ouders. Thuisbehandeling werd geïntroduceerd als een relatief nieuwe behandelingsstrategie, die voor een belangrijk deel in de thuisomgeving van het kind plaatsvindt. Tot nu toe hebben de eerste studies, hoewel beperkt van omvang, aangetoond dat de effecten van thuisbehandeling veelbelovend zijn.
Het onderhavige onderzoek had ten doel op systematische wijze de thuisbehandeling te evalueren in vergelijking tot de traditionele ziekenhuisbehandeling voor kinderen met diabetes en hun ouders. Er werd verondersteld dat de toepassing van thuisbehandeling de diabeteszorg zou optimaliseren en een gunstig effect zou hebben op het "medisch" en psychologisch functioneren van deelnemers aan het thuisbehandelingsprogramma.

Om inzicht te krijgen in de behoefte aan en de toepassing van thuisbehandeling, is het van belang het klinisch beeld van diabetes te kennen, te weten wat de behandeling inhoudt en te begrijpen wat de psychologische consequenties van diabetes zijn. Het eerste deel van deze dissertatie beschrijft derhalve de kenmerken van diabetes, de mogelijke behandelingsstrategieën en andere belangrijke aandachtspunten in het onderzoeksveld.

In Hoofdstuk 1 worden het klinisch beeld en de levenslange implicaties van diabetes, ontstaan op de kinderleeftijd, samengevat. Insuline-afhankelijke diabetes mellitus is een chronische metabole aandoening die gepaard gaat met lichamelijke acute complicaties en levensbedreigende chronische complicaties op de lange termijn. De behandeling van diabetes omvat complexe zelfcontrole en zelfregulatie, met als doel de bewerkstelliging en handhaving van het kwetsbare evenwicht tussen insulinedosis, dieet en fysieke inspanning, met als uiteindelijk streven het benaderen van normoglycaemie.
Tegenwoordig ondervinden hulpverleners die in hun klinische praktijk bij kinderen met diabetes betrokken zijn een verscheidenheid aan psychologische en sociale problemen bij deze kinderen en hun ouders, welke van invloed zijn op het beloop van de ziekte en de behandeling daarvan.

Hoofdstuk 2 beschrijft een reeks aan studies naar oorzaken en consequenties van diabetes bij kinderen. Ondanks de klinische indrukken, laat het merendeel van de studies zien dat

er geen aanwijzingen zijn voor algemene psychologische stoornissen bij kinderen met diabetes vergeleken met "gezonde" controlegroepen. De meest overtuigende onderzoeksbevindingen tonen echter aan dat kinderen sociale problemen ondervinden, met name in hun relaties met leeftijdsgenoten of met belangrijke andere personen in hun naaste omgeving. Het psychosociaal onderzoek werd vervolgens gericht op subgroepen van kinderen en toonde bijvoorbeeld aan dat kinderen met diabetes vanaf jonge leeftijd, d.w.z. voor het vijfde levensjaar, een hoger risico hebben op neurocognitieve stoornissen.
Inconsistentie in onderzoeksbevindingen naar psychosociale stoornissen bij kinderen met diabetes werden met name toegeschreven aan methodologische tekortkomingen, zoals bijvoorbeeld kleine steekproeven en het retrospectieve karakter van veel studies. Een ander probleem in dit onderzoeksveld bleek de complexe relatie tussen psychosociale en metabole factoren te zijn. Enerzijds konden psychosociale problemen als oorzaak van verstoorde metabole regulatie gedefinieerd worden, terwijl zij anderzijds als een gevolg daarvan aangetoond werden. Bovendien werd verondersteld dat psychosociale problemen en metabole factoren beïnvloed worden door mediërende factoren zoals stress en de trouw aan de diabetesvoorschriften. Verschillende auteurs concludeerden dat longitudinale, prospectieve en systematische studies noodzakelijk zijn om de psychosociale consequenties van diabetes goed in kaart te kunnen brengen.

In Hoofdstuk 3 worden een aantal behandelingsstrategieën voor het reguleren van diabetes beschreven. Technische verbeteringen, een toegenomen verantwoordelijkheid van de patiënt zelf voor zelfzorg en het reguleren van diabetes legden de basis van de tegenwoordige diabeteszorg. Zelfzorgstrategieën, educatieprogramma's en psychosociaal georiënteerde programma's werden ontworpen en toegevoegd om de medische zorg te optimaliseren. Het onderzoek naar de effecten van deze behandelingsstrategieën liet echter uiteenlopende resultaten zien. Een relatief nieuwe benadering werd gekozen in de thuisbehandeling. In deze behandelingsstrategie verschaft een gespecialiseerde verpleegkundige educatie en steun aan kinderen met diabetes en hun ouders in hun thuisomgeving. Voorlopige en (nog) onvolledige onderzoeksresultaten lieten zien dat thuisbehandeling een waardevolle benadering zou kunnen zijn. Systematische evaluatie ontbrak echter tot nu toe en werd nodig geacht om de effecten vast te stellen van thuisbehandeling op metabole regulatie en het psychologisch functioneren van het kind.

In Hoofdstuk 4 worden de doelstellingen en de onderzoeksopzet van een longitudinale en gecontroleerde studie uiteengezet, waaraan meerdere ziekenhuizen hun medewerking verleenden. De belangrijkste vraagstelling van de studie omvatte de evaluatie van thuisbehandeling in vergelijking tot de traditionele ziekenhuiszorg. Drie ziekenhuizen werkten mee in het thuisbehandelingsprogramma als experimentele groep, terwijl drie andere ziekenhuizen opgenomen werden als controlegroep die de traditionele ziekenhuisbehandeling verzorgden. Uitsluitend patiënten met langer bestaande diabetes en in de leeftijd van 5 tot 16 jaar werden opgenomen in de studie; kinderen met recent gediagnosticeerde diabetes werden van deelname aan de studie uitgesloten. Psychologische metingen werden verricht na 9, 19 en 31 maanden na de aanvang van de behandeling. Medische uitkomstvariabelen werden elke drie maanden gemeten tijdens de polikliniekbezoeken, in totaal op 10 meetpunten.

In Hoofdstuk 5 worden de kenmerken van de onderzoeksgroep bij aanvang van de studie beschreven. 104 Kinderen met diabetes en hun ouders namen deel aan de studie. Als gevolg van de niet-gerandomiseerde opzet van de studie werden verschillen tussen deelnemers van verschillende ziekenhuizen uitvoerig bestudeerd en getoetst. Er werden geen significante verschillen gevonden tussen ziekenhuisgroepen voor wat betreft de socio-demografische en aan diabetes gerelateerde gegevens bij aanvang van de studie. Echter, het psychologisch en medisch functioneren liet een aantal significante verschillen zien tussen de ziekenhuisgroepen, die in het algemeen wezen op minder gunstige scores voor de experimentele groep in vergelijking tot de controlegroep. Bij vergelijking van de sociale competentie-scores van alle aan het onderzoek deelnemende kinderen met een op geslacht en leeftijd gematchte steekproef uit de algemene populatie werden significant lagere scores gevonden voor het functioneren van de diabetes-groep.

In Hoofdstuk 6 worden de lange-termijn resultaten van de deelnemers aan de thuisbehandeling vergeleken met de controlegroep en worden de verschillen tussen de groepen beschreven. De diabetes-steekproef als geheel bleek in de loop van het onderzoek een verbetering te laten zien voor wat betreft gedragsscores, kennisnivo en aanpassing aan de diabetes. Andere uitkomsten, zoals trouw aan de diabetesvoorschriften, zelfzorggedrag, HbA1% en insulinedoseringen, lieten schommelingen zien gedurende de studie.
Vervolgens werden analyses verricht om de belangrijkste doelstelling van de studie te onderzoeken: de psychologische en medische verschillen op de lange termijn tussen de thuisbehandelingsgroep en controlegroep. Als gevolg van de niet-gerandomiseerde opzet van de studie werden de uitkomsten geanalyseerd voor elk ziekenhuis afzonderlijk.
Kwantitatieve uitkomstvariabelen werden geanalyseerd met behulp van covariantieanalyses. De resultaten van deze analyses toonden uitsluitend significante verschillen voor de variabele zelfzorggedrag. De deelnemers aan de thuisbehandeling verbeterden hun zelfzorggedrag significant in vergelijking tot de controlegroep (volgens de rapportage van de ouders).

Dichotome uitkomstvariabelen werden onderzocht met behulp van een logistisch regressiemodel met random effecten. Van de 22 geanalyseerde variabelen vertoonden 5 variabelen significant verschillende effecten in de thuisbehandelingsgroep in vergelijking tot de controlegroep. De ouders van de kinderen in de thuisbehandelingsgroep vermeldden een verbeterd zelfzorggedrag en een lagere frequentie van de reguliere polikliniekbezoeken. Anderzijds namen de niet-reguliere polikliniekbezoeken toe in de thuisbehandelingsgroep. Verder rapporteerden de kinderen uit de thuisbehandelingsgroep minder gunstige scores ten aanzien van hun zelfzorggedrag en de beoordeelden zij de kwaliteit van hun insulinespuitplaatsen als minder vergeleken met de controlegroep. Deze laatste bevinding geeft waarschijnlijk weer dat de verpleegkundige die de kinderen thuis bezocht, het controleren van de kwaliteit van de spuitplaatsen als een belangrijke taak zag.
Binnen de thuisbehandelingsgroep als geheel nam het aantal huisbezoeken door de verpleegkundige in de loop van de studie af en nam het aantal telefonische verzoeken om hulp toe.

In Hoofdstuk 7 worden exploratieve analyses beschreven waarin de invloed van de frequentie van het aantal huisbezoeken is onderzocht. Dit in tegenstelling tot voorgaande analyses waarin thuisbehandeling opgevat werd als een eenduidig vastgestelde behandeling. Er werd verondersteld dat een ongunstige score aan het begin van de studie een hoger aantal huisbezoeken zou teweegbrengen, terwijl frequente huisbezoeken, op verzoek van de ouders of op initiatief van de verpleegkundige, een gunstig effect zouden hebben op de uitkomsten aan het eind van de studie.
Correlatieanalyses bevestigden deze hypothese ten dele. De resultaten lieten zien dat gedragsproblemen, lagere scores voor zelfzorggedrag en voor kennis van diabetes bij zowel kinderen als ouders bij aanvang van de studie een samenhang vertoonden met een groter aantal huisbezoeken. Echter, aan het eind van de studie bleek dat een groter aantal huisbezoeken gerelateerd was aan ongunstige uitkomsten. Met name lagere scores voor zelfzorggedrag, zoals gerapporteerd door de kinderen zelf, werden ook na een groot aantal huisbezoeken nog gevonden. Anderzijds lieten activiteitsscores betreffende vrijetijdsbesteding van de kinderen zien dat een hogere frequentie van huisbezoeken gerelateerd was aan gunstige uitkomsten aan het eind van de studie.
Exploratieve analyses naar de bijdragen van huisbezoeken aan de verandering in uitkomstscores lieten geen significante resultaten zien. In de context van de bovengenoemde bevindingen werd de rol van de verpleegkundige besproken.

Conclusies

De resultaten van de studie zullen in deze paragraaf nader belicht worden en in een breder perspectief geplaatst worden. Verder worden methodologische kanttekeningen bij het onderzoek beschreven en worden suggesties voor toekomstig onderzoek en voor een optimale diabetesbehandeling gegeven.

Ondanks de inspanningen die geleverd zijn in het thuisbehandelingsprogramma heeft het onderzoek slechts enkele significante verschillen opgeleverd voor de thuisbehandelingsgroep in vergelijking tot een controlegroep gedurende een follow-up periode van 31 maanden. Deze uitkomst vraagt om een nadere beschouwing.

Het geringe aantal significante verschillen tussen experimentele en controlegroep suggereert dat zowel het thuisbehandelingsprogramma als de traditionele ziekenhuiszorg voldoende waarborg biedt voor het bereiken en handhaven van een bepaald (adequaat) nivo van functioneren in beide groepen patiënten. Dit betekent echter niet dat elke behandelingsstrategie geschikt zou zijn voor alle diabetespatiënten. Het moge duidelijk zijn dat een behandelingswijze voldoende kwaliteit moet bieden en moet voldoen aan bepaalde voorwaarden, bijvoorbeeld deskundige medische behandeling, aandacht en ondersteuning, om een geschikte behandelingsmethode te kunnen zijn voor kinderen met diabetes en hun ouders. Blijkbaar voldeden de behandelingsmethoden die in deze studie geëvalueerd werden beiden voldoende aan deze voorwaarden waardoor vergelijkbare waarden werden gevonden voor het functioneren van kinderen en ouders. Bovendien dient hierbij in gedachten gehouden te worden dat de kinderen gemiddeld 4 jaar diabetes hadden. In deze studie hadden we aldus te maken met kinderen die in het algemeen gedurende langere tijd vertrouwd waren met diabetes en op enigerlei wijze zich aangepast hadden aan de ziekte.

Bovendien roepen de uitkomsten van de studie de vraag op of de vergeleken behandelingsmethoden zich voldoende van elkaar onderscheiden om significante verschillen teweeg te brengen tussen relatief kleine groepen kinderen bij een klein aantal ziekenhuizen. Immers, beide behandelingsmethoden streven naar stabiele metabole regulatie en psychologisch welbevinden en beide methoden hebben in hun programma educatie betreffende zelfcontrole en zelfregulatie opgenomen. De mate van overeenstemming tussen de behandelingsmethoden heeft mogelijk voorkomen dat significante verschillen in effecten van de behandeling bij follow-up naar voren kwamen.

Deze overwegingen geven aanleiding om te stellen dat, naast de behandelingsaspecten, de kenmerken en kwaliteiten van professionele hulpverleners van het grootste belang zijn om een gunstig metabole regulatie en psychologisch functioneren bij kinderen met diabetes te bewerkstelligen.

De resultaten van deze studie geven duidelijke verschillen te zien tussen de onderzoeksgroepen van de verschillende ziekenhuizen aan het begin van de studie. Deze verschillen impliceren dat ziekenhuis-afhankelijke factoren een belangrijke invloed hebben op het psychologisch en medisch functioneren van patiënten. Andere auteurs hebben verondersteld dat de behandelingsattitude in het algemeen en de individuele behandeling van de kinderarts verantwoordelijk zijn voor de gevonden verschillen in functioneren tussen ziekenhuisgroepen (Kaplan et al., 1989; Linn et al., 1982: Dugdale et al., 1977). Bovendien zou, in breder perspectief, het ziekenhuisbeleid en de organisatiestruktuur van invloed zijn op de behandelingsmethoden en dientengevolge op de uitkomsten van onderzoek.
In elk geval kunnen de verschillen tussen de ziekenhuisgroepen, geobserveerd bij aanvang van de studie, enkele van de inconsistente resultaten verklaren in het psychologisch en medisch functioneren van kinderen. Zover wij weten heeft onderzoek naar de psychologische en medische kenmerken van kinderen met diabetes niet eerder expliciet rekening gehouden met de invloed van dergelijke ziekenhuis- of behandelingsfactoren.
Naast het ziekenhuis-afhankelijke karakter van de resultaten is het van belang op te merken dat de resultaten waarschijnlijk sterk samenhangen met de attitude en andere specifieke kenmerken van de verpleegkundige die in dit onderzoek betrokken was. Derhalve is een vergelijking van de resultaten met andere studies nauwelijks mogelijk en kunnen de gegevens slechts beperkt gegeneraliseerd worden.

Hoewel de psychologische en medische voordelen van thuisbehandeling vergeleken met de traditionele behandeling op basis van de bovengenoemde resultaten gering lijken, gaven een aanzienlijk aantal van de deelnemers aan de thuisbehandeling blijk van hun tevredenheid over de behandeling en noemden zij belangrijke voordelen van de methode. Het is denkbaar dat thuisbehandeling tevredenheid bij de deelnemers teweegbracht en tegelijkertijd onverwachte psychologische en medische uitkomsten gaf. Als voorbeeld kan de veronderstelling genoemd worden dat thuisbehandeling het aantal niet-reguliere polikliniekbezoeken zou doen verminderen. De resultaten laten echter zien dat het aantal niet-reguliere huisbezoeken van de thuisbehandelingsgroep juist toenam vergeleken met de controlegroep. Deze "ongunstige" uitkomst laat mogelijk een onvoorzien effect van de behandeling zien, bijvoorbeeld de verlaging van de drempel voor polikliniekbezoeken. Op deze wijze zou het tegelijk voorkomen van tevredenheid met de behandeling en de afwezigheid van "gunstige" uitkomsten verklaard kunnen worden. Deze uitkomst geeft tevens aan dat de doelstellingen van thuisbehandeling in overeenstemming met patiënten, ouders, artsen en andere hulpverleners vastgesteld moeten worden. De doelstellingen van de meest bij de behandeling betrokkenen komen echter lang niet altijd overeen (Schut, 1990).

De geobserveerde verschillen voor wat betreft (on)tevredenheid met de behandeling kunnen beschouwd worden als een signaal dat thuisbehandeling wenselijk is voor een subgroep van patiënten en ouders. Voorlopige resultaten laten geen duidelijk patroon van kenmerken zien die aangeven welke gezinnen het thuisbehandelingsprogramma waardeerden en welke bezwaar maakten tegen het programma. Omdat een minderheid van de deelnemers aan het programma niettemin bezwaren vermeldde, wordt de conclusie gesteund dat thuisbehandeling niet geschikt is voor alle deelnemers. De bevinding dat een speciaal behandelingsprogramma geen positieve effecten heeft voor een onderzoeksgroep als geheel werd ook al bevestigd door onderzoeksresultaten in andere gebieden van psychologisch onderzoek, zoals bijvoorbeeld in het evaluatie-onderzoek naar educatieprogramma's voor volwassen diabeten (Schut, 1990) en in het onderzoek naar de effecten van cardiologische revalidatieprogramma's (Uniken Venema-van Uden, 1990; Zoeteweij et al., 1991).

Tenslotte kan gesteld worden dat de afwezigheid van duidelijke effecten van thuisbehandeling in vergelijking met de traditionele behandeling samenhangt met het complexe karakter van diabetes en de behandeling. Zoals beschreven in hoofdstuk 2 interacteren metabole regulatie en psychologische kenmerken van diabetespatiënten op ingewikkelde wijze. Ondanks de inclusie van interveniërende variabelen in de evaluatie van thuisbehandeling versus traditionele behandeling is het mogelijk dat (tot nog toe) onbekende en individuele mediatoren duidelijke effecten van (één van beide) behandelingswijzen verhuld hebben.

Kanttekeningen bij de opzet en methoden van het onderzoek

Enkele methodologische kanttekeningen kunnen vermeld worden bij de evaluatie van thuisbehandeling versus traditionele behandeling in dit onderzoek.
Zoals eerder beschreven ontbrak randomisatie van patiënten binnen ziekenhuizen in deze studie; een dergelijke randomisatie was niet mogelijk vanwege redenen van voornamelijk organisatorische aard.
Enigszins onverwacht lieten de resultaten bij aanvang van de studie zien dat de ziekenhuisgroepen significant verschilden voor wat betreft psychologisch en medisch functione-

ren van de deelnemers. Voor de studie had dit tot gevolg dat analyses betreffende de effecten van thuisbehandeling versus traditionele behandeling gebaseerd moesten worden op de ziekenhuisgroepen als zodanig. Deze benadering kan de manifestatie van duidelijke behandelingseffecten beperkt hebben, aangezien het aantal ziekenhuizen in elk behandelingsprogramma klein was.

De meetinstrumenten die gebruikt werden in het onderzoek kunnen eveneens kritisch beschouwd worden. Nadat de dataverzameling gecompleteerd was, bleek dat de HbA1%-metingen in de diverse ziekenhuizen niet volledig gestandaardiseerd plaatsvonden. HbA1% werd gemeten met verschillende procedures in de verschillende ziekenhuislaboratoria. Om de vergelijking van de lange-termijn-resultaten tussen de ziekenhuizen mogelijk te maken, werd het noodzakelijk geacht de HbA1-uitkomsten te standaardiseren door middel van een transformatieprocedure. Verder werd besloten de getransformeerde gegevens te evalueren naast de analyses van de originele ongestandaardiseerde HbA1-waarden. Het moge duidelijk zijn dat de nauwkeurigheid van de resultaten verminderd werd door deze tekortkomingen in de meetprocedures van HbA1% en dat de transformatieprocedure mogelijk enige bias heeft geïntroduceerd.
De psychologische uitkomstmaten vragen tevens om een kritische beschouwing. Voor de Gedragsvragenlijst voor kinderen (CBCL) geldt dat de lijst niet primair bedoeld is voor het evalueren van thuisbehandeling versus traditionele behandeling. Als gevolg hiervan kan gesteld worden dat de lijst mogelijk onvoldoende gevoelig was voor de subtiele verschillen tussen behandelingsmethoden. Anderzijds kan beargumenteerd worden dat speciaal ontworpen instrumenten, zoals bijvoorbeeld voor het meten van diabetes-kennis en diabetes-aanpassing, ook geen significante verschillen tussen behandelingsstrategieën lieten zien. Andere meetinstrumenten, bijvoorbeeld instrumenten die zelfzorg en trouw aan leefregels meten, vertoonden schommelingen in de uitkomsten gedurende de studie, daarmee aangevende dat deze instrumenten juist gevoelig waren voor korte-termijn veranderingen in functioneren. Mogelijk waren de periodes tussen de metingen voor het gebruik van deze meetinstrumenten te groot.

Het ontbreken van een gestandaardiseerd protocol voor de uitvoering van de thuisbehandeling kan als een beperking van het onderzoek genoemd worden. Huisbezoeken vonden plaats op geleide van de deelnemers of op initiatief van de verpleegkundige of kinderarts. Deze strategie was juist verkozen om de thuisbehandeling zo goed mogelijk af te kunnen stemmen op de individuele patiënt. Een nadelig gevolg hiervan was de wisselende intensiteit van de thuisbehandeling waardoor de responses van deelnemers beïnvloed zijn. Expliciete standaardisatie van thuisbehandeling is nodig om uniformiteit te waarborgen en om manifestatie van verschillen tussen behandelingsstrategieën mogelijk te maken.

Ondanks de hiervoor genoemde kanttekeningen kan gesteld worden dat de gepresenteerde verschillen tussen thuisbehandeling en traditionele behandeling voornamelijk als insignificant beschouwd kunnen worden. Immers, belangrijke overall-verschillen tussen behandelingsmethoden zouden ondanks methodologische beperkingen naar voren zijn gekomen.

Implicaties voor toekomstig onderzoek en voor de behandeling van diabetes.

Het zou onjuist zijn uit deze studie te concluderen dat thuisbehandeling geen voordelen te bieden heeft. Gedurende het onderzoek hebben vele deelnemers aan de thuisbehandeling voordelen van de methode genoemd, die verdere exploratie en toepassing rechtvaardigen. Met name de intrigerende vraag of thuisbehandeling voor een subgroep van kinderen met diabetes en hun ouders waardevol zou kunnen zijn vraagt om nader onderzoek. Toekomstig onderzoek zou zich vooral moeten richten op het afstemmen van vastomlijnde behandelingsstrategieën op individuele patiënten en vice versa.

Toekomstig evaluatie-onderzoek naar de behandeling van diabetes zou gebaat zijn bij methodologische verbeteringen ten aanzien van de onderzoeksopzet. Het verdient aanbeveling de doelstellingen en inhoud van een behandelingsprogramma vooraf expliciet vast te leggen. Wanneer de effecten van verschillende behandelingsmethoden vergeleken worden, is randomisatie van patiënten binnen ziekenhuizen noodzakelijk om de aan- of afwezigheid van effecten duidelijk te kunnen aantonen. Verder is deelname van een redelijk aantal ziekenhuizen, een voldoende aantal patiënten en van voldoende gestandaardiseerde effectmaten een voorwaarde om behandelingseffecten met voldoende nauwkeurigheid te kunnen vaststellen. Een verbetering van gedragsinstrumenten als ook de standaardisatie van metabole effectmaten zullen tevens bijdragen aan meer gedetailleerde kennis van behandelingseffecten.

De resultaten van de onderhavige studie hebben met name laten zien dat de invloed van ziekenhuis-afhankelijke variabelen, zoals bijvoorbeeld de attitude van de arts en diens uitvoering van de behandeling, op effecten van behandelingsmethoden zorgvuldig meegewogen moeten worden in toekomstig onderzoek. Bovendien zouden de kenmerken van deelnemers aan een thuisbehandelingsprogramma nader in ogenschouw genomen kunnen worden. In de huidige studie waren kinderen opgenomen met een langer bestaande diabetes. Het is mogelijk dat thuisbehandeling effectiever is voor kinderen met recent gediagnosticeerde diabetes. Voor deze laatste groep van patiënten kan de toepassing van thuisbehandeling betekenen dat ziekenhuisopname vanwege metabole disregulatie na diagnose voorkomen kan worden. Juist recent gediagnosticeerde patiënten en hun ouders kunnen hun voordeel doen met educatie en steun, ontvangen in de thuisomgeving door middel van regelmatige bezoeken van de verpleegkundige. Voor deze patiëntengroep kan de thuisbehandeling grote voordelen bieden in vergelijking tot de traditionele ziekenhuiszorg. Derhalve is het belangrijk dat toekomstig onderzoek zich juist richt op de effecten van thuisbehandeling bij recent gediagnosticeerde patiënten.

Om de diabetesbehandeling te kunnen optimaliseren zou ook de rol van de verpleegkundige nader bekeken kunnen worden. De resultaten van dit onderzoek laten zien dat gedragsproblemen in het algemeen niet verbeterden als gevolg van een hogere frequentie aan huisbezoeken. Het moge duidelijk zijn dat de taken en capaciteiten van de verpleegkundige ook niet primair geschikt waren voor het oplossen van psychosociale problemen. Derhalve zou aanvullende training voor de verpleegkundige op psychosociaal gebied belangrijk kunnen zijn om de effecten van een behandelingsprogramma te optimaliseren. Met name het opsporen van en oplossingen bieden voor sociale problemen bij jeugdigen, één van de belangrijkste problemen bij kinderen met diabetes zoals ook uit deze studie blijkt, zou een belangrijke taak voor de diabetesverpleegkundige kunnen zijn.

In het algemeen overwegen kinderartsen verwijzing voor psychiatrische consultatie, wanneer psychologische problemen al enige tijd voortduren en de gezondheid van het kind en metabole regulatie bedreigen. Als gevolg hiervan is de traditionele rol van de psycholoog of psychiater beperkt. Verdere integratie van de gedragsspecialist in de diabetes gezondheidszorg werd al aanbevolen door andere auteurs (e.g., Johnson, 1980; Van Swet, 1987) om een effectieve behandeling van psychologische problemen te bewerkstelligen of, nog belangrijker, om toekomstige psychologische problemen te voorkomen.
Dit betekent overigens niet dat elke patiënt verwezen moet worden naar een psychiater. Integendeel, het zou geschikter zijn wanneer de kennis en ervaring van de gedragsspecialist, bijvoorbeeld op het gebied van ontwikkelingsvraagstukken en betreffende arts-patiënt attitudes, meer geïntegreerd zouden worden in training en educatie van medische stafleden en andere hulpverleners (Johnson, 1980; Perrin et al., 1984; Jacobson et al., 1984).

Als conclusie kan gesteld worden dat hulpverleners kenmerken van kinderen met diabetes en hun ouders op voorhand zouden moeten beschouwen evenals de kwaliteiten van behandelingsmethoden voor patiënten, vóór zij patiënten toewijzen aan behandelingsprogramma's zoals thuisbehandeling, traditionele ziekenhuisbehandeling, psychiatrische consultatie, enz. Het afstemmen van kwaliteitsbehandelingen op individuele patiënten zal van het grootste belang zijn voor een optimale metabole regulatie en voor het psychologisch welbevinden van kinderen met diabetes.

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APPENDICES

V. **1. About how many close friends does your child have?** ☐ None ☐ 1 ☐ 2 or 3 ☐ 4 or more

2. About how many times a week does your child do things with them? ☐ less than 1 ☐ 1 or 2 ☐ 3 or more

---

VI. **Compared to other children of his/her age, how well does your child:**

	Worse	**About the same**	**Better**
a. Get along with his/her brothers & sisters?	☐	☐	☐
b. Get along with other children?	☐	☐	☐
c. Behave with his/her parents?	☐	☐	☐
d. Play and work by himself/herself?	☐	☐	☐

VII. **1. Current school performance—for children aged 6 and older:**

☐ Does not go to school

	Failing	**Below average**	**Average**	**Above average**
a. Reading or English	☐	☐	☐	☐
b. Writing	☐	☐	☐	☐
c. Arithmetic or Math	☐	☐	☐	☐
d. Spelling	☐	☐	☐	☐
Other academic subjects—for example: history, science, foreign language, geography. e. ________	☐	☐	☐	☐
f. ________	☐	☐	☐	☐
g. ________	☐	☐	☐	☐

2. Is your child in a special class?

☐ No ☐ Yes—what kind?

3. Has your child ever repeated a grade?

☐ No ☐ Yes—grade and reason

4. Has your child had any academic or other problems in school?

☐ No ☐ Yes—please describe

When did these problems start?

Have these problems ended?

☐ No ☐ Yes—when?

VIII. Below is a list of items that describe children. For each item that describes your child **now or within the past 6 months**, please circle the 2 if the item is **very true or often true** of your child. Circle the 1 if the item is **somewhat or sometimes true** of your child. If the item is **not true** of your child, circle the 0. Please answer all items as well as you can, even if some do not seem to apply to your child.

0 = Not True (as far as you know) **1 = Somewhat or Sometimes True** **2 = Very True or Often True**

0 1 2 1. Acts too young for his/her age 16
0 1 2 2. Allergy (describe): ____________
____
0 1 2 3. Argues a lot
0 1 2 4. Asthma
0 1 2 5. Behaves like opposite sex 20
0 1 2 6. Bowel movements outside toilet
0 1 2 7. Bragging, boasting
0 1 2 8. Can't concentrate, can't pay attention for long
0 1 2 9. Can't get his/her mind off certain thoughts; obsessions (describe): ____________
____
0 1 2 10. Can't sit still, restless, or hyperactive 25
0 1 2 11. Clings to adults or too dependent
0 1 2 12. Complains of loneliness
0 1 2 13. Confused or seems to be in a fog
0 1 2 14. Cries a lot
0 1 2 15. Cruel to animals 30
0 1 2 16. Cruelty, bullying, or meanness to others
0 1 2 17. Day-dreams or gets lost in his/her thoughts
0 1 2 18. Deliberately harms self or attempts suicide
0 1 2 19. Demands a lot of attention
0 1 2 20. Destroys his/her own things 35
0 1 2 21. Destroys things belonging to his/her family or other children
0 1 2 22. Disobedient at home
0 1 2 23. Disobedient at school
0 1 2 24. Doesn't eat well
0 1 2 25. Doesn't get along with other children 40
0 1 2 26. Doesn't seem to feel guilty after misbehaving
0 1 2 27. Easily jealous
0 1 2 28. Eats or drinks things that are not food (describe): ____________
____
0 1 2 29. Fears certain animals, situations, or places, other than school (describe): ____________
____
0 1 2 30. Fears going to school 45
0 1 2 31. Fears he/she might think or do something bad
0 1 2 32. Feels he/she has to be perfect
0 1 2 33. Feels or complains that no one loves him/her
0 1 2 34. Feels others are out to get him/her
0 1 2 35. Feels worthless or inferior 50
0 1 2 36. Gets hurt a lot, accident-prone
0 1 2 37. Gets in many fights
0 1 2 38. Gets teased a lot
0 1 2 39. Hangs around with children who get in trouble
0 1 2 40. Hears things that aren't there (describe): ____________
____________ 55
0 1 2 41. Impulsive or acts without thinking
0 1 2 42. Likes to be alone
0 1 2 43. Lying or cheating
0 1 2 44. Bites fingernails
0 1 2 45. Nervous, highstrung, or tense 60
0 1 2 46. Nervous movements or twitching (describe): ____________
____
0 1 2 47. Nightmares
0 1 2 48. Not liked by other children
0 1 2 49. Constipated, doesn't move bowels
0 1 2 50. Too fearful or anxious 65
0 1 2 51. Feels dizzy
0 1 2 52. Feels too guilty
0 1 2 53. Overeating
0 1 2 54. Overtired
0 1 2 55. Overweight 70
56. Physical problems without known medical cause:
0 1 2 a. Aches or pains
0 1 2 b. Headaches
0 1 2 c. Nausea, feels sick
0 1 2 d. Problems with eyes (describe): ____________
0 1 2 e. Rashes or other skin problems 75
0 1 2 f. Stomachaches or cramps
0 1 2 g. Vomiting, throwing up
0 1 2 h. Other (describe): ____________
____

PAGE 3

Please see other side

0 = Not True (as far as you know)   1 = Somewhat or Sometimes True   2 = Very True or Often True

0 1 2 57. Physically attacks people
0 1 2 58. Picks nose, skin, or other parts of body (describe): ________
________ 80

0 1 2 59. Plays with own sex parts in public 16
0 1 2 60. Plays with own sex parts too much

0 1 2 61. Poor school work
0 1 2 62. Poorly coordinated or clumsy

0 1 2 63. Prefers playing with older children 20
0 1 2 64. Prefers playing with younger children

0 1 2 65. Refuses to talk
0 1 2 66. Repeats certain acts over and over; compulsions (describe): ________
____

0 1 2 67. Runs away from home
0 1 2 68. Screams a lot 25

0 1 2 69. Secretive, keeps things to self
0 1 2 70. Sees things that aren't there (describe):
____
____

0 1 2 71. Self-conscious or easily embarrassed
0 1 2 72. Sets fires

0 1 2 73. Sexual problems (describe):
____
________ 30

0 1 2 74. Showing off or clowning

0 1 2 75. Shy or timid
0 1 2 76. Sleeps less than most children

0 1 2 77. Sleeps more than most children during day and/or night (describe): ________
____

0 1 2 78. Smears or plays with bowel movements 35

0 1 2 79. Speech problem (describe): ________
____

0 1 2 80. Stares blankly

0 1 2 81. Steals at home
0 1 2 82. Steals outside the home

0 1 2 83. Stores up things he/she doesn't need (describe):
________ 40

0 1 2 84. Strange behavior (describe): ________
____

0 1 2 85. Strange ideas (describe):
____

0 1 2 86. Stubborn, sullen, or irritable

0 1 2 87. Sudden changes in mood or feelings
0 1 2 88. Sulks a lot 45

0 1 2 89. Suspicious
0 1 2 90. Swearing or obscene language

0 1 2 91. Talks about killing self
0 1 2 92. Talks or walks in sleep (describe):
____

0 1 2 93. Talks too much 50
0 1 2 94. Teases a lot

0 1 2 95. Temper tantrums or hot temper
0 1 2 96. Thinks about sex too much

0 1 2 97. Threatens people
0 1 2 98. Thumb-sucking 55

0 1 2 99. Too concerned with neatness or cleanliness
0 1 2 100. Trouble sleeping (describe):
____

0 1 2 101. Truancy, skips school
0 1 2 102. Underactive, slow moving, or lacks energy

0 1 2 103. Unhappy, sad, or depressed 60
0 1 2 104. Unusually loud

0 1 2 105. Uses alcohol or drugs (describe):
____

0 1 2 106. Vandalism

0 1 2 107. Wets self during the day
0 1 2 108. Wets the bed 65

0 1 2 109. Whining
0 1 2 110. Wishes to be of opposite sex

0 1 2 111. Withdrawn, doesn't get involved with others
0 1 2 112. Worrying

113. Please write in any problems your child has that were not listed above:
0 1 2 ________ 70
0 1 2 ________
0 1 2 ________

PLEASE BE SURE YOU HAVE ANSWERED ALL ITEMS.   PAGE 4   UNDERLINE ANY YOU ARE CONCERNED ABOUT.

A2. School absence (item added to Child Behavior Checklist)
Did your child stay away from school during the past year?
No
Yes, how many days? ....
why? ....

A3. *Self-care*
In semi-structured interview with the parents:
During the past three months:
1. Who injects insulin? child / parent or other
2. Who monitors blood-glucose control? child / parent or other
3. Does your child handle diet guidelines at right points of time? yes, independently/ no
   ....
4. Does your child handle extra food intake at right points of time? yes, independently/ no
   ....
5. Does your child handle insulin injections at right points of time? yes, independently/ no
   ....
6. Does your child handle blood glucose monitoring at right points of time?
   yes, independently/ no
   ....
7. What do you do when your child reports symptoms of near-hypoglycaemia (headache, paleness, etc.)?
   ....
8. What do you do when your child experiences a severe hypo (dizziness, faintness)?
   ....

Items 3, 4, 5 and 6 comprise the self-care scale.

In semi-structured interview with the child:
During the past three months:
9. Who injects insulin? child / parent or other
10. What do you do when you feel symptoms of a hypo (headache, paleness, etc.)?
    ....

A4. *Regimen adherence*
In semi-structured interview with the parents:
1. Does your child adhere to diet guidelines? always/sometimes/scarcely
   ....
2. Does your child handle extra food intake at right points of time? always/sometimes/scarcely
   ....
3. Does your child handle insulin injections at right points of time? always/sometimes/scarcely
   ....
4. Does your child handle blood-glucose monitoring at right points of time?
   always/sometimes/scarcely
   ....

A5. *Child adjustment to IDDM*

Written questionnaire:

1. I am always hungry yes / ? / no
2. I enjoy eating sweets yes / ? / no
3. I don't like insulin injections yes / ? / no
4. I don't like pricking to control bloodsugar yes / ? / no
5. Sometimes I get sick yes / ? / no
6. I have to go to the bathroom more than other students yes / ? / no
7. I am always thirsty yes / ? / no
8. I don't like birthday parties yes / ? / no
9. I have thought about calling the children's telephone service yes / ? / no
10. I don't like to talk about diabetes yes / ? / no
11. I enjoy eating with my friends yes / ? / no
12. My friends come often to my place to play yes / ? / no
13. I prefer playing on my own yes / ? / no
14. I often quarrel with my friends yes / ? / no
15. I don't like school yes / ? / no
16. I told my friends at school that I have diabetes yes / ? / no
17. I dislike to celebrate my birthday at school yes / ? / no
18. I like my mother or father to give the insulin injections yes / ? / no
19. I know quite well what I may eat yes / ? / no
20. I like gymnastics yes / ? / no
21. I don't like swimming yes / ? / no
22. I keep my promises yes / ? / no
23. Sometimes unpleasant duties have to be done yes / ? / no

The scores of items (scores 3, 2, or 1) are added up; a high total score means good adjustment to IDDM

In semi-structured interview with the parents:

Can you observe distress in your child as a result of having diabetes?

24. Yes, aggressive behavior: ....
25. Yes, withdrawal: ....
26. Yes, depression: ....
27. No, well adjusted behavior: ....

A6. *Parental adjustment to IDDM*
Written questionnaire:

1. I know more than anyone else about how to take care of my child's diabetes yes / ? / no
2. I worry about my child with diabetes more than I do about anyone else in the family yes / ? / no
3. Sometimes I think that diabetes is God's punishment for peoples sins yes / ? / no
4. I only tell people about my child's diabetes, when I really have to yes / ? / no
5. Lots of things are worse than having diabetes yes / ? / no
6. Sometimes I worry that my child will get complications from diabetes yes / ? / no
7. I suspect that my child eats candy, cake or cokes without telling me yes / ? / no
8. To keep from having problems. the only things my child needs are nourishment and a chance to relax yes / ? / no
9. My child's diabetes limits the time we have to do other things we enjoy as a family yes / ? / no
10. My child with diabetes will probably be able to live on his/her own yes / ? / no
11. Doctors and nurses really understand what it is like to live with diabetes yes / ? / no
12. My child get fewer invitations to go places because people think that (s)he is going to get sick yes / ? / no
13. Most people think that kids with diabetes are handicapped yes / ? / no
14. I can handle my child's diabetes myself without help from anyone else yes / ? / no
15. We don't go to restaurants that often because our child has diabetes yes / ? / no
16. Children with diabetes must go to bed earlyin order to stay healthy yes / ? / no
17. We have had problems making vacation plans because of our child's diabetes yes / ? / no
18. Anyone can tell that my child has diabetes yes / ? / no
19. It's up to the doctors to find out how to control my child's diabetes yes / ? / no
20. Kids without diabetes can do much more than my child, who has the illness yes / ? / no
21. A child with diabetes should see a doctor at least once every month yes / ? / no
22. A parent can't be too careful when a child has diabetes yes / ? / no
23. My child sometimes eats too many sweets yes / ? / no
24. I watch everything my child eats yes / ? / no
25. Children are cruel to my child when they find out (s)he has diabetes yes / ? / no
26. I know there are times when my child tries to use diabetes to get his/her way yes / ? / no
27. My child likes me to give his/her shots even though (s)he can do it by his/her self yes / ? / no
28. At times I am unsure if my child's physical complaints are real or exaggerated yes / ? / no
29. People who know my child has diabetes treat us differently yes / ? / no
30. If my child gets more serious health problems in the future it will be my fault because I failed to take good enough care of his/her diabetes yes / ? / no
31. Diabetes limits the amount of independence I can permit my child yes / ? / no
32. My child can do anything as well as anybody yes / ? / no
33. I pay close attention to my child's sugar levels yes / ? / no
34. The diabetes doctors know less about the illness than I do yes / ? / no
35. I keep track of how often my child goes to the bathroom yes / ? / no
36. Sometimes my child tries to convince hard work is bad for people who have diabetes yes / ? / no
37. Hospitals are for people who have problems controlling their diabetes by themselves yes / ? / no
38. Most employers don't like to hire people with diabetes yes / ? / no
39. My child's health is in the hands of others yes / ? / no
40. I would rather my child be seen by a family doctor than in a special diabetes clinic yes / ? / no

The scores of items (scores 3 ,2 or 1) are added up; a high total score means poor adjustment.

A7. *Child knowledge about IDDM*
Written questionnaire:

1. Can you tell me what diabetes is?
   ....
2. Insulin causes a rise or lowering in blood sugar levels?
   ....
3. What should you do when you fill dizzy?
   ....
4. What should you do when you are thirsty and go often to the bathroom?
   ....
5. Why do you need to know your blood sugar level?
   ....
6. What are acceptable blood sugar levels?
   ....
7. What is a hypo?
   ....
8. May children with diabetes participate in sports?
   ....
9. How do you get lumps after injecting insulin?
   ....
10. Do you need to inject yourself when you are sick?
    ....

A8. *Parental Knowledge about IDDM*
Written questionnaire:

1. What is diabetes?
   a. The pancreas produces too much insulin
   b. The pancreas produces too little insulin
   c. The pancreas produces too much glucose
   d. The pancreas produces too little glucose
   e. I don't know

2. a. Insulin provides a rise in blood glucose levels
   b. Insulin provides a lowering in blood glucose levels
   c. Insulin provides stable blood glucose levels
   d. I don't know

3. When your child is dizzy and pale, (s)he should
   a. lie down and go to sleep
   b. take extra food
   c. inject additional insulin
   d. I don't know

4. When your child is thirsty and goes often to the bathroom, (s)he should
   a. inject additional insulin
   b. inject less insulin than in normal circumstances
   c. drink more water
   d. I don't know

5. Acceptable blood sugars are
   a. less than 4
   b. 4-10
   c. 10-20
   d. I don't know

6. When your child feels a hypo, than there is
   a. a surplus of insulin in the body
   b. a shortage of insulin in the body
   c. I don't know

7. Are children with diabetes allowed to participate in sports?
   a. Yes
   b. No
   c. I don't know

8. How do lumps emerge after insulin injection?
   a. Wrong injection technique
   b. Too often usage of the same injection sites
   c. Alternative a and b are both correct
   d. I don't know

9. Does your child need insulin injections when (s)he is sick?
   a. Yes
   b. No
   c. I don't know

A9. *Parental concerns about the future*
In semi-structured interview with the parents:
Do you worry about the future of your child? no / ? / yes
If yes, about which aspects do you worry most?
....

A10. *Treatment satisfaction* (at second psychological measurement)
In semi-structured interview with the parents:
Did you value the home-care program ? ....
If yes, which aspects did you value most?
....
If no, which objections would you like to make?
....

Medical variables

A11. *Metabolic control, insulin dosage per weight and ratio weight/height*
These medical variables were documented during outpatient visits to the clinic using a hospital form.

A12. *Frequency of outpatient clinic visits*
Number of regular or planned outpatient visits: ....
Number of acute or non-planned outpatient visits: ....

A13. *Hospital admission rate*
Hospital admission rate during a period of nine months: ....

A14. *Hypoglycaemias*
Number of hypoglycaemias during a period of three months prior to the first measurement: ....

A15. *Quality of injection sites*
In semi-structured interview with the child:
Do you consider your injection sites as acceptable,
moderate
or poor?

Intervening variables

A16. *Life events*
In semi-structured interview with the parents:
Describe life events in your child's life during the year prior to the study?
....

A17. *Extra-education*
In semi-structured interview with the parents:
Did you participate in extra-curricular programs, information courses, self-care training programs, etc. prior to the study?
....

A18. *Membership of DVN*
In semi-structured interview with the parents:
Are you a member of the patient organization DVN? yes / no

A19. *Interviewer*
Interviewer: A, B, C, D.

A20. *Socio-demographic data*
In semi-structured interview with the parents:
Gender: male / female
Date of birth: ../../19..
School: ....
Father's type of work: ....

A21. *IDDM-related initial data*
In semi-structured interview with the parents:
Age at diabetes onset: ....
Duration of IDDM: ....
General health status of the child: ....
Other disease or handicap? ....

A22. *Descriptive measures of home care (at the second psychological measurement)*
Number of home visits: ....
Home visits requested by parents, child, family: ....
Home visits initiated by the nurse or paediatrician: ....
Reasons for home visits: ....
Number of telephone calls: ....
Reasons for telephone calls: ....

APPENDIX B. TRANSFORMATION PROCEDURE FOR HBA1%

The HbA1-percentages of each hospital sample were transformed by means of linear regression to the values of hospital 1.

a = HbA1% of IDDM children of home-care hospital 1
b = HbA1% of IDDM children of one of the five other hospitals

home-care hospital 2: $a = 1.07978 + 0.96656 \times b$ $R^2 = 0.93$
home-care hospital 3: $a = -0.37223 + 0.91109 \times b$ $R^2 = 0.98$
control hospital 4 : $a = 1.33764 + 0.84549 \times b$ $R^2 = 0.97$
control hospital 5 : $a = -0.07557 + 0.61499 \times b$ $R^2 = 0.98$
control hospital 6 : $a = -2.23338 + 1.23628 \times b$ $R^2 = 0.95$

APPENDIX C. EXCLUSION OF VARIABLES

These following variables were excluded from statistical analyses due to low response frequency, insufficient variability or response bias:

Psychosocial strain on the child caused by IDDM
Sense of shame about IDDM
Future expectations in IDDM children
Physical complaints
Subjective estimation of metabolic regulation
Pedagogic attitude of parents in case of non-adherence of their child

APPENDIX D. PSYCHOSOCIAL AND MEDICAL OUTCOMES FOR EACH HOSPITAL SAMPLE AT 4 PSYCHOLOGICAL AND 10 MEDICAL MEASUREMENT POINTS

Home-care hospitals:	H1, H2, H3
Control hospitals :	H4, H5, H6

Psychological measurement points:	M1, M2, M3, M4
Medical measurement points :	M1 to M10

Quantitative variables

	M1		M2		M3		M4	
	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)
Behavior problems								
H1	17.28	(11.61)	18.47	(11.47)	18.63	(12.08)	16.31	(15.17)
H2	15.25	(14.18)	16.25	(16.06)	13.25	(15.43)	12.88	(14.74)
H3	33.56	(23.14)	32.50	(19.81)	27.07	(18.09)	25.67	(25.24)
H4	17.75	(19.87)	19.00	(20.74)	14.50	(19.32)	21.75	(14.08)
H5	16.90	(13.06)	16.41	(14.45)	13.63	(11.21)	13.25	(12.44)
H6	14.58	(12.71)	10.16	(9.60)	10.96	(8.49)	9.35	(7.98)
Activities								
H1	4.89	(2.35)	5.68	(2.30)	5.41	(2.82)	6.25	(2.28)
H2	5.13	(2.76)	5.41	(2.35)	5.30	(2.75)	5.36	(2.41)
H3	5.60	(1.67)	5.11	(2.28)	5.25	(2.15)	6.17	(1.82)
H4	6.63	(2.67)	5.31	(2.94)	6.71	(1.29)	7.07	(1.77)
H5	4.92	(2.10)	4.82	(1.95)	4.19	(2.53)	6.44	(2.13)
H6	5.39	(1.92)	4.90	(2.13)	5.35	(2.00)	5.55	(1.98)
Social activities								
H1	5.19	(1.31)	5.18	(0.79)	5.63	(1.46)	6.46	(0.78)
H2	5.20	(1.86)	5.59	(1.59)	5.57	(1.50)	6.03	(1.42)
H3	4.86	(1.61)	4.54	(2.24)	4.11	(2.46)	5.50	(2.47)
H4	6.94	(1.55)	6.75	(2.27)	6.94	(1.70)	7.00	(1.71)
H5	5.85	(1.34)	5.28	(1.59)	5.14	(1.46)	5.86	(1.23)
H6	5.79	(1.12)	5.68	(1.27)	5.85	(0.90)	6.02	(1.67)
School scale								
H1	4.50	(1.24)	4.56	(1.28)	4.50	(1.43)	4.91	(1.00)
H2	4.89	(1.57)	4.64	(1.57)	4.71	(1.21)	4.54	(1.35)
H3	4.44	(1.09)	4.39	(1.04)	3.92	(1.37)	4.15	(1.31)
H4	5.07	(1.02)	5.07	(1.02)	4.86	(0.95)	4.81	(1.07)
H5	4.97	(0.83)	4.90	(1.02)	4.65	(1.28)	4.54	(1.52)
H6	4.75	(1.49)	4.77	(1.13)	4.72	(1.05)	4.68	(1.10)
Social competence								
H1	15.00	(3.30)	15.78	(2.79)	15.96	(3.76)	17.67	(2.46)
H2	14.71	(5.69)	15.14	(4.07)	15.32	(4.73)	15.38	(3.56)
H3	14.89	(2.82)	14.27	(4.33)	13.46	(4.06)	15.25	(2.98)
H4	18.50	(3.45)	16.57	(4.48)	18.86	(2.38)	18.43	(3.37)
H5	15.78	(2.34)	15.25	(3.11)	13.96	(3.60)	16.69	(3.65)
H6	15.92	(3.51)	15.29	(3.25)	16.11	(2.56)	16.61	(2.95)

Appendix D

	M1		M2		M3		M4	
	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)
Self-care								
H1	3.00	(1.24)	2.82	(0.92)	3.06	(1.24)	2.88	(1.07)
H2	2.38	(1.50)	2.50	(1.10)	3.13	(0.89)	2.63	(1.20)
H3	2.94	(0.34)	3.07	(1.00)	2.93	(1.16)	2.77	(1.42)
H4	2.50	(0.76)	2.25	(1.28)	3.00	(0.93)	2.25	(1.67)
H5	2.35	(0.82)	2.98	(0.89)	3.25	(1.07)	3.13	(1.09)
H6	2.69	(1.16)	3.04	(1.02)	3.28	(1.14)	2.22	(1.17)
Regimen adherence								
H1	6.58	(1.69)	6.69	(1.51)	7.10	(1.54)	7.33	(1.04)
H2	7.39	(0.92)	7.03	(1.29)	7.63	(1.09)	6.95	(1.14)
H3	5.50	(2.42)	5.44	(2.74)	6.50	(2.29)	6.49	(2.68)
H4	7.00	(1.51)	6.39	(1.00)	7.62	(0.65)	6.67	(1.28)
H5	7.21	(1.32)	6.57	(1.22)	6.96	(1.87)	5.56	(1.91)
H6	7.39	(0.97)	6.42	(1.69)	7.11	(1.57)	6.45	(1.64)
Child adjustment								
H1	33.48	(5.94)	34.50	(6.68)	35.16	(5.74)	34.53	(6.79)
H2	34.07	(7.20)	33.52	(4.34)	35.25	(4.34)	36.27	(5.09)
H3	29.48	(6.30)	31.50	(5.95)	34.49	(6.08)	34.46	(6.67)
H4	35.41	(3.94)	33.22	(6.35)	35.25	(6.14)	36.63	(6.30)
H5	35.20	(5.16)	34.53	(4.77)	35.75	(5.07)	37.27	(4.62)
H6	36.06	(4.95)	36.49	(5.32)	36.22	(5.04)	37.50	(4.50)
Parental adjustment								
H1	30.20	(10.45)	29.21	(10.32)	30.51	(11.87)	23.13	(7.09)
H2	28.36	(8.29)	27.51	(9.36)	25.88	(7.68)	25.68	(6.56)
H3	33.06	(5.95)	31.98	(7.16)	32.94	(8.01)	30.81	(7.99)
H4	26.75	(7.19)	25.59	(6.80)	25.33	(7.47)	27.95	(7.47)
H5	25.86	(7.25)	22.98	(5.54)	26.06	(8.77)	23.88	(6.15)
H6	27.66	(5.13)	25.99	(5.76)	24.57	(6.82)	22.99	(5.73)
Child knowledge								
H1	21.44	(7.58)	23.81	(7.02)	24.72	(6.46)	25.75	(4.77)
H2	20.80	(6.47)	23.49	(6.09)	24.63	(5.11)	24.81	(5.26)
H3	18.41	(5.58)	22.36	(7.14)	24.77	(5.31)	26.92	(3.04)
H4	22.63	(4.87)	23.50	(4.90)	25.38	(4.90)	25.88	(1.81)
H5	23.32	(5.37)	23.44	(2.37)	27.19	(2.37)	27.06	(2.27)
H6	22.71	(5.00)	23.68	(5.57)	24.29	(5.14)	26.41	(2.86)
Parental knowledge								
H1	7.85	(1.07)	8.22	(1.00)	7.71	(1.37)	7.72	(1.03)
H2	8.07	(0.70)	8.06	(0.77)	8.32	(0.66)	7.98	(0.99)
H3	7.79	(1.41)	8.14	(0.90)	7.99	(0.76)	7.77	(0.93)
H4	8.13	(1.12)	8.38	(1.06)	8.13	(0.84)	8.50	(0.93)
H5	8.11	(0.66)	8.20	(0.72)	8.44	(0.73)	8.12	(0.81)
H6	8.26	(0.56)	8.20	(0.50)	8.02	(1.12)	8.08	(0.67)

Metabolic control (HbA1% x 10)

	M1		M2		M3		M4		M5	
	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)
H1	98.6	(38.5)	91.8	(26.7)	89.1	(26.2)	91.7	(22.5)	88.0	(21.5)
H2	76.2	(11.8)	76.2	(9.8)	72.2	(10.9)	76.8	(10.6)	73.7	(9.1)
H3	120.5	(35.3)	115.3	(29.3)	106.7	(29.5)	101.5	(29.2)	95.0	(23.7)
H4	77.3	(26.0)	83.5	(44.5)	83.6	(26.2)	66.2	(16.7)	78.5	(6.0)
H5	94.5	(11.8)	95.5	(15.3)	90.2	(10.9)	97.4	(16.6)	107.3	(18.1)
H6	121.7	(23.9)	121.4	(25.6)	118.5	(23.4)	123.1	(18.8)	121.3	(20.3)

	M6		M7		M8		M9		M10	
	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)
H1	82.9	(20.3)	87.3	(26.3)	96.6	(28.5)	94.1	(24.5)	93.1	(24.9)
H2	75.3	(11.7)	78.1	(13.6)	80.7	(11.1)	79.3	(12.3)	79.8	(11.7)
H3	97.9	(33.3)	99.2	(22.7)	93.7	(21.1)	95.6	(23.3)	110.4	(26.9)
H4	84.2	(24.8)	86.8	(34.6)	77.3	(10.4)	74.5	(13.9)	85.8	(21.3)
H5	104.3	(17.4)	105.3	(16.8)	102.6	(16.2)	106.8	(21.1)	102.8	(12.8)
H6	121.7	(32.4)	122.9	(28.9)	124.8	(23.8)	125.9	(30.2)	123.9	(19.6)

Ratio weight/height

	M1		M2		M3		M4		M5	
	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)
H1	102.1	(8.2)	104.8	(9.1)	103.4	(8.8)	105.5	(9.6)	106.1	(9.9)
H2	101.3	(10.3)	103.5	(9.3)	103.6	(9.7)	104.6	(10.6)	103.9	(10.5)
H3	111.1	(9.7)	110.8	(10.8)	112.3	(10.6)	117.7	(10.9)	115.3	(10.3)
H4	106.5	(17.9)	112.1	(20.2)	101.6	(5.2)	103.4	(6.9)	112.7	(20.2)
H5	98.5	(10.9)	101.1	(10.3)	100.9	(13.1)	98.6	(11.5)	98.4	(11.9)
H6	103.6	(11.5)	106.5	(11.4)	106.5	(11.8)	106.1	(13.0)	106.8	(13.3)

	M6		M7		M8		M9		M10	
	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)
H1	106.9	(10.6)	106.6	(10.7)	106.0	(9.6)	106.9	(11.9)	106.7	(10,7)
H2	104.7	(10.7)	105.1	(11.2)	105.0	(10.9)	105.3	(11.5)	105.3	(10.4)
H3	114.5	(10.3)	113.2	(9.1)	113.9	(8.9)	110.9	(8.9)	117.6	(11.7)
H4	116.6	(13.1)	109,4	(13.9)	111.8	(18.1)	115.0	(16.3)	108.9	(13.7)
H5	98.9	(12.7)	99.9	(11.6)	99.9	(11.5)	99.3	(11.6)	96.7	(7.7)
H6	106.8	(12.4)	106.4	(11.9)	105.4	(12.2)	105.1	(11.5)	105.4	(11.9)

Insulin dosage per kg body weight

	M1		M2		M3		M4		M5	
	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)
H1	0.83	(0.25)	0.82	(0.25)	0.79	(0.24)	0.86	(0.22)	0.87	(0.20)
H2	0.74	(0.24)	0.76	(0.23)	0.78	(0.20)	0.82	(0.20)	0.82	(0.20)
H3	0.80	(0.27)	0.86	(0.26)	0.83	(0.34)	0.96	(0.19)	0.93	(0.25)
H4	0.86	(0.23)	0.82	(0.23)	0.81	(0.21)	0.81	(0.19)	0.80	(0.20)
H5	0.97	(0.18)	0.97	(0.21)	0.98	(0.22)	0.99	(0.17)	0.99	(0.17)
H6	0.79	(0.30)	0.70	(0.27)	0.84	(0.28)	0.88	(0.25)	0.88	(0.26)

Insulin dosage per kg body weight (continued)

	M6		M7		M8		M9		M10	
	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)	Mean	(Sd)
H1	0.90	(0.25)	0.84	(0.18)	0.86	(0.18)	0.88	(0.19)	0.92	(0.18)
H2	0.83	(0.20)	0.84	(0.20)	0.83	(0.22)	0.91	(0.17)	0.87	(0.19)
H3	0.91	(0.23)	0.82	(0.33)	0.86	(0.21)	0.87	(0.26)	0.89	(0.30)
H4	0.79	(0.30)	0.83	(0.25)	0.90	(0.29)	0.86	(0.25)	0.89	(0.28)
H5	0.99	(0.16)	0.98	(0.19)	1.03	(0.20)	1.00	(0.19)	0.98	(0.21)
H6	0.91	(0.22)	0.91	(0.23)	0.92	(0.21)	0.93	(0.23)	0.95	(0.26)

Dichotomous variables

			Number of children (%)			
Child adjustment to IDDM			M1	M2	M3	M4
Parental report:	*adjustment*					
		H1	6 (33)	6 (33)	9 (56)	8 (50)
		H2	6 (38)	5 (31)	5 (31)	7 (44)
		H3	4 (24)	4 (29)	3 (21)	3 (23)
		H4	3 (38)	2 (25)	4 (50)	2 (25)
		H5	4 (21)	3 (16)	2 (13)	4 (25)
		H6	7 (27)	7 (28)	10 (40)	3 (13)
	aggression					
		H1	5 (28)	5 (28)	8 (50)	3 (19)
		H2	4 (25)	4 (25)	4 (25)	1 (6)
		H3	7 (41)	8 (57)	6 (43)	3 (23)
		H4	3 (38)	1 (13)	3 (38)	3 (38)
		H5	7 (37)	5 (26)	5 (31)	2 (13)
		H6	8 (31)	3 (12)	7 (28)	7 (30)
	withdrawal					
		H1	4 (22)	4 (22)	5 (31)	6 (38)
		H2	5 (31)	4 (25)	7 (44)	7 (44)
		H3	4 (24)	5 (36)	3 (21)	6 (46)
		H4	1 (13)	5 (63)	0 (0)	2 (25)
		H5	7 (37)	9 (47)	7 (44)	8 (50)
		H6	7 (27)	10 (40)	6 (24)	12 (52)
	depression					
		H1	3 (17)	3 (17)	1 (6)	1 (6)
		H2	1 (6)	3 (19)	0 (0)	1 (6)
		H3	2 (12)	0 (0)	2 (14)	1 (8)
		H4	1 (13)	0 (0)	1 (13)	1 (13)
		H5	1 (5)	2 (11)	1 (6)	2 (13)
		H6	4 (15)	5 (20)	2 (8)	1 (4)
School absence						
-Parental report (item added to Child Behavior Checklist)						
-frequent or sometimes school absence		H1	11 (79)	13 (76)	13 (81)	5 (45)
		H2	8 (62)	8 (57)	8 (50)	8 (53)
		H3	8 (62)	10 (77)	7 (50)	6 (50)
		H4	2 (29)	2 (25)	3 (38)	2 (25)
		H5	6 (46)	6 (35)	4 (25)	7 (50)
		H6	10 (48)	10 (40)	13 (54)	9 (39)

		Number of children (%)			
School absence (continued) -Teacher report -frequent or sometimes		M1	M2	M3	M4
	H1	7 (44)	12 (71)	6 (55)	5 (45)
	H2	5 (36)	4 (31)	5 (36)	6 (50)
	H3	12 (80)	6 (75)	7 (58)	6 (67)
	H4	2 (33)	0 (0)	2 (33)	1 (17)
	H5	11 (73)	5 (38)	7 (78)	8 (89)
	H6	12 (50)	8 (44)	8 (50)	9 (50)
Self-care -Parental report -Self-injection	H1	7 (39)	6 (35)	6 (40)	11 (73)
	H2	6 (38)	6 (38)	6 (38)	8 (50)
	H3	10 (59)	5 (36)	10 (67)	9 (69)
	H4	5 (63)	5 (63)	6 (75)	5 (63)
	H5	13 (68)	15 (79)	10 (63)	12 (75)
	H6	9 (35)	8 (32)	7 (28)	11 (48)
-Child report -Self-injection	H1	8 (44)	7 (41)	8 (53)	9 (60)
	H2	7 (47)	6 (40)	7 (44)	8 (50)
	H3	12 (71)	7 (50)	7 (54)	9 (69)
	H4	5 (63)	5 (63)	6 (75)	5 (63)
	H5	16 (84)	16 (89)	11 (69)	11 (69)
	H6	11 (44)	9 (36)	8 (33)	8 (36)
-Parental report -Self-monitoring blood glucose	H1	8 (44)	10 (56)	10 (63)	12 (75)
	H2	5 (31)	9 (56)	10 (63)	9 (56)
	H3	6 (43)	8 (57)	11 (73)	10 (77)
	H4	4 (50)	2 (25)	3 (38)	4 (50)
	H5	7 (37)	14 (74)	14 (88)	12 (75)
	H6	14 (54)	12 (48)	18 (72)	16 (70)
-Child report -Self-care - hypo symptoms	H1	6 (33)	3 (17)	5 (28)	3 (17)
	H2	4 (25)	2 (13)	3 (19)	2 (13)
	H3	4 (24)	4 (24)	4 (24)	3 (18)
	H4	0 (0)	0 (0)	2 (25)	0 (0)
	H5	3 (16)	2 (11)	5 (26)	4 (21)
	H6	1 (4)	1 (4)	7 (27)	4 (15)
-Parental report -Self-care - hypo symptoms	H1	4 (22)	5 (28)	7 (39)	13 (72)
	H2	1 (6)	1 (6)	5 (31)	8 (50)
	H3	4 (24)	4 (24)	9 (53)	9 (53)
	H4	3 (38)	3 (38)	6 (75)	4 (50)
	H5	3 (16)	5 (26)	10 (53)	11 (58)
	H6	4 (15)	9 (35)	13 (50)	16 (62)

Self-care (continued)
-Parental report
-Self-care - Hypos

	Number of children (%)			
	M1	M2	M3	M4
H1	1 (6)	9 (50)	11 (61)	10 (56)
H2	3 (19)	7 (44)	10 (63)	13 (81)
H3	2 (12)	3 (18)	7 (41)	7 (41)
H4	5 (63)	4 (50)	4 (50)	4 (50)
H5	9 (47)	8 (42)	7 (37)	8 (42)
H6	6 (23)	10 (39)	11 (42)	13 (50)

Parental concerns about the future
-Parents concerned

	Number of parents (%)			
	M1	M2	M3	M4
H1	16 (89)	14 (78)	12 (75)	14 (88)
H2	12 (75)	12 (75)	12 (75)	13 (81)
H3	12 (71)	12 (86)	12 (80)	11 (85)
H4	7 (88)	5 (63)	6 (75)	6 (75)
H5	16 (84)	14 (74)	14 (88)	14 (88)
H6	19 (73)	19 (76)	19 (76)	19 (76)

Frequency of outpatient clinic visits
Regular planned visits
1= every three months a visit or less frequently
2= more frequently

		Number of children (%)			
		M1	M2	M3	M4
H1	1	10 (56)	12 (67)	12 (75)	14 (88)
	2	8 (44)	6 (33)	4 (25)	2 (13)
H2	1	14 (88)	13 (81)	15 (94)	15 (94)
	2	2 (13)	3 (19)	1 (6)	1 (6)
H3	1	12 (75)	11 (79)	13 (87)	13 (100)
	2	4 (25)	3 (21)	2 (13)	0 (0)
H4	1	5 (63)	5 (63)	4 (50)	3 (38)
	2	3 (38)	3 (38)	4 (50)	5 (63)
H5	1	17 (89)	17 (89)	13 (81)	14 (88)
	2	2 (11)	2 (11)	3 (19)	2 (13)
H6	1	7 (27)	11 (44)	11 (44)	10 (43)
	2	19 (73)	14 (56)	14 (56)	13 (57)

Non-planned outpatient clinic visits
1= no visits
2= one or more visits

H1	1	12 (67)	8 (44)	7 (54)	10 (63)
	2	6 (33)	10 (56)	6 (46)	6 (38)
H2	1	11 (69)	10 (71)	10 (71)	9 (60)
	2	5 (31)	4 (29)	4 (29)	6 (40)
H3	1	11 (65)	8 (62)	9 (75)	7 (58)
	2	6 (35)	5 (38)	3 (25)	5 (42)
H4	1	4 (50)	5 (63)	4 (50)	5 (63)
	2	4 (50)	3 (38)	4 (50)	3 (38)
H5	1	10 (53)	13 (72)	11 (69)	11 (73)
	2	9 (47)	5 (28)	5 (31)	4 (27)
H6	1	16 (62)	14 (56)	15 (63)	16 (73)
	2	10 (38)	11 (44)	9 (38)	6 (27)

Hospital admission rate					
At M1: during a period of nine months prior to the study					
At M2: period between M1 and M2					
At M3: period between M2 and M3			Number of children (%)		
At M4: period between M3 and M4		M1	M2	M3	M4
-One admission or more					
	H1	3 (17)	4 (22)	3 (19)	0 (0)
	H2	1 (6)	1 (6)	1 (6)	0 (0)
	H3	2 (13)	4 (29)	3 (20)	4 (31)
	H4	1 (13)	0 (0)	1 (13)	1 (13)
	H5	3 (16)	3 (16)	1 (6)	3 (20)
	H6	1 (4)	0 (0)	0 (0)	1 (4)
Hypoglycaemias					
> 5 hypo's	H1	4 (22)	11 (69)	6 (43)	10 (62)
	H2	2 (23)	9 (64)	10 (67)	11 (69)
	H3	6 (40)	8 (72)	6 (40)	9 (69)
	H4	3 (43)	2 (25)	2 (25)	5 (62)
	H5	6 (33)	9 (56)	7 (44)	6 (43)
	H6	6 (29)	14 (61)	15 (60)	16 (73)
Quality of injection sites					
-Quality acceptable					
	H1	10 (59)	6 (35)	11 (73)	9 (60)
	H2	9 (69)	8 (53)	12 (75)	6 (38)
	H3	10 (63)	7 (50)	9 (69)	9 (69)
	H4	4 (50)	6 (75)	6 (75)	6 (75)
	H5	10 (53)	12 (67)	11 (69)	13 (81)
	H6	13 (54)	14 (56)	16 (67)	13 (59)
Life events			Number of children		
-Number of life events	H1	0/13/5	5/10/3	7/7/4	8/7/3
(0/1/2)	H2	0/12/4	4/11/1	5/10/1	5/7/4
	H3	0/15/2	6/6/5	5/6/6	6/7/4
	H4	0/6/2	1/5/2	1/7/0	2/5/1
	H5	0/15/4	3/12/4	6/11/2	5/10/4
	H6	0/19/9	7/11/8	10/14/2	12/14/0
Extra-education	Number of children (%)				
-prior to the study		M1			
	H1	7 (39)			
	H2	4 (27)			
	H3	10 (59)			
	H4	3 (38)			
	H5	15 (79)			
	H6	18 (69)			
Membership of DVN			Number of parents (%)		
		M1	M2	M3	M4
	H1	14 (78)	13 (72)	12 (71)	12 (75)
	H2	14 (88)	14 (88)	14 (88)	14 (88)
	H3	16 (94)	14 (93)	14 (93)	13 (100)
	H4	6 (75)	6 (75)	6 (75)	6 (75)
	H5	19 (100)	19 (100)	19 (100)	15 (94)
	H6	26 (100)	25 (100)	24 (100)	23 (100)

APPENDIX E. SUMMARY OF RESULTS FROM INTERVIEWS WITH PAEDIATRICIANS PARTICIPATING IN THE STUDY

After completing the psychological and medical data collection, an independent interviewer visited all paediatricians of the 6 participating hospitals to examine the individual characteristics of each paediatric practice and physician attitude. A semi-structured interview was executed in the hospital. The results of the interviews are summarized here.

Number of participating paediatricians per hospital:
hospital 1: 1 paediatrician
hospital 2: 1 paediatrician
hospital 3: 1 paediatrician
hospital 4: 3 paediatricians
hospital 5: 1 paediatrician
hospital 6: 1 paediatrician

Summary of results from the interviews:

Three hospitals provided home care

All hospitals provided a 24-hour service and five hospitals had a special clinic for IDDM children.

In the home-care hospitals, differences in cooperation between nurse and paediatrician were found:
In 2 hospitals the nurse acted to some extent independently from the physician compared to the third hospital, where her plans were discussed with the physician before practice.

Some paediatricians stressed the importance of the psychosocial status of the child and attempted to recognize aspects signalling disturbances during outpatients visits to the clinic. For this purpose, they asked the child about, e.g., the family situation, functioning of the child at home, behavior disturbance. When serious psychosocial problems turned up, the paediatricians firstly attempted to solve the problems. If they did not succeed they decided to refer the child for psychiatric consultation. Other paediatricians underlined the physical condition of the child and decided to early referral of children in case of serious psychosocial disturbances.

The average time of an outpatient visit diverged from 15 to 30 minutes per patient.

The role of the dietician showed differences. Some paediatricians advised patient to consult the dietician on a regular basis (e.g., twice a year), whereas others advised consultation guided by the needs of the patient.

Some paediatricians advocated a lenient diabetes regimen with emphasis on a pleasant life; others stressed self-control and stable metabolic control.

Different age limits were used for self-care: some paediatricians stimulated self-care at the age of 8, others at the age of 10 years old.

Different standards for acceptable metabolic control were used: HbA1-percentage 8 was acceptable for some doctors, but was too high for others.

Some paediatricians told children about the long-term complications to encourage regimen adherence, others did not tell them or instructed the nurse to do so.

Some hospitals provided different education programs or information courses.

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CURRICULUM VITAE

Moniek Zoeteweij werd geboren op 17 augustus 1959 te Rotterdam. Na het behalen van het diploma VWO-ongedeeld te Rotterdam studeerde zij psychologie aan de Rijksuniversiteit Leiden. In 1985 voltooide zij deze studie met het doctoraal examen in de hoofdrichting Ontwikkelingspsychologie.

Van september 1985 tot juni 1988 was zij verbonden als onderzoeker aan de Afdeling Medische Psychologie & Psychotherapie van de Erasmus Universiteit te Rotterdam (hoofd: Prof. Dr. F. Verhage). In deze functie werkte zij mee aan een wetenschappelijk onderzoek naar hartrevalidatie in opdracht van de Nederlandse Hartstichting.

Daarnaast werd zij van april 1986 tot december 1990 aangesteld als wetenschappelijk medewerker, eveneens aan de Afdeling Medische Psychologie & Psychotherapie, om het onderzoek te verrichten dat in deze dissertatie is beschreven.

Van september 1991 tot maart 1992 was zij werkzaam als psycholoog van de kinderafdeling van het Sint Clara Ziekenhuis te Rotterdam. In deze functie verrichtte zij (poli)klinische behandelingen bij kinderen en/of ouders.

Sinds januari 1991 is zij verbonden aan de Medisch Psychologische en Psychiatrische Consultatieve Dienst van de Erasmus Universiteit Rotterdam en verricht zij in deze functie patiëntenzorg.

Daarnaast is zij sinds mei 1992 werkzaam als psycholoog bij het Klinisch Genetisch Centrum van het Academisch Ziekenhuis te Leiden en draagt zij zorg voor de begeleiding van erfelijkheidsadviesvragers.

Onlangs is zij aangevangen met de basisopleiding Psychotherapie, hoofdrichting Gedragstherapie.