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Routine hospital admission versus out-patient or home care in children at diagnosis of type 1 diabetes mellitus (Review)

Clar C, Waugh N, Thomas S

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TABLE OF CONTENTS

[Intervention Review]

Routine hospital admission versus out-patient or home care in children at diagnosis of type 1 diabetes mellitus

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ABSTRACT

Background

In many places, children newly diagnosed with type 1 diabetes mellitus are admitted to hospital for metabolic stabilisation and training, even if they are not acutely ill. Out-patient or home based management of these children could avoid the stress associated with a hospital stay, could provide a more natural learning environment for the child and its family, and might reduce costs for both the health care system and the families.

Objectives

To assess the effects of routine hospital admission compared to out-patient or home-based management in children newly diagnosed with type 1 diabetes mellitus.

Search methods

We searched *The Cochrane Library*, MEDLINE, EMBASE, CINAHL, and the British Nursing Index. Additionally, we searched reference lists of relevant studies identified and contacted one of the trialists about further studies.

Selection criteria

Comparative studies of initial hospitalisation compared to home-based and/or out-patient management in children with newly diagnosed type 1 diabetes.

Data collection and analysis

Studies were independently selected by two reviewers. Data extraction and quality assessment of trials were done independently by two reviewers. Authors of included studies were contacted for missing information. Results were summarised descriptively, using tables and text.

Main results

Seven studies were included in the review, including a total of 298 children in the out-patient/home group. The one high quality trial identified suggested that home-based management of children with newly diagnosed type 1 diabetes may lead to slightly improved long term metabolic control (at two and three years follow-up). No differences between comparison groups were found in any of the psychosocial and behavioural variables assessed or in rates of acute diabetic complications within two years. Parental costs were found to be decreased, while health system costs were increased, leaving total social costs virtually unchanged. None of the other studies assessing

metabolic control found a difference between the comparison groups. There seemed to be no differences in hospitalisations or acute diabetic complications between the out-patient/home groups and the hospital groups.

Authors' conclusions

Due to the generally low quality or limited applicability of the studies identified, the results of this review are inconclusive. On the whole, the data seem to suggest that where adequate out-patient/home management of type 1 diabetes in children at diagnosis can be provided, this does not lead to any disadvantages in terms of metabolic control, acute diabetic complications and hospitalisations, psychosocial variables and behaviour, or total costs.

PLAIN LANGUAGE SUMMARY

Routine hospital admission versus outpatient or home care in children at diagnosis of type 1 diabetes mellitus

Traditionally, children newly diagnosed with type 1 diabetes have been admitted to hospital to make sure that blood sugar and symptoms of the disease are well controlled and to teach the child and his/her family how to manage the diabetes. In some cases, the child is acutely ill and needs hospital admission to receive intravenous fluids, but in many cases the child is not acutely ill. Being in hospital is often stressful for children and their families and home-based care may provide a more natural environment for the children and families to learn how to deal with the diabetes. This review asked the question whether there are any benefits or dangers of using this type of care. We found only data of limited quality and or applicability, so no clear answers are possible. The seven studies we looked at suggested that home management of children newly diagnosed with type 1 diabetes does not lead to any disadvantages in terms of blood glucose, acute diabetic complications and hospitalisations, psychological variables and behaviour, or total costs. This would be particularly relevant for children not acutely ill, but also for children who require a short period of initial treatment in the hospital.

BACKGROUND

Description of the condition

Diabetes mellitus is a metabolic disorder resulting from a defect in insulin secretion, insulin action, or both. A consequence of this is chronic hyperglycaemia (that is elevated levels of plasma glucose) with disturbances of carbohydrate, fat and protein metabolism. Long term complications of diabetes mellitus include retinopathy, nephropathy and neuropathy. The risk of cardiovascular disease is increased. The most common types of diabetes are type 1 and type 2 diabetes, where type 1 diabetes involves an absolute insulin dependence and generally starts in childhood. For a detailed overview of diabetes mellitus, please see under 'Additional information' in the information on the Metabolic and Endocrine Disorders Group in *The Cochrane Library* (see 'About', 'Cochrane Review Groups (CRGs)'). For an explanation of methodological terms, see the main Glossary in *The Cochrane Library*.

Description of the intervention

Hospital admission at diagnosis of type 1 diabetes

At diagnosis of type 1 diabetes mellitus, some children are acutely ill and need to be admitted to hospital. Symptoms at presentation of type 1 diabetes are generally subdivided into mild, moderate and severe. Mild symptoms include polydipsia (abnormal thirst, leading to drinking of large amounts of fluid), polyuria (copious urine), loss of weight, exhaustion and problems with concentration. In the moderate form, dehydration is present in addition to the named symptoms, and the severe form includes mild to moderate ketoacidosis with severe dehydration (ketoacidosis is an elevated production of ketone bodies in type 1 diabetes due to a deranged fat metabolism, leading to increased acidity of the blood). The moderate and severe forms require infusion therapy to achieve rehydration, replacement of electrolytes, insulin substitution and calory supply, and thereby necessitate hospitalisation (Hürter 2000). Reported proportions of the different manifestations at diagnosis of type 1 diabetes vary greatly, partially depending on the delay between the onset of the disease and the time when a doctor is seen. In Western European countries and the USA, about a third to half of newly diagnosed children present with the mild symptoms and up to about a third present with ketoacidosis (Chase 1992; Hamman 1985; Hürter 2000; Neu 2001; Sadauskaite 2002). In some Arabian countries however, diabetic ketoacidosis is present in 67% to 80% of patients presenting with type 1 diabetes (Kulaylat 2001; Punnose 2002).

This means that up to half of the patients are not acutely ill and can be managed on an out-patient basis. There are conflicting beliefs concerning hospital admission in children who are not acutely ill at diagnosis of type 1 diabetes mellitus. Some clinicians think that admission provides an opportunity for intensive education which will provide benefits regarding long term outcomes. Others think that admission encourages dependence on hospital support and that patient empowerment - and thereby competence regarding self-management - will be greater if the children are not admitted to hospital. It is known that there is considerable variation in the number of admissions to hospital in the years following diagnosis, from none at all to over 50 in a 10-year period (Scottish Study Group for the Care of Diabetes in the Young, unpublished data). It is possible that the type of care at diagnosis influences subsequent admission rates.

The main tasks after diagnosis of type 1 diabetes in children are to achieve metabolic stabilisation and minimise diabetes-related acute complications (for example, ketoacidosis, hypoglycaemia), to reassure patients and family and to educate them with respect to diabetes management. Considerations regarding hospitalisation at diagnosis (for children who are not dehydrated or ketotic) therefore fall into three (interlinked) domains: 1. Which form of care is better for achieving metabolic stabilisation without acute complications such as diabetic ketoacidosis or severe hypoglycaemia? 2. Which form of care provides the best psychological support for children with diabetes and their families and the best environment for learning diabetes self-management, while maintaining patient empowerment? and 3. Which form of care provides better long term control of diabetes?

Practice

Practices regarding hospitalisation of children at diagnosis of diabetes vary both within countries and internationally. Some centres, for example in the UK and in the USA, use largely out-patient care alone when children are not acutely ill at presentation (Agwu 2005; Kostraba 1992; McEvilly 2005; Schneider 1983; Swift 1993; Walker 1953; Wilson 1986), whereas in other countries (for example, some east European countries and Finland) average durations of hospital stay after diagnosis of type 1 diabetes have been a month or more (in the early 1990s)(Simell 1991).

Modes of care for children newly diagnosed with type 1 diabetes

Whether inpatient or out-patient and home management of diabetes at diagnosis are more beneficial will not only depend on the site of management but also on the systems and expertise that can be called upon in the different settings. For example, home care ideally requires multidisciplinary teams, or at least a specialised nurse, that can spend time with families at home and provide 24-hour coverage (Farquhar 1980; Swift 1993). In situations where systems for adequate home support are not available, reducing hospitalisation of children may be counterproductive. Additionally, various scenarios are possible, ranging from a child spending several days or weeks in hospital, ideally in the company of a parent, to children not being admitted but visiting the ward daily (or regularly), or the care taking place mostly at home, with specialised healthcare personnel visiting the families. If a parent is admitted into the hospital with the child, their involvement may also take various forms, ranging from a pure parenting role to the accomplishment of some clinical tasks or to active participation in all aspects of the child's care as a full member of the treatment care team. Similarly, the mode of hospital care will be different regionally and will have changed over time.

Psychosocial factors

From a psychosocial point of view, various arguments have been brought up for and against initial hospital care of children who are not acutely ill after diagnosis of type 1 diabetes (Dougherty 1998; Farquhar 1980; Lowes 2000; Rosenbloom 1984; Swift 1993).

From the child's point of view, staying in hospital may be traumatising and threatening, whereas staying at home in familiar surroundings may help the child adjust to a new and threatening situation more easily. The child may be able to get into a routine more easily and not be stigmatised by a feeling of 'being ill'.

From the family's point of view, hospitalisation of a child after diagnosis may have both advantages and disadvantages. The realisation that a long term and potentially life threatening chronic disease has begun will be a shock for most and it has been suggested that this shock period may last for one to two weeks and make parents less receptive to any education during that time and that the hospitalisation of the child may take a lot of the burden off the family and reduce the anxiety of having to care for a newly diagnosed child without sufficient expertise. Additionally, even though parents often assume that the home environment is more conducive to learning about the diabetes and its management, in practice there are often many disruptions in a busy household and the hospital environment may provide a better environment for concentrated learning at the onset of the disease. Home management may convey the wrong message about the severity of the condition which could affect glycaemic control adversely.

On the other hand, out-patient and/or home care with practical parent involvement from the beginning may help parents adjust more easily. Depending on the degree of involvement of parents in the in-hospital care, admittance of a parent often leads to negative feelings on the part of the parents, including boredom, the feeling of being on trial and being constantly watched and monitored, and not being able to care enough for siblings who may also be having a stressful time. Also, if parents are not involved in the child's care from the beginning, there is a danger that the child will regard the hospital staff as the experts and not trust the parents enough in their care. Out-patient visits of nurses or other clinical staff to the child's home will take into account the real life situation including normal day-to-day diet and activity, as well as the family situation and responses of different family members.

Finally, whether home or hospital care at diagnosis of type 1 diabetes is more appropriate may depend on a number of individual factors, such as the child's age, the socioeconomic and educational status of the family, and the level of anxiety of the parents (children's anxiety is linked to parent anxiety and as home care is more parent-dependent, the child will be more sensitive to the parents' emotional reactions).

Costs

Overall costs of treatment have been suggested to be similar when comparing inpatient to home care (although this is composed of higher short term health system costs offset by lower parental costs) (Dougherty 1998) or lower for home care (Charron 1997; Simell 1991; Spaulding 1976).

Why it is important to do this review

One non-systematic review has summarised some evidence on out-patient versus inpatient care of children newly diagnosed with type 1 diabetes (Charron 1997). However, the methodology of the review is not described and it includes mainly data from non-comparative studies. In addition, it does not include information on one randomised controlled trial investigating inpatient versus home care that has been published since (Dougherty 1998). One Health Technology Assessment (Parker 2002) investigated the effectiveness of paediatric home care in general, including home care for children with type 1 diabetes (although not necessarily at diagnosis and not necessarily exclusive home care versus hospital care). Based on one randomised controlled trial and three other types of comparative studies (two of which did not fulfil the inclusion criteria of the present review), they found no conclusive results regarding the effectiveness of paediatric home care on clinical or "social" outcomes in children with type 1 diabetes or their families. The authors stress the necessity of high quality trials of models of home care for children with diabetes, exploring which children and families would benefit the most.

The present review aims to summarise the evidence in this area systematically, according to specified quality criteria and taking into account all relevant clinical and psychosocial outcomes. The present review focused on children who are not acutely ill only, to take account of the possibility that even short term hospital exposure may lead to reduced empowerment and increased hospital dependence of the patient. The review will be regularly updated to take account of new evidence.

OBJECTIVES

To assess the effects of routinely admitting children who are not acutely ill to hospital at diagnosis of type 1 diabetes mellitus on metabolic control and wellbeing and self-efficacy of the patient and his/her family.

Additionally, if either hospital or out-patient/home care of patients is more effective in achieving good glycaemic control, lower levels of acute complications and psychosocial benefits, to identify the factors that contribute to the effect (for example, different levels of in-hospital involvement of parents, home visits of nurses versus out-patient visits etc.).

METHODS

Criteria for considering studies for this review

Types of studies

We looked preferentially for randomised controlled trials, but also considered quasi-randomised or non-randomised controlled clinical trials, cohort studies and case-control studies. We had planned only to include prospective controlled trials in any meta-analysis and to assess the effect of randomisation in a sensitivity analysis, if possible. We had planned to consider studies in which participants have been followed for at least one year (although longer follow-up periods would be desirable). Due to the sparsity of data identified, we subsequently also included studies of shorter duration.

Types of participants

Children with newly diagnosed type 1 diabetes who are not acutely ill (that is no ketoacidosis or dehydration, eating and drinking, no other acute illnesses, such as infections).

To be consistent with changes in classification and diagnostic criteria of type 1 diabetes mellitus through the years, the diagnosis should have been established using the standard criteria valid at the time of the beginning of the trial (for example, ADA 1997; ADA 1999; WHO 1980; WHO 1985; WHO 1998). Ideally, diagnostic criteria should have been described. The use of diagnostic criteria may seem unnecessary because childhood diabetes is usually type 1 and presents in an unequivocal manner. But in some countries, an increasing number of children with childhood diabetes have type 2 diabetes.

Types of interventions

The following intervention and comparison interventions were compared:

Intervention

Hospital admission of children as described above following diagnosis of type 1 diabetes mellitus (irrespective of duration and level of parent involvement)

Comparison

Out-patient management (that is children and parents visiting the hospital (or, potentially, any other medical services) regularly for treatment and education without staying overnight) or home management (that is treatment and education taking place (mainly) at the child's home) - or a combination of both.

If data had been available, different durations of initial hospitalisation would have been considered separately, the effect of out-patient versus home care would have been compared, and different intensities of out-patient or home care would have been considered.

Due to the sparsity of data available we also included comparative studies in which some of the children in the home/out-patient group were briefly hospitalised.

Types of outcome measures

Primary outcomes

- metabolic control as indicated by glycated haemoglobin;
- admissions to hospital in the first two years after diagnosis.

Secondary outcomes

- number of contacts with clinical services, especially hospital visits;
- acute diabetes complications (for example, severe hypoglycaemia, diabetic ketoacidosis, number of patients with adverse diabetes-related events, number of adverse diabetes-related events per patient);
- parent psychosocial measures, such as: diabetes knowledge, regimen adherence, efficacy regarding diabetes management, family impact, stress, satisfaction with treatment, quality of life, child behaviour, disruption of parents' work time;
- child/adolescent psychosocial measures, such as: diabetes knowledge, regimen adherence, self-efficacy regarding diabetes management, stress, satisfaction with treatment, quality of life, school absence;
- other adverse events;
- costs (time, money).

Behavioural and psychological factors and quality of life should (ideally) have been measured using a validated instrument. For behavioural outcomes, using objective measures in addition to only self-reported data would be desirable.

Timing of outcome measurement

Outcomes were assessed in the short (follow-up at up to three months), medium (three months to a year) and long term (more than a year).

Search methods for identification of studies

Electronic searches

We used the following sources for the identification of trials:

- *The Cochrane Library* (issue 3, 2006);
- MEDLINE (until November 2006);
- EMBASE (until February 2003);
- CINAHL (until February 2003);
- The British Nursing Index (until February 2003).

(The last three databases were not included in the update of the search - CINAHL and the British Nursing Index had not contributed any new studies to the previous search and therefore were not used again, and data from EMBASE are included in the Cochrane Library; EMBASE itself was not accessible at the time of the review update.)

We also searched databases of ongoing trials: Current Controlled Trials (www.controlled-trials.com - with links to other databases of ongoing trials).
The described search strategy (see for a detailed search strategy Appendix 1) was used for MEDLINE. For use with EMBASE and *The Cochrane Library* this strategy was slightly adapted.

Simplified searches of databases of ongoing trials were also carried out (UK National Research Register and www.controlled-trials.com). We also carried out a simplified search on Lilacs.

Searching other resources

In addition, we searched the reference lists of relevant trials and reviews identified. The author of one of the trials (G. Dougherty) was contacted to identify any overlooked, unpublished or ongoing trials.

During the searches, the terms 'ambulatory' and 'domiciliary' were identified as describing home or out-patient care. However, including them in the search did not yield any relevant additional studies. Studies published in any language were considered.

Data collection and analysis

Selection of studies

To determine the studies to be assessed, two independent observers (CC, NW) reviewed the titles, abstract sections and keywords of every record retrieved. Full articles were retrieved for further assessment when the information given suggested that the study: 1. included children newly diagnosed with type 1 diabetes mellitus, 2. compared routine hospital admission with out-patient or home-based care, 3. assessed one or more relevant clinical outcome measure. When there was any doubt regarding these criteria from the information given in the title and abstract, the full article was retrieved for clarification. We had planned to measure interrater agreement using the kappa statistic (Cohen 1960) and to discuss any differences in opinion with a third party. However, as the number of suitable studies was small and there was no disagreement on inclusion, this was not done.

Data extraction and management

Data concerning details of study population, intervention and outcomes were extracted independently by two reviewers (CC, ST)

using a standard data extraction form. The standard data extraction form included at the following items:

- general information: published/unpublished, title, authors, source, contact address, country, urban/rural etc., language of publication, year of publication, duplicate publications, sponsoring, setting;
- trial characteristics: design, randomisation (and method), allocation concealment (and method), blinding of outcome assessors;
- intervention(s): interventions(s), comparison intervention(s), duration of intervention(s), level of parent involvement in hospital care;
- patients: sampling (random/convenience), exclusion criteria, total number and number in comparison groups, sex, age, baseline characteristics, diagnostic criteria, diabetes medication and regime, parental education and socioeconomic status, parent anxiety, similarity of groups at baseline (including any co-morbidity), assessment of compliance, withdrawals/losses to follow-up (reasons/description), subgroups;
- outcomes: outcomes specified above, any other outcomes assessed, other events, length of follow-up, quality of reporting of outcomes;
- results: for outcomes and times of assessment (including a measure of variation), if necessary converted to measures of effect specified below; intention-to-treat analysis.

Differences in data extraction were resolved by consensus, referring back to the original article. All but the author of the oldest study were contacted for additional information.

Assessment of risk of bias in included studies

The methodological quality of randomised controlled trials was assessed based largely on the quality criteria specified by Schulz and by Jadad (Schulz 1995; Jadad 1996). In particular, the following factors were studied:

(1) Minimisation of selection bias - a) was the randomisation procedure adequate? b) was the allocation concealment adequate?
(2) Minimisation of attrition bias - a) were withdrawals and dropouts completely described? b) was analysis by intention-to-treat?
(3) Minimisation of detection bias - were outcome assessors blind to the intervention?

Blinding of people administering the intervention is impossible in this case and blinding of participants is considered difficult, so blinding was not assessed as a quality criterion.

Based on these criteria, studies were broadly subdivided into the following three categories (see *Cochrane Handbook for Systematic Reviews of Interventions*):
A - all quality criteria met: low risk of bias;
B - one or more of the quality criteria only partly met: moderate risk of bias;
C - one or more criteria not met: high risk of bias.

We had planned to use this classification as the basis of a sensitivity analysis. Additionally, we had planned to explore the influence of individual quality criteria in a sensitivity analysis.

The quality of non-randomised trials and case-control studies were assessed using the criteria suggested by the Centre for Reviews and Dissemination, York (CRD 2000):

Cohort studies:

- Is there sufficient description of the groups and the distribution of prognostic factors?
- Are the groups assembled at a similar point in their disease progression?
- Is the intervention/treatment reliably ascertained?
- Were the groups comparable on all important confounding factors?
- Was there adequate adjustment for the effects of these confounding variables?
- Was a dose-response relationship between intervention and outcome demonstrated?
- Was outcome assessment blind to exposure status?
- Was follow-up long enough for the outcomes to occur?
- What proportion of the cohort was followed-up?
- Were drop-out rates and reasons for drop-out similar across intervention and unexposed groups?

Case-control studies:

- Is the case definition explicit?
- Has the disease state of the cases been reliably assessed and validated?
- Were the controls randomly selected from the source of population of the cases?
- How comparable are the cases and controls with respect to potential confounding factors?
- Were interventions and other exposures assessed in the same way for cases and controls?
- How was the response rate defined?
- Were the non-response rates and reasons for non-response the same in both groups?
- Is it possible that over-matching has occurred in that cases and controls were matched on factors related to exposure?
- Was an appropriate statistical analysis used (matched or unmatched)?

Each trial was assessed independently by two reviewers (CC, ST). We had planned to calculate interrater agreement using the kappa-statistic and to consult the rest of the group and make a judgement based on consensus in cases of disagreement. However, there was no disagreement on quality assessment and so this was not done.

Data synthesis

We had planned to summarise data statistically if they had been available, sufficiently similar, and of sufficient quality. Only prospective controlled trials were to be included in a meta-analysis, other data were to be summarised in tabular form. We expected both dichotomous and continuous data. Dichotomous data were to be expressed as relative risks (RR). To increase the ease of interpretation of the results for the reader, these were to be converted to the numbers needed to treat (NNT), if possible (for example, similar follow-up periods). Continuous data were to be expressed as weighted mean differences (WMD) and an overall WMD

was to be calculated. Overall results were to be calculated based on the random effects model. Heterogeneity was to be tested for using the Z score and the Chi square statistic with significance being set at $P < 0.1$. Possible sources of heterogeneity were to be assessed by subgroup and sensitivity analysis as described below. A funnel plot was to be used to assess small study bias.

As the studies identified were not easily comparable and of limited quality, we decided only to describe their results in a tabular form. If suitable data become available in future, these will be summarised statistically as described above and below.

Comparisons included:

- hospital admission versus out-patient or home care;
- hospital admission versus (mainly) out-patient care;
- hospital admission versus (mainly) home care.

Subgroup analysis and investigation of heterogeneity

The following subgroups were considered relevant and were to be investigated if the results for at least one of the main outcome measures were significant:

- sex;
- age (pre-school (from 0 to four years), primary school (from 5 to 11 years), secondary school (from 11 to 16 years));
- severity of disease at onset (mild or moderate, (largely) as defined above (severe cases will not be included));
- parental education or income (lower education/income or higher education/income, based on data);
- parental anxiety regarding the disease (more anxious or less anxious, based on data);
- level of parental involvement in hospital care (more involved or less involved, based on data);
- length of hospital stay (short stay versus longer stay, based on data);
- frequency of home visits by nurse/care team (more frequent or less frequent, based on data).

Division into subgroups 'based on data' were to be done as follows: the range of the parameter in question across the different studies was to be established and studies were then to be divided into a 'high' group and a 'low' group at the mid-point of the range. We had also considered doing a comparison of the highest and lowest quartiles.

Sensitivity analysis

We were planning to perform sensitivity analyses in order to explore the influence of the following factors on effect size:

- repeating the analysis excluding unpublished studies (if there were any)
- repeating the analysis taking account of study quality, as specified above
- repeating the analysis excluding any very long or large studies to establish how much they dominate the results
- repeat the analysis excluding studies using the following filters: diagnostic criteria, language of publication, source of funding (industry versus other), country, time period (pre 1980, 1980 to 1989, 1990 to present)

The robustness of the results was also be tested by repeating the analysis using different measures of effects size (risk difference, odds ratio etc.) and different statistical models (fixed and random effects models).

RESULTS

Description of studies

Results of the search

The initial search identified 539 records. Sixty-two of these were dealing with an assessment of home versus hospital care for people with diabetes, and 29 were possibly comparative studies. The others were excluded as they were not directly related to the question under study. Most studies were identified in the MEDLINE search, but 19 records were identified using searching of reference lists. Six studies were included in the final review (Chase 1992; Dougherty 1998; Galatzer 1982; Simell 1995; Siminerio 1999; Spaulding 1976). Main reasons for exclusion of studies were: studies not being comparative; articles being reviews, comments or editorials; studies not comparing hospitalisation at diagnosis with out-patient or home care; studies investigating mainly adults (see Characteristics of excluded studies).

None of the included studies fulfilled the original inclusion criteria completely. The only randomised controlled trial that seemed to fulfil the inclusion criteria was published as an abstract only and data were very incomplete (Simell 1995). Two studies included children who were initially hospitalised in the out-patient group (Chase 1992; Dougherty 1998), two studies only had follow-up periods of up to five weeks (Siminerio 1999; Spaulding 1976), and two studies did not provide important data at baseline, such as a measure of glycaemic control or diabetes severity, to allow a comparison between groups (Galatzer 1982; Siminerio 1999). As these six studies were however relatively close to the original inclusion criteria, it was decided to provide a descriptive overview of them.

The 2006 search update identified one other relevant study (Srinivasan 2004). Three more potentially relevant studies were excluded as they were narrative reviews and not comparative studies (Lowes 2004a; Lowes 2004b; McEvilly 2005).

Interrater agreement

Study selection was done in a number of stages by CC and NW. Each stage was followed by discussions. There was agreement on studies to be looked at further at the pre-selection stage. Possible comparative studies were summarised by CC and there was agreement on the final selection.

There was no disagreement on the quality assessment of studies.

Obtaining missing information

The authors of the following studies were contacted for further information (Chase 1992; Dougherty 1998; Galatzer 1982; Simell 1995; Siminerio 1999; Srinivasan 2004), as indicated in the table of Included studies. Three authors answered (Chase 1992; Dougherty 1998; Siminerio 1999), but were only able to provide limited information.

Included studies

Details of the characteristics of included studies are given in the table Characteristics of included studies. The following provides a brief overview.

Study types

Two of the studies were randomised controlled trials (Dougherty 1998; Simell 1995), although one was only published as an abstract. Three studies were cohort studies in which an out-patient/home cohort was compared to a cohort either obtained from hospital or diabetes register records (Chase 1992; Spaulding 1976) or was compared with patients referred to the centre after diagnosis (Galatzer 1982). These were retrospective studies in that patients diagnosed in the past were compared at the time of the study based on the intervention they had received at diagnosis. In another study, out-patient and hospital cohorts were compared in a prospective design (Siminerio 1999). In one study, two cohorts were compared before (hospitalisation) and after (outpatient care) introduction of a diabetes day care centre (Srinivasan 2004).

Duration of follow-up varied between one month and up to 15 years. Two trials only had short periods of follow-up of up to 5 weeks (Siminerio 1999; Spaulding 1976), one trial had a follow-up of one year (Srinivasan 2004), two trials had a follow-up of two years (Dougherty 1998; Simell 1995), and the remaining studies had follow-up periods of between three and 15 years (Chase 1992; Galatzer 1982).

Four of the studies were conducted in North America (USA (Chase 1992; Siminerio 1999) and Canada (Dougherty 1998; Spaulding 1976)), one in Finland (Simell 1995), one in Israel (Galatzer 1982), and one in Australia (Srinivasan 2004). All studies were published in English.

Participants

Numbers of participants ranged from 20 to 223, with a total of 298 participants in the out-patient/home group. Age and sex of participants were not mentioned in the study by Simell et al. (Simell 1995), and sex was not mentioned in the study by Srinivasan et al. (Srinivasan 2004), but all other studies included similar numbers of boys and girls. The mean age of most groups was between ten and thirteen years (between 8 and 9 years in the study by Srinivasan et al. (Srinivasan 2004).

Some studies (usually those allowing for a short period of hospitalisation initially) also included more severe cases in the out-patient/home care group (Chase 1992 - not mentioned explicitly by the other studies), whereas others excluded more severe cases (ketoacidosis, dehydration) from the study (Spaulding 1976; Simell 1995; Siminerio 1999). Two of the studies stated explicitly that they included patients in the out-patient/home group who had been hospitalised for a short period of time initially for metabolic stabilisation and/or rehydration and correction of ketoacidosis (Chase 1992; Dougherty 1998), however, in the study by Chase et al. more than 50% of patients in the intervention group were not hospitalised (Chase 1992, personal communication). In the study by Srinivasan et al. (Srinivasan 2004) patients with ketoacidosis or severe dehydration were excluded, but some children with ketoacidosis and severe dehydration were subsequently included after initial hospitalisation for correction of their metabolic and fluid derangement. There was no initial hospitalisation in the studies by Spaulding et. al, Simell et al. and Siminerio et al. (Simell 1995; Siminerio 1999; Spaulding 1976).

None of the studies described diagnostic criteria in detail. Most studies required new diagnosis with type 1 diabetes - this requirement was less clear in the study by Spaulding et al., which was dealing more generally with initiation of insulin therapy and in which the group of children and adolescents was assumed to have had type 1 diabetes (Spaulding 1976). This judgement is slightly uncertain as the group also contained three patients who had been diagnosed one, two and four months prior to the initiation of insulin therapy.

Interventions

All the studies had an out-patient element, but some also included home visits by members of the care team (Dougherty 1998; Galatzer 1982; Spaulding 1976). Most care teams contained a nurse, a social worker, a psychologist, a dietician, and a physician (diabetologist, paediatric endocrinologist, etc.).

The interventions mostly contained the following elements: 1. an individualised education programme lasting from several days to several weeks, 2. continuous psychosocial support (sometimes including regular telephone contact), 3. regular follow-up visits. The comparison intervention was hospitalisation at diagnosis (or initiation of insulin treatment) which lasted between three and twelve days. Some studies tried to ensure that the education and social support for the two groups was similar and carried out by the same teams (Chase 1992; Dougherty 1998; Siminerio 1999).

Outcome measures

Metabolic control

Four studies gave some indication of blood sugar levels (Chase 1992; Dougherty 1998; Simell 1995; Spaulding 1976). Two gave HbA1c values with standard deviations at baseline and follow-up (Dougherty 1998) or at one year and follow-up (Chase 1992), two only reported HbA1c values at follow-up (Simell 1995) or at various follow-up times but not baseline (Srinivasan 2004), and one gave a very incomplete set of blood glucose values both at baseline and follow-up (Spaulding 1976). Three studies (Dougherty 1998; Simell 1995; Srinivasan 2004) also assessed insulin doses given.

Hospital admissions and emergency visits

These outcomes were directly measured in two studies (Chase 1992; Siminerio 1999) and implicitly mentioned in one study (Spaulding 1976). Srinivasan et al. (Srinivasan 2004) reported detailed hospital length of stay data only at diagnosis, but monitored complications and re admissions throughout the study.

Parent psychosocial measures

Three studies measured parental diabetes knowledge (Dougherty 1998; Siminerio 1999; Srinivasan 2004), three studies assessed treatment adherence (compliance) as reported by parents (Dougherty 1998; Galatzer 1982; Siminerio 1999), three studies investigated some form of impact on family life/relationship (Dougherty 1998; Galatzer 1982; Siminerio 1999), two studies looked at coping or stress (Dougherty 1998; Siminerio 1999), one study considered parental treatment satisfaction (Dougherty 1998), one parental quality of life (Siminerio 1999), and one parental emotional adjustment and diabetes responsibility and conflict (Srinivasan 2004). Most of the assessment instruments used in the

studies by Dougherty et al., Siminerio et al. and Srinivasan et al. were previously validated scales, although some were adapted for use in the study (Dougherty 1998; Siminerio 1999; Srinivasan 2004). The instruments were self-administered. The development of the assessment tool in the study by Galatzer et al. was not explained; the assessment was carried out by the social worker and the psychologist (Galatzer 1982).

Child/adolescent psychosocial measures

In the study by Dougherty et al., diabetes knowledge, treatment adherence, perceived stress, and treatment satisfaction were also measured in adolescents older than twelve years (Dougherty 1998). School absences or performance at school/work were assessed by Galatzer et al. and Dougherty et al. (Dougherty 1998; Galatzer 1982). Two studies looked at child behaviour or sociability (Dougherty 1998; Galatzer 1982).

Acute diabetes complications

Acute diabetes complications, such as severe hypoglycaemia, ketoacidosis, and hyperglycaemia, were assessed by two studies (Chase 1992; Dougherty 1998). One study calculated a composite diabetes score that incorporated diabetic acidosis, hypoglycaemia, and hyperglycaemia (Spaulding 1976).

Other adverse events

None of the studies assessed any other adverse events.

Costs

Costs were assessed in the studies by Spaulding et al. and Dougherty et al. (Dougherty 1998; Spaulding 1976). The latter included a very detailed analysis of parental and health system costs (that is of social costs). Parental costs were expressed both in terms of time and money.

Timing of outcome measurement

Only two studies provided data both at baseline and at follow-up (Dougherty 1998; Spaulding 1976). Two provided data shortly after diagnosis and at follow-up (Chase 1992; Siminerio 1999), while the remaining three only provided follow-up data (Galatzer 1982; Simell 1995; Srinivasan 2004).

Risk of bias in included studies

Methodological study quality is summarised in Appendix 1. Only one study could be classified as 'high quality' (Dougherty 1998) - the study was a randomised controlled trial using an adequate randomisation procedure and allocation concealment. The study assessed a wide range of outcome measures, including glycaemic control, acute diabetic complications, psychosocial measures and costs, with a follow-up time of two years. There were no losses to follow-up and outcome assessment was blind (personal communication). The comparison groups were similar with respect to age, sex, socioeconomic status, and initial HbA1c - but there was a difference in sexual maturity between the groups.

Allocation

Only two studies were randomised (Dougherty 1998; Simell 1995) and only in one (Dougherty 1998) could an adequate randomisation procedure and allocation concealment be ascertained.

Blinding

Most studies did not mention blinding of outcome assessment. Outcome assessment was reported to have been blinded in the study by Galatzer et al. and was also blinded in the study by Dougherty et al. (personal communication)(Dougherty 1998; Galatzer 1982).

Incomplete outcome data

Losses to follow-up were not described in one of the randomised controlled trials (Simell 1995), the other two prospective studies (Dougherty 1998; Siminerio 1999) had no losses to follow-up. The three retrospective cohort studies by definition had no losses to follow-up. However, for two of them, some of the data were incomplete (Chase 1992; Spaulding 1976), particularly the blood glucose data in the study by Spaulding et al. (Spaulding 1976). In the study by Srinivasan et al. (Srinivasan 2004), questionnaires were returned by 67-92% of participants, the data on HbA1c and insulin dose were complete (personal communication).

Other potential sources of bias

Similarity at baseline

Most studies reported some socio demographic data at baseline, except the study by Simell et al. (Simell 1995). Most comparison groups were similar with respect to age, sex. socioeconomic levels etc., but there were also important differences and omissions. Minor differences included the slight difference in sexual maturity in the comparison groups in the study by Dougherty et al. (Dougherty 1998), and a slight difference in the diabetes education received in the study by Chase et al., with the intervention group being taught to use a sugar-restricted diet and the hospital group being taught to use an exchange diet (Chase 1992). In two studies, no information on either diabetes severity nor on glycaemic control at baseline were given (Galatzer 1982; Srinivasan 2004), and information on glycaemic control at baseline was also absent in the study by Siminerio et al. (Siminerio 1999). In the study by Spaulding et al., participants in the hospital group had significantly more severe manifestations of diabetes than those in the control group (Spaulding 1976).

Adequacy of length of follow-up

Four studies had adequate follow-up periods of two years or more (Chase 1992; Dougherty 1998; Galatzer 1982; Simell 1995). Two studies had very short follow-up periods of up to five weeks (Siminerio 1999; Spaulding 1976).

Effects of interventions

(for details of results see Data and analyses)

Physiological measures

Metabolic control

Of the four studies assessing HbA1c values (Chase 1992; Dougherty 1998; Simell 1995; Srinivasan 2004), two (Chase 1992; Simell 1995) showed no differences in HbA1c levels after five (Chase 1992), two (Simell 1995) and one (Srinivasan 2004) years of follow-up, whereas in the third study (Dougherty 1998), HbA1c values were lower in the out-patient/home group by about 0.7% both at two ($P < 0.05$) and three ($P < 0.02$) years follow-up. HbA1c levels varied considerably amongst studies, with Chase et al. reporting levels of

around 11%, Dougherty et al. reporting levels between 6 and 7.5%, and Simell et al. and Srinivasan et al. reporting levels of around 8%. There were no differences in blood glucose values between the comparison groups in the study by Spaulding et al. at follow-up (Spaulding 1976). Where measured (Spaulding 1976; Dougherty 1998), there were no significant differences in metabolic control (blood glucose or HbA1c, respectively) between the comparison groups at baseline.

In the three studies measuring insulin dose, two observed no significant difference in insulin dose used after one (Srinivasan 2004) and two years (Simell 1995), whereas in the study by Dougherty et al. a slightly greater increase in insulin dose over time during the two years of follow-up was observed in the out-patient/home group compared to the control group (difference at two years: 0.2 IU/kg/day) (Dougherty 1998). It is not clear whether this difference was statistically significant.

Complications

Hospital admissions and emergency visits

In the study by Chase et al., there were no significant differences in diabetes-related hospitalisations between the comparison groups (Chase 1992). The study by Siminerio et al. reported that there were no emergency room visits and/or hospital (re)admissions for severe hypoglycaemia or diabetic ketoacidosis during their one month follow-up period in either comparison group (Siminerio 1999). In the study by Spaulding et al., hospital admissions were not specifically measured, but it was reported that none of the patients in the intervention group required hospitalisation during follow-up. However, as the comparison group was only followed until discharge from hospital, data from the intervention and the control group cannot be compared (Spaulding 1976). In the study by Srinivasan et al. (Srinivasan 2004) there were no significant differences between the groups in re admissions for re stabilisation or intercurrent illnesses.

Acute diabetes complications

Chase et al. reported no significant differences in episodes of severe hypoglycaemia or diabetic ketoacidosis between the two comparison groups over more than five years (Chase 1992). Similarly, Dougherty et al. reported no significant differences in episodes of severe hypoglycaemia, hyperglycaemia and ketosis, diabetic ketoacidosis, chronic hyperglycaemia, total diabetes-related adverse events, number or patients with adverse events and adverse events per patient between the two groups over two years (Dougherty 1998). In the study by Spaulding et al., diabetes scores (incorporating urine glucose, urine ketones, diabetic acidosis, hypoglycaemia, and hyperglycaemia) were significantly worse at baseline in the hospital group, but there was no significant difference between groups at follow-up. The change in scores between baseline and follow-up was not significantly different between the two groups (Spaulding 1976). In the study by Srinivasan et al. (Srinivasan 2004) there were no significant differences between the groups in episodes of severe hypoglycaemia.

Psychosocial and behavioural measures

Diabetes knowledge

The three studies measuring parental diabetes knowledge (Dougherty 1998; Siminerio 1999; Srinivasan 2004) found no significant difference in knowledge between the comparison groups at any of the time points assessed. Knowledge was generally high and ranged between 83 and 96%. In the study by Dougherty et al., there was no significant difference in diabetes knowledge in adolescents at any of the time points assessed, although knowledge increased with time. Diabetes knowledge ranged from 72 to 85% (Dougherty 1998).

Treatment adherence

Dougherty et al. found no difference in treatment adherence between the comparison groups at 1, 12 or 24 months, as either reported by parents or by adolescents. Reported adherence ranged from 66 to 86% (Dougherty 1998). By contrast, Galatzer et al. reported higher adherence rates in the out-patient/home group than in the hospital group (85 versus 65.5%, $P < 0.001$), but this effect seemed to be due to the behaviour of the average to high socioeconomic status group rather than that of the low socioeconomic status group (Galatzer 1982). Siminerio et al. reported high rates of adherence on the sub scales of food regulation and exercise, with no significant difference between groups, whereas the hospital group scored significantly higher on the blood glucose regulation sub scale ($P < 0.01$) and the out-patient group scored significantly higher on the emergency precautions sub scale ($P < 0.001$) (Siminerio 1999).

Family impact

In the study by Dougherty et al., no differences were found between the two groups in the scores on the Family Assessment Scale at 1, 12 or 24 months (Dougherty 1998). Galatzer et al. reported higher rates of positive adjustment in familial relationship in the out-patient/home group (84 versus 68%, $P < 0.02$), but again, this was result was found to be due to the behaviour of the higher socioeconomic status group and not evident in the lower socioeconomic status group (Galatzer 1982). Siminerio et al., using the Family Assessment Device, found no significant difference between groups on the general functioning, problem solving, communication, affective involvement, and affective responsiveness sub scales at either time point assessed. However, the out-patient group had better scores on the behaviour control ($P < 0.005$) and roles ($P < 0.05$) sub scales at one month. No significant differences between the out-patient and hospital groups were observed for sharing of diabetes care responsibilities between children and their families (Siminerio 1999). Srinivasan et al. (Srinivasan 2004) found no significant differences between the two groups in the Parent Emotional Adjustment to Diabetes Scale or in the Diabetes Responsibility and Conflict Scale at 6 or 12 months.

Coping and stress

Dougherty et al. found no significant differences between the two groups on the Perceived Stress Scale administered to parents at 1, 12 or 24 months. There was a significant difference between groups at one month when the Perceived Stress Scale was administered to adolescents (older than 12 years), but this was attributable to four patients scoring unusually low in the hospital groups and the difference had disappeared at 12 and 24 months. Reported stress levels after one month approached the population mean (Dougherty 1998). Siminerio et al. reported no significant differences between groups on any of the sub scales of the Coping Inventory for Parents (maintaining family integration, maintaining social support, understanding medical situation through communication) at either of the time points

assessed. Similarly, there were no significant differences on any of the sub scales of the Coping Inventory for Children (moody, irritable, acts out; develops competence and optimism; feels different and withdraws; complies with treatment; seeks support). Children in the hospital group had significantly worse scores on the 'moody, irritable, acts out' sub scale at one month than at the initial assessment (P < 0.05) (Siminerio 1999).

Treatment satisfaction and quality of life

Dougherty et al. reported no differences between groups in either parents or adolescents on the Satisfaction Scale at 1, 12 or 24 months (Dougherty 1998). Siminerio et al. reported no differences in any of the sub scales of the Parental Diabetes Quality of Life Scale (satisfaction, diabetes impact, diabetes worry) between the two groups at either of the time points assessed (Siminerio 1999).

School absences and school/work performance
Neither the study by Galatzer et al. nor the study by Dougherty et al. found any significant differences between the two groups in school/work performance or school absences, respectively (Galatzer 1982; Dougherty 1998).

Child behaviour and sociability

There was no significant difference in child behaviour between the two groups at 1, 12 or 24 months in the study by Dougherty et al. (Dougherty 1998). Galatzer et al. reported a higher level of sociability in the out-patient group 93% versus 78% positive adjustment, P < 0.025), and this difference was attributable to a difference between the lower rather than the higher socioeconomic groups (Galatzer 1982).

Costs

The detailed cost analysis in the study by Dougherty et al. suggested that overall, there was no significant difference in costs between the two interventions, with the out-patient treatment being a non-significant CAN$ 48 (EUR 29.50) more expensive than the hospital treatment, when parents' time was valued at CAN$ 11.88 per hour (EUR 7.30). This cost decreases when parental time is valued more highly. Health system costs for the home care programme were CAN $ 768 (EUR 472.70) more than for the hospital care, but this was offset by parental costs being reduced by CAN$ 720 (EUR 443.20). During the first month, 52.1 hours of parental time were saved in the home group compared to the hospital group (P < 0.001) and parents' out-of-pocket expenses were CAN$ 100.53 (EUR 61.90) lower than those in the hospital group, although this difference just failed to reach significance (P = 0.06). It should be noted that these calculations are based on only an average of 2.8 fewer hospital ward days in the home group compared to the hospital group (and that most hospital ward days in the intervention group occurred just after diagnosis) (Dougherty 1998).

Spaulding et al. compared medical costs (including salaries of staff, physician's fees, laboratory costs, standard bed rate) between the two groups and found that the costs for the out-patient/home care were almost ten times lower (CAN$ 154 (EUR 94.80) versus CAN$ 1445 (EUR 889.40)) than for the hospital group (based on 12 fewer hospital ward days in the out-patient/home group) (Spaulding 1976).

Short term versus long term studies

No clear differences in effect could be observed when comparing short (less than two months) and long (one year or more) term studies.

Studies with and without initial hospitalisations in the intervention group

Similarly, no clear differences in effect could be observed when comparing studies including children that had been briefly hospitalised in the intervention group with those that did not.

DISCUSSION

Summary of main results

The results of this review are inconclusive. The one high quality trial identified suggested that home-based management of children with newly diagnosed type 1 diabetes may lead to slightly improved long term metabolic control. No differences between comparison groups were found in any of the psychosocial and behavioural variables assessed or in rates of acute diabetic complications. Parental costs were found to be decreased, while health system costs were increased, leaving total social costs virtually unchanged (Dougherty 1998). However, the trial did not strictly address the question of this review, as it included children in the intervention group who required hospitalisation at diagnosis. The 32 children in the intervention group were hospitalised for a total of 70 days, mostly at diagnosis, and there was only a 2.8 day difference in hospital ward days between the two groups (that is with fewer hospital days in the home-based group or a greater difference in hospital ward days, costs for the home-based group would have been lower than for the hospital group). While trials including all children newly diagnosed with type 1 diabetes may be sensible, as they reflect the 'real life situation', it would be desirable for such studies clearly to differentiate between children who were hospitalised and/or who were acutely ill and those who were not, so that possible differences in outcomes between those two groups can be identified. Furthermore, it is unclear to what extent the findings of a single trial of limited size in a single setting can be transferred to other settings.

The remaining studies were all of lower quality. None of the other studies assessing metabolic control found a difference between the comparison groups. There seemed to be no differences in hospitalisations or acute diabetic complications between the out-patient/home groups and the hospital groups. Results with respect to psychosocial and behavioural variables are inconclusive, with the study by Siminerio et al. only finding significant results on some very selected sub scales of tests used (Siminerio 1999). In the study by Galatzer et al., the out-patient/home group did significantly better on the assessments of treatment adherence, familial relationship and sociability, but upon further analysis this only seemed to apply to selected socioeconomic subgroups, with no clear explanations offered (Galatzer 1982). These results have to be treated with additional caution as the study does not explain what initial intervention the control group had received at diagnosis. On the whole, the data seem to suggest that out-patient/home management of type 1 diabetes in children at diagnosis does not lead to any disadvantages in terms of metabolic control, acute diabetic complications and hospitalisations, psychosocial variables and behaviour, or total costs.

Overall completeness and applicability of evidence

It has been stressed that an out-patient/home-based system is only safe and feasible if an experienced care team is readily available. In the studies assessed, care teams were generally composed of a doctor in a suitable specialty (paediatrics, diabetology, endocrinology), a nurse (with skills in teaching and diabetes), a dietician, a psychologist, and a social worker. None of the studies addressed the question what the optimum composition of a care team should be, but most seemed to regard the multi-disciplinary team as outlined above to be necessary for adequate care of the patient. However, there is little evidence to support this (for example, no comparisons of different compositions of teams). Additionally, geographical factors will play a role, for example, home care may not be feasible in rural areas with a low density of specialist diabetes clinics and care teams (Lowes 2004a).

As suggested earlier, the results may vary with socio-economic factors, and it is possible that there may be approximate equivalence overall, but that some children from more deprived areas might do better in hospital.

Potential biases in the review process

The conclusions of this review are limited by the quality of the data identified. Unfortunately, we were unsuccessful in obtaining further data on the only other randomised controlled trial available, which only included children in the control group who were not hospitalised (Simell 1995). The information available in abstract format is very limited and does not allow a judgement on the quality of the trial. Two studies did not provide any clear description of the intervention received by the control group (Spaulding 1976; Galatzer 1982), two studies reported no data on blood glucose control (Galatzer 1982; Siminerio 1999) and one only data of very limited use (Spaulding 1976). Using Dougherty et al.'s power calculation as a rough standard, at least two studies were underpowered (Siminerio 1999; Spaulding 1976) (although the power calculation was based on detecting a difference in HbA1c and it is unclear what power would be required for detecting a difference in the psychosocial variables). Two studies only had a follow-up of about one month (Siminerio 1999; Spaulding 1976).

Agreements and disagreements with other studies or reviews

Two randomised controlled trials related to the current question are worth mentioning. Simell et al. (1991) compared short term (9±3 days) with long term (23±4 days) initial hospitalisation in 61 Finnish children (31 long term versus 30 short term) newly diagnosed with type 1 diabetes. There were no significant differences in HbA1c values between the two groups over two years (values at two years were just under 8%). There were no significant differences between the two groups in a range of psychosocial parameters (ability to function, achievement of own treatment goals, fears, anxiety, time needed to build family-confidence in coping with diabetes, grades at school, changes in siblings' status in the family, hobbies; as reported by parents). The costs (including both medical and parent costs) for the shorter stay group were £6928 and £10834 for the longer stay group over two years. The first month's expenses were twice as high in the short term as in the long term group (Simell 1991).

In a Swedish trial (Forsander 1995), 19 children receiving traditional hospital care (for about three weeks) at diagnosis of type 1 diabetes were compared with 19 children discharged to a training apartment (for about three weeks) after a very short initial stay in hospital. The child stayed at the training apartment with his/her whole family and received active support and education by a psychotherapist and diabetes team. During the five years follow-up, there was no significant difference in HbA1c values between the two groups (values ranged between 7.2 and 7.7% at five years). There was no significant difference in hospital re-admission and acute diabetic complications between the two groups. Family satisfaction, assessed after the end of the intervention, was significantly greater in the training apartment group.

Hatton et al. (1993) compared four centres in Canada, the USA and the UK that used both out-patient/home care and hospitalisation (or cooperated with hospitals when hospitalisation was required) in children newly diagnosed with type 1 diabetes. The study was questionnaire- and interview-based and the author compared practices, views of staff and parents and costs (main data on two centres only). Outcomes were not assessed nor were any data on the children involved in the programmes provided. The results suggest lower medical service costs for out-patient or day care compared to in-patient care in all cases assessed. Parental costs were not taken into account in detail. In psychosocial terms, the data suggested that the out-patient programmes had the advantage of avoiding the stress, trauma and disruption associated with hospitalisation. Hospitalisation was associated with fear and sleep deprivation from the point of view of the child, and exhaustion, experience of loss of control over the child, worry about the rest of the family and reduced ability to learn from the point of view of the parents. The out-patient and home environment was seen to provide more freedom and flexibility and allowed the diabetes regimen to blend in with the family lifestyle. Absence of hospital distractions was seen as being more conducive to learning. No major losses were seen by the families except for the necessity to take time off work, but this was similar for parents of children receiving in-patient or out-patient education. Health care professionals found that it was an advantage to identify problems at the home of a child that would not be evident in a hospital setting. Consistent follow-up visits (home or out-patient) were seen as contributing to improved long term diabetic control and avoidance of hospitalisations (due to ketoacidosis etc.). The main disadvantages of the out-patient programmes were seen to be unpredictable work loads and the need to work flexible hours. Physician anxiety regarding the child's initial management was increased in the out-patient setting and close collaboration of the care team and early education of parents and others in managing hypoglycaemia was deemed essential. Out-patient treatment reduced in-patient training opportunities for medical students and nurses (Hatton 1994).

Various other reports describing the experience of out-patient programmes also mention the reduced levels of anxiety and emotional stress on the parts of the parents and children (Mair 1989; Schneider 1983) and reduced costs as being major advantages of out-patient management of children at onset of diabetes (Banion 1987; Bruce 1987; Duncan 1986; Lee 1992; Rayner 1984; Strock 1988). It must be kept in mind however, that some of these cost estimates are not very complete as they tend to consider only medical care costs, and not other costs, such as those incurred by parents/family or costs in setting up an out-patient system (Dougherty 1998; Kaplan 1986).

AUTHORS' CONCLUSIONS

Implications for practice

There are insufficient high quality data to answer the question whether out-patient and/or home-based management of children who have been newly diagnosed with type 1 diabetes and who are not acutely ill is as good as, or better than, in-patient care. The only high quality study included hospitalised children in the intervention group and therefore a clear conclusion on non-hospitalised children alone is not possible. The studies assessed suggest that if adequate out-patient/home management can be provided, this does not lead to any disadvantages in terms of metabolic control, acute diabetic complications and hospitalisations, psychosocial variables and behaviour, or total costs.

Implications for research

High quality randomised controlled trials are needed to clarify the question reviewed. Studies are needed that clearly distinguish between children in the intervention group who required brief hospitalisation because they were acutely ill, and those who did not require hospitalisation, so that any possible differential effects on these two groups become evident (including reduced empowerment of the hospitalised group). Studies must be adequately powered and follow participants for at least two years. Outcome measures assessed should include measures of glycaemic control (particularly HbA1c), hospital admissions and emergency room visits, acute diabetic complications (hypoglycaemia, diabetic ketoacidosis etc.), psychosocial and behavioural measures, as well as costs. Cost assessments need to take into account costs of the medical services, costs of setting up an out-patient/home care system (where not already in place) and costs to parents/families.

Research needs: We suggest that a randomised controlled trial of hospital admission versus out-patient/home care be carried out in children as specified above.

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REFERENCES

References to studies included in this review

Chase 1992 *{published data only}*

* Chase PH, Crews KR, Garg S, Crews MJ, Cruickshanks KJ, Klingenschmith G, et al. Outpatient management vs in-hospital management of children with new-onset diabetes. *Clinical Pediatrics* 1992;**31**(8):450-6.

Dougherty 1998 *{published data only}*

* Dougherty G, Schiffrin A, White D, Soderstrom L, Sufrategui M. Home-based management can achieve intensification cost-effectively in type 1 diabetes. *Pediatrics* 1999;**103**(1):122-8.

Dougherty GE, Soderstrom L, Schiffrin A. An economic evaluation of home care for children with newly diagnosed diabetes - Results from a randomized controlled trial. *Medical Care* 1998;**36**(4):586-97.

Galatzer 1982 *{published data only}*

* Galatzer A, Shoshana A, Gil R, Karp M, Laron Z. Crisis intervention programme in newly diagnosed diabetic children. *Diabetes Care* 1982;**5**(4):414-9.

Simell 1995 *{published data only}*

* Simell T, Putto-Laurila A, Näntö-Salonen K, Salomaa P, Piekkala P, Hakalax J, Simell O. Randomized prospective trial of ambulatory treatment and one-week hospitalisation of children with newly diagnosed IDDM. *Diabetes* 1995;**Suppl 1**:162A.

Siminerio 1999 *{published data only}*

* Siminerio LM, Charron-Prochownik D, Banion C, Schreiner B. Comparing outpatient and inpatient diabetes education for newly diagnosed pediatric patients. *The Diabetes Educator* 1999;**25**(6):895-906.

Spaulding 1976 *{published data only}*

King B, Spaulding WB, Wright AD. Problem-oriented diabetic day care. *The Canadian Nurse* 1974;**70**:19-22.

Noviks L, King B, Spaulding WB. The diabetic day-care unit. I. Development of an index to evaluate diabetes control. *Canadian Medical Association Journal* 1976;**114**:777-9.

* Spaulding R, Spaulding W. The diabetic daycare unit. II. Comparisons of patients and costs of initiating insulin therapy in the unit and a hospital. Canadian Medical Association Journal. 114 1976; Vol. 114:780-3. [MEDLINE: 68]

Srinivasan 2004 *{published data only}*

* Srinivasan S, Craig ME, Beeney L, Hayes R, Harkin N, Ambler G, et al. An ambulatory stabilisation programe for children with newly diagnosed type 1 diabetes. *Medical Journal of Australia* 2004;**180**:277-80.

References to studies excluded from this review

Banion 1987 *{published data only}*

* Banion C, Klingensmith G, Giordano B, Radcliffe J. Efficacy of outpatient managment of new onset diabetes in children. *Diabetes* 1987;**Suppl 1**:118A.

Bruce 1987 *{published data only}*

* Bruce DG, Clark EM, Danesi GA, Campbell LV, Chisholm DJ. Outpatient initiation of insulin therapy in patients with diabetes mellitus. *The Medical Journal of Australia* 1987;**146**:19-22.

Duncan 1986 *{published data only}*

* Duncan JA, Malone JI. An out-of-hospital approach to the newly diagnosed diabetic. *Contemporary Pediatrics* 1986;**3**:79-86.

Forsander 1995 *{published data only}*

Forsander G, Persson B, Sundelin J, Berglund E, Snellman K, Hellstrom R. Metabolic control in children with insulin-dependent diabetes mellitus 5 y after diagnosis. Early detection of patients at risk for poor metabolic control. *Acta Paediatrica* 1998;**87**(8):857-64.

* Forsander GA. Family attitudes to different management regimens in diabetes mellitus. *Practical Diabetes International* 1995;**12**(2):80-5.

Forsander GA, Sundelin J, Persson B. Influence of the initial management regimen and family social situation on glycemic control and medical care in children with type I diabetes mellitus. *Acta Paediatrica* 2000;**89**(12):1462-8.

Hamman 1985 *{published data only}*

* Hamman RF, Cook M, Keefer S, Young WF, Finch JL, Lezotte D, et al. Medical care patterns at the onset of insulin-dependent diabetes mellitus: association with severity and subsequent complications. *Diabetes Care* 1985;**8**(Suppl 1):94-100. [MEDLINE: 57]

Hatton 1994 *{unpublished data only}*

* Hatton DL. Study of the benefits and cost-effectiveness of an outpatient day care management and education program for children newly diagnosed with diabetes and their families. Report and recommendations (unpublished report). British Columbia Children's Hospital, Vancouver BC 1994.

Kaplan 1986 *{published data only}*

* Kaplan RM, Davis WK. Evaluating the costs and benefits of outpatient diabetes care and nutrition counselling. *Diabetes Care* 1986;**9**:81-6.

Kostraba 1992 *{published data only}*

* Kostraba JN, Gay EC, Rewers M, Chase HP, Klingensmith GJ, Hamman RF. Increasing trend of outpatient management of children with newly diagnosed IDDM. Colorado IDDM Registry, 1978-1988. *Diabetes Care* 1992;**15**(1):95-100. [MEDLINE: 22]

Lee 1992 *{published data only}*

* Lee PD. An outpatient-focused program for childhood diabetes: design, implementation, and effectiveness. *Texas Medicine* 1992;**88**(7):64-8.

Lester 1990 *{published data only}*

* Lester FT, Demissie Y, Negash A. Insulin injection technique can be taught without hospitalization. *Ethiopian Medical Journal* 1990;**28**(4):191-5.

Lipman 2000 *{published data only}*

* Lipman TH. Toward evidence-based practice. Comparing outpatient and inpatient diabetes education for newly diagnosed pediatric patients. *MCN: American Journal of Maternal and Child Nursing* 2000;**25**(3):168.

Lowes 2000 *{published data only}*

* Lowes L, Lyne P. Your child has diabetes: hospital or home at diagnosis?. *British Journal of Nursing* 2000;**9**(9):542-8.

Lowes 2004a *{published data only}*

Lowes L, Gregory JW. Management of newly diagnosed diabetes: home or hospital?. *Archives of Disease in Childhood* 2004;**89**:934-7.

Lowes 2004b *{published data only}*

Lowes L, Lyne P, Gregory JW. Childhood diabetes: parents' experience of home management and the first year following diagnosis. *Diabetic Medicine* 2004;**21**:531-8.

McEvilly 2005 *{published data only}*

McEvilly A, Kirk J. Twenty years of a multidisciplinary paediatric diabetes home care unit. *Archives of Disease in Childhood* 2005;**90**:342-5.

Schneider 1983 *{published data only}*

* Schneider AJ. Starting insulin therapy in children with newly diagnosed diabetes. *American Journal of Diseases of Children* 1983;**137**(8):782-6. [MEDLINE: 30]

Simell 1991 *{published data only}*

* Simell T, Kaprio EA, Mäenpää J, Tuominen J, Simell O. Randomised prospective study of short-term and long-term initial stay in hospital by children with diabetes mellitus. *Lancet* 1991;**337**:656-60.

Simell T, Moren R, Keltikangas-Järvinen L, Hakalax J, Simell O. Short-term and long-term initial stay in hospital of children with insulin-dependent diabetes: adjustment of families after two years. *Acta Paediatrica* 1995;**84**:41-50.

Simell T, Simell O, Sintonen H. The first two years of type 1 diabetes in children: length of the initial hospital stay affects costs but not effectiveness of care. *Diabetic Medicine* 1993;**10**(9):855-62.

Swift 1993 *{published data only}*

* Swift PG, Hearnshaw JR, Botha JL, Wright G, Raymond NT, Jamieson KF. A decade of diabetes: keeping children out of hospital. *British Medical Journal* 1993;**307**(6896):96-8. [MEDLINE: 19]

Whitehouse 1983 *{published data only}*

* Whitehouse FW, Whitehouse IJ, Cox MS, Goldman J, Kahkonen DM, Patiamian JO, Tamayo RC. Outpatient regulation of the insulin-requiring person with diabetes (an alternative to hospitalisation). *Journal of Chronic Diseases* 1983;**36**:433-8.

Wilson 1986 *{published data only}*

* Wilson RM, Clarke P, Barkes H, Heller SR, Tattersall RB. Starting insulin treatment as an outpatient. Report of 100 consecutive patients followed up for at least one year. *Journal of the American Medical Association* 1986;**256**(7):877-80. [MEDLINE: 28]

Additional references

ADA 1997

American Diabetes Association. Report on the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care* 1997;**20 Suppl 1**:S5-20.

ADA 1999

The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Report of the Expert Committee on the diagnosis and classification of diabetes mellitus. *Diabetes Care* 1999;**22 Suppl 1**:S5-19.

Agwu 2005

Agwu JC. Home management versus inpatient care of adolescents with newly diagnosed type 1 diabetes mellitus: survey of current practice. *Archives of Disease in Childhood* 2005;**90**(5):547.

Charron 1997

Charron-Prochownik D, Maihle T, Siminerio L, Songer T. Outpatient versus inpatient care of children newly diagnosed with IDDM. *Diabetes Care* 1997;**20**(4):657-60.

Cohen 1960

Cohen J. A coefficient of agreement for nominal scales. *Educational and Psychological Measurement* 1960;**20**:37-46. [MEDLINE: 4]

CRD 2000

Khan KS, ter Riet G, Glanville J, Sowden AJ, Kleijnen J. Undertaking systematic reviews of research on effectiveness: CRD's guidance for carrying out or commissioning reviews. http://www.york.ac.uk/inst/crd/report4.htm 2000. [MEDLINE: 5]

Farquhar 1980

Farquhar JW, Campbell ML. Care of the diabetic child in the community. *British Medical Journal* 1980;**281**:1534-7.

Hürter 2000

Hürter P. Diabetes mellitus im Kindesalter. In: Berger M editor(s). Diabetes mellitus. 2. München: Urban und Fischer, 2000. [MEDLINE: 67]

Jadad 1996

Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds JM, Gavaghan DJ, McQuay HJ. Assessing the quality of reports of

randomized clinical trials: Is blinding necessary?. *Controlled Clinical Trials* 1996;**17**:1-12. [MEDLINE: 1]

Kulaylat 2001

Kulaylat NA, Narchi H. Clinical picture of childhood type 1 diabetes mellitus in the Eastern Province of Saudi Arabia. *Pediatric Diabetes* 2001;**2**:43-7. [MEDLINE: 64]

Mair 1989

Mair EJ. Paediatric home care - a flexible approach to the family centred care of children with diabetes mellitus. *Practical Diabetes* 1989;**6**(4):173-5.

Neu 2001

Neu A, Ehehalt S, Willasch A, Kehrer M, Hub R, Ranke MB. Varying clinical presentations at onset of type 1 diabetes mellitus in children - epidemiological evidence for different subtypes of the disease?. *Pediatric Diabetes* 2001;**2**:147-53. [MEDLINE: 65]

Parker 2002

Parker G, Bhakta P, Lovett CA, Paisley S, Olsen R, Turner D, Young B. A systematic review of the costs and effectiveness of different models of paediatric home care. Health Technology Assessment 2002; Vol. 6, issue 35.

Punnose 2002

Punnose J, Agarwal MM, El Khadir A, Devadas K, Mugamer IT. Childhood and adolescent diabetes mellitus in Arabs residing in the United Arab Emirates. *Diabetes Research and Clinical Practice* 2002;**55**:29-33. [MEDLINE: 62]

Rayner 1984

Rayner PHW. A home care unit for diabetic children. *Practical Diabetes* 1984;**1**(1):5-6.

Rosenbloom 1984

Rosenbloom AL. Starting insulin therapy in children with newly diagnosed diabetes: an outpatient approach. *American Journal of Diseases in Children* 1984;**138**(1):103. [MEDLINE: 29]

Sadauskaite 2002

Sadauskaite-Kuehne V, Samuelsson U, Jasinskiene E, Padaiga Z, Urbonaite B, Edenvall H, et al. Severity at onset of childhood type 1 diabetes in countries with high and low incidence of the condition. *Diabetes Research and Clinical Practice* 2002;**55**:247-54. [MEDLINE: 63]

Schulz 1995

Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias: dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *Journal of the American Medical Association* 1995;**273**:408-12. [MEDLINE: 3]

Strock 1988

Strock E, Sandell J. The ambulatory insulin program: initiating therapy in an outpatient setting. *Diabetes Educator* 1988;**14**:339-45.

Walker 1953

Walker JB. Field work of a diabetic clinic. *Lancet* 1953;**ii**:445-7. [MEDLINE: 61]

WHO 1980

WHO Expert Committee on Diabetes Mellitus. Second report. Technical Report Series 646. Geneva. WHO, 1980.

WHO 1985

WHO Expert Committee on Diabetes Mellitus. World Health Organization, 1985. Technical Report Series 727.

WHO 1998

Alberti KM, Zimmet PZ. Definition, diagnosis and classification of diabetes mellitus and its compliactions. Part I: diagnosis and classification of diabetes mellitus. Provisional report of a WHO consultation. *Diabetic Medicine* 1998;**15**:539-53.

References to other published versions of this review

Clar 2003

Clar C, Waugh N, Thomas S. Routine hospital admission versus out-patient or home care in children at diagnosis of type 1 diabetes mellitus. *Cochrane Database of Systematic Reviews* 2003, Issue 3.

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Chase 1992

Methods	DESIGN: cohort study with control group, retrospective COUNTRY: USA
Participants	N=121 AGE: (age at diagnosis) intervention: 13.0±4.6; control: 12.9±4.5 SEX: intervention: 25 male, 16 female; control: 38 male, 42 female DIABETES SEVERITY: (based on bicarbonate and pH) intervention: 23/37 normal, 13/37 mild-moderate, 1/37 severe; control: 35/75 normal, 30/75 mild-moderate, 10/75 severe INCLUSION CRITERIA: 1. Newly diagnosed with type 1 diabetes between Jan 1980 and Dec 1984, 2. Residents of Colorado at diagnosis, 3. Less than 18 years at diagnosis, 4. Placed on insulin within 2 weeks

Chase 1992 *(Continued)*

	of diagnosis, 5. Caucasian (non-Hispanic), 5. Initially managed at either the Barbara Davis Centre for Childhood Diabetes or The Children's Hospital, Colorado; intervention group: hospitalised for no longer than one night (for correction of ketoacidosis where this could not be achieved in an out-patient setting) EXCLUSION CRITERIA: patients with insufficient data or unavailable records, data from Hispanics and non-Caucasians (no sufficient data for statistical analysis) SUBGROUPS: none
Interventions	INTERVENTION N=41 Setting: out-patient Team: nurse, social worker, psychologist, dietician Description: out-patient education at Barbara Davis Center for Childhood Diabetes (see below) Initial hospitalisation: possible hospitalisation of 1 night, but probably more than 50% not hospitalised (personal communication) Duration: 4-5 days education programme, follow-up every 3 months CONTROL N=80 Description: hospitalisation at The Children's Hospital, Denver Duration of hospitalisation: mean 4.5 days BOTH GROUPS: Initial (and ongoing, if needed) psychosocial support from the same social worker and psychologist; education: 4-5 day period of individual family teaching, both health care teams followed patients at approx. 3 month intervals as out-patients at the Barbara Davis Center; nurses from both groups met at regular intervals to ensure consistency of teaching; main difference between two groups: routine teaching of exchange diet in inpatient group and sugar-restricted diet in out-patient group DIABETES MANAGEMENT: not described
Outcomes	1.HbA1c 2.Episodes of diabetes-related illness requiring hospitalisation for one or more nights 3.Severe hypoglycaemia (episodes involved loss of consciousness) 4.Ketoacidosis (episodes severe enough to require treatment with intravenous fluids) (no clear subdivision into main and additional outcomes) OUTCOMES MEASURED AT: 3-6 months after diagnosis and at last follow-up; mean follow-up times 6.5 years for intervention group and 6.6 years for control group, time of follow-up measurement at least 5 years
Notes	Author contacted for missing information: 1. Details about how many patients in the out-patient group were initially hospitalised, 2. Details about how many patients the glycohaemoglobin data referred to. Author responded but could only give approximate information.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Dougherty 1998

Methods	DESIGN: randomised controlled trial COUNTRY: Canada
Participants	N=63 AGE: intervention: 10.7±3.9 years; control: 9.8±3.9 years

Dougherty 1998 *(Continued)*

	SEX: intervention: 13 male, 19 female; control: 15 male, 16 female DIABETES SEVERITY: not described in detail, mean days spent in intensive care at diagnosis: intervention: 0.2±0.5 days, control: 0.3±0.5 days INCLUSION CRITERIA: newly diagnosed type 1 diabetes, older than 2 years and younger than 17, no sibling with type 1 diabetes, at least one parent able to provide needed care, living within 1 hour of the hospital EXCLUSION CRITERIA: none stated SUBGROUPS: none
Interventions	INTERVENTION N=32 Setting: home and out-patient Team: nurse, diabetologist, dietician, psychologist, social worker Description: availability of diabetes-treatment nurse who accompanied family to the home and offered flexibly scheduled teaching sessions and who in collaboration with diabetologist implemented initial and almost all subsequent insulin treatment; during first 2-3 days nurse visited 1-2 times daily (instruction, supervision of practical and theoretic aspects of treatment); same material as for hospital group, paced material to match family's individual needs, continued reinforcement until family had understood all information necessary for self-management; complementary teaching by dietitian and diabetologist (identical to that offered to hospital group) at ˜ 2 weeks after diagnosis at the clinic; during follow-up, nurse was encouraged to solve problems in diabetes management through telephone contact and home visiting when possible; follow-up out-patient visits scheduled every 3-4 months; nurse of home-based group expected to spend more time with patients, both during initial period and follow-up Initial hospitalisation: intensive care: 0.2±0.5 days; mean hospital ward days: 2.2±1.6 nights (70 total (most at diagnosis): diagnosis at night (8) or at weekends (31), treatment for DKA and rehydration (24), family problems (7)) Duration: Initial education about 2 weeks CONTROL N=31 Description: hospitalisation for metabolic stabilisation, implementation of initial insulin therapy, and teaching (3 teaching sessions by diabetes clinic nurse, 3 by dietitian, 3-4 by diabetologist, additional sessions if needed) Duration of hospitalisation: 4.7±1.6 nights (147 total) BOTH GROUPS: same treating team, same education materials, telephone consultation with nurse or physician available to all patients 24 h/day DIABETES MANAGEMENT: insulin therapy: twice-daily injections of isophane (NPH) and regular insulin throughout treatment period, supported by capillary blood glucose measurements; home glucose monitoring 4 times daily (breakfast, lunch, supper, bedtime) plus 3 to 4 am on two consecutive days once a month; blood sugar level target 4-7 mmol/L at breakfast, lunch, supper; 7 mmol/L bedtime, > 5 mmol/L at 3-4 am.
Outcomes	1.HbA1c 2.Psychosocial measures completed by parents: a. Diabetes knowledge (Diabetes knowledge scale with added items as the original scale was found to be too easy (ceiling effect)) b. Adherence (Diabetes regimen adherence questionnaire-R) c. Impact on family scale (4 subscales: financial, familial/social, personal strain, mastery) d. School absences e. Perceived Stress scale f. Scale on satisfaction with treatment (developed for study, not formally evaluated) g. Achenbach child behaviour checklist h. Modified life events scale (also completed by the treating team) 3.Psychosocial measures completed by adolescents > 12 years: a. Diabetes knowledge b. Adherence c. Perceived Stress scale d. Satisfaction scale

Dougherty 1998 *(Continued)*

	4.Number of significant diabetes-related adverse events 5.Social costs (no clear subdivision into main and additional outcomes) OUTCOMES MEASURED AT: 1.HbA1c: quarterly during first 24 months, at 36 months 2.Self-report instruments administered at 1, 12 and 24 months after diagnosis 3.Life events once during second year of follow-up
Notes	Author contacted for missing information: 1. Details about how many children in the intervention group were initially hospitalised, 2. Details of randomisation procedure/allocation concealment. Author responded: No separate information available on children not hospitalised, randomisation procedure clarified.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Galatzer 1982

Methods	DESIGN: cohort study with control group, retrospective COUNTRY: Israel
Participants	N=223 AGE: 7-24 (mean 15) years at time of study (i.e. not at time of diagnosis) SEX: 112 male, 111 female DIABETES SEVERITY: not stated INCLUSION CRITERIA: type 1 diabetes patients; intervention: diagnosed in the centre or referred to centre less than 1 month following diagnosis; control: diagnosed elsewhere, referred to the centre 2 months to 3 years after diagnosis; under regular follow-up for periods between 3 and 15 years EXCLUSION CRITERIA: patients referred from other clinics specifically for psychological adjustment problems SUBGROUPS: lower versus average or above average socioeconomic status
Interventions	INTERVENTION N=107 Setting: out-patient and home Team: doctor, nurse, dietician, psychologist and social worker (P-S) team Description: guiding principles: avoidance of hospitalisation; individualised programme; multi-disciplinary approach; intensive follow-up, including home visits, contacts with school staff, support given by veteran patients and their families. First day of treatment: Patient first seen by physician (anamnestic information, brief explanation of the disease); then nurse starts basic education on diabetic regimen (testing of urine, injection of insulin, etc.); then dietician gives general explanation of required diet with instructions for the first day; then patient and family see one of the members of the P-S team - chance to express their feelings, air anything they have ever learnt about disease, given assurance that they have support of the full staff of the clinic; patient also meets veteran patients on the first day; take home telephone numbers of all the staff members and are encouraged to call in case of need. During first week, patient is seen daily, for balancing of blood sugar levels and for education. Next three weeks: patient seen twice per week, then once a month for the next 2 months, then once every three months. Any patients with identified adjustment problems subjected to an intensive intervention designed to overcome the problem. Initial hospitalisation: not stated Duration: continuous, intensive phase lasted three months

Galatzer 1982 *(Continued)*

	CONTROL N=116 Description: not specified, patients referred from other clinics between 2 months and 3 years following diagnosis Duration of hospitalisation: not stated DIABETES MANAGEMENT: not described
Outcomes	Psycho-social measures: two-level scale of adjustment and maladjustment of the following parameters (independent assessment by psychologist and social worker): 1.Compliance (positive: keeps prescribed diet, injects himself, tests urine daily and knows what to do when there are changes in blood sugar levels, regularly attends follow-up visits and brings in urine specimens when necessary; negative: does not keep prescribed diet, does not inject himself, is not regular in making urine tests, does not know how to react to changes in blood sugar levels, fails to keep follow-up appointments or bring in urine collections) 2.Familial relationship (positive: whole family accepts idea that diabetes is a chronic disease and that they must cope with it, no signs of overprotectiveness, no disputes between parents and child with respect to daily routine, no deviations of parents from normal social or vocational life, no obvious guilt feelings from parents; negative: overprotection, daily disputes about daily regimen, changes made by parents in social and vocational activities) 3.Sociability (positive: participates in all normal activities of peers (sports, outings, parties); negative: fails to join in activities, no friends, feels he is different because of diabetes) 4.Performance at school/work (positive: no academic or social problems attributable to diabetes, absences and late arrivals no more frequent than in normal children, no attempt to use diabetes for secondary gain; negative: academic and social problems obviously related to diabetes, use disease to reduce school work and excuse absences or late arrivals, inability to hold down a job) (no clear subdivision into main and additional outcomes) OUTCOMES MEASURED AT: at the time of the study, i.e. between 3 and 15 years after diagnosis
Notes	Author contacted for missing information: 1. Details about initial diabetes severity in patients, 2. Details about initial hospitalisation of any patients, 3. Details about glycaemic control or acute diabetic complications. No response to date.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Simell 1995

Methods	DESIGN: randomised controlled trial COUNTRY: Finland
Participants	N=60 AGE: not stated SEX: not stated DIABETES SEVERITY: not stated INCLUSION CRITERIA: non-ketoacidotic children with newly diagnosed type 1 diabetes EXCLUSION CRITERIA: not stated SUBGROUPS: none
Interventions	INTERVENTION N=30 Setting: out-patient Team: not stated

Simell 1995 *(Continued)*

	Description: treatment on out-patient basis Initial hospitalisation: none Duration: not stated CONTROL N=30 Description: hospitalisation Duration of hospitalisation: 5.9±1.0 days BOTH GROUPS: insulin treatment and content of education identical in the two groups DIABETES MANAGEMENT: not described
Outcomes	MAIN OUTCOME: HbA1c ADDITIONAL OUTCOMES: 1.Insulin dose 2.C-peptide positivity OUTCOMES MEASURED AT: 2 years
Notes	Abstract only - authors contacted for more information (no response to date).

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Siminerio 1999

Methods	DESIGN: cohort study with control group, prospective COUNTRY: USA
Participants	N=32 AGE: intervention: mean 10.2 (range 6-18); control: 10.1 (range 6-18) SEX: intervention: 9 male, 7 female; control: 10 male, 6 female DIABETES SEVERITY: not stated INCLUSION CRITERIA: newly diagnosed type 1 diabetes, 6-18 years, no significant family dysfunction and/or limited intellectual functioning as determined on intake interview by a diabetes nurse educator, English speaking, pH > 7.25, HCO3 > 15 mEq/L, dehydration < 5%, no significant changes in mental status EXCLUSION CRITERIA: see above SUBGROUPS: none
Interventions	INTERVENTION N=16 Setting: out-patient Team: paediatric endocrinologist, nurse educator, dietician, social worker Description: Denver Children's Hospital and Texas Children's Hospital out-patients Initial hospitalisation: none Duration: education 3-5 days CONTROL N=16 Description: hospitalisation Pittsburgh Children's Hospital Duration of hospitalisation: 3-5 days

Siminerio 1999 *(Continued)*

	BOTH GROUPS: similar team; education individualised, provided one-to-one by diabetes educator; information on basic pathophysiology, self monitoring of blood glucose, insulin action and injection technique, nutrition, exercise, symptoms, treatment, prevention of hypo- and hyperglycaemia; each educational session lasted 3-6 hours, total 10-12 hours over 3 days (7-9 h with diabetes nurse educator and 3 with dietitian on nutrition topics); follow-up at all three sites: daily phone calls from diabetes educator for at least 1 week following discharge from inpatient or out-patient programme; patient and family met with entire team at the visit scheduled 1 month postdiagnosis DIABETES MANAGEMENT: self-monitoring of glucose at premeal and bedtime snack and at 2 am until insulin requirements stabilised, three injections per day, rotation of injection sites, followed nutrition plan; encouraged to exercise as usual, to wear medical identification tag, to carry sugar source for hypoglycaemia, to assume diabetes care tasks coopertively with parents
Outcomes	1.Readmission/emergency room visit rates (for severe hypoglycaemia or diabetic ketoacidosis) 2.Psychosocial measures completed by parents: a. Knowledge: test of diabetes knowledge (39-item multiple choice) b. Responsibility for care: diabetes family responsibility questionnaire (subscales: general health maintenance, regimen tasks, social presentation) c. Adherence: self-care inventory (adherence to diabetes care recommendations: blood glucose regulation, insulin and food regulation, exercise, emergency precautions) d. Family functioning: family assessment device (60 items, 7 subscales: 1. general functioning, 2. problem-solving, 3. communication, 4. roles, 5. affective involvement, 6. affective involvement, 7. behaviour control) e. Coping: coping health inventory for parents (45 items, 3 subscales: maintaining family integration, maintaining social support, understanding the medical situation through consultation with medical support); coping health inventory for children f. Parents' quality of life: Diabetes Control and Complications Trial Research Group's Diabetes Quality of Life measure (37 items, 3 subscales: 1. diabetes life satisfaction, 2. disease impact, 3. disease-related worries) (no clear subdivision into main and additional outcomes) OUTCOMES MEASURED AT: after new-onset education at diagnosis and after 1 month: knowledge, family functioning, coping; only at 1 month: readmission/emergency room visits, responsibility of care, adherence, quality of life
Notes	Author contacted for missing information: 1. Details about initial diabetes severity in patients, 2. Details about glycaemic control. Author responded but cannot provide information.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Spaulding 1976

Methods	DESIGN: cohort study with control group, retrospective COUNTRY: Canada
Participants	N=20 young people (18 matched in 9 pairs, 2 unmatched) AGE: intervention: 12±3 (7-19) years; control: 12±5 (4-20) years SEX: intervention: 7 male, 4 female; control: 5 male, 4 female DIABETES SEVERITY: mean diabetes score intervention group: 6.8±2.4 (blood glucose 342±153 mg/dl); control: 9.3±2.1 (blood glucose 444.7±169.4 mg/dl) at baseline INCLUSION CRITERIA: patients initiated on insulin therapy; intervention: patients with diabetes referred to the day-care unit and followed for at least 6 months, insulin treatment initiated at the unit;

Spaulding 1976 *(Continued)*

	control: patients from hospital records matched for 1. age, 2. duration of diabetes prior to insulin treatment, 3. sex EXCLUSION CRITERIA: acidosis at beginning of insulin treatment (serum pH < 7.25 or serum bicarbonate < 20 mmol/l) SUBGROUPS: none
Interventions	INTERVENTION N=11 Setting: out-patient and home Team: nurse practitioners, nutritionist, social worker, secretary, specialists in paediatrics, internal medicine, psychiatry and ophthalmology Description: patients attended day-care unit 2-3 times during first two weeks of insulin therapy; responsible nurse visits home several times and keeps in touch by phone daily, monitors symptoms and the results of urine and blood tests, adjusts the dosage of insulin and instructs the patient and family, primarily at home Initial hospitalisation: none Duration: continuous CONTROL N=9 Description: admission to hospital in the region - no details of care given Duration of hospitalisation: 12 days on average DIABETES MANAGEMENT: not described
Outcomes	1.Composite diabetes score: points allocated for urine glucose, urine ketones, diabetic acidosis, hypoglycaemia, hyperglycaemia and added up (higher points=more severe state) 2.Blood glucose (but very incomplete data, see notes) 3.Costs (no clear subdivision into main and additional outcomes) OUTCOMES MEASURED AT: pre-insulin and at 2-5 weeks (day-care group) or at discharge (hospital group)
Notes	Author could not be contacted - study too old. The study also investigated 9 adults, but these were ignored for this review. No comments on diabetes diagnosis (or distinction by type 1 and 2), 17 patients had new diabetes, but three already had diabetes for 1, 2 and 4 months prior to initiation of insulin therapy (is this really type 1?). Blood glucose values only available for 7/9 in intervention group at time 0 and 3/9 at 2-5 wks; control group 9/9 at time 0 and 8/9 at discharge.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Srinivasan 2004

Methods	DESIGN: cohort study with historic control group (group before introduction of day care programme versus group after introduction of daycare programme), unclear if prospective COUNTRY: Australia
Participants	N=110 AGE: intervention: 8.1 (1.1-15.9) years; control: 8.8 (1.2-16.2) years SEX: not stated

Srinivasan 2004 *(Continued)*

	DIABETES SEVERITY: not stated; median length of initial hospital stay 1.70 days (0-10) intervention, 5.14 days (2-10) control INCLUSION CRITERIA: age >2 years; absence of diabetic ketoacidosis (pH >7.2 and serum bicarbonate >15 mmol/L); absence of significant intercurrent illness or dehydration; living less than an hours' drive from the hospital; speaking English sufficiently well; not having adverse psychosocial issues (e.g. significant parental conflict); some children with ketoacidosis or significant dehydration were able to participate in the programme after admission for correction of metabolic and fluid derangement EXCLUSION CRITERIA: not stated; ineligible patients admitted for traditional inpatient programme SUBGROUPS: none
Interventions	INTERVENTION (diagnosed during 9 months after daycare programme introduction) N=61 Setting: diabetes daycare centre Team: diabetes educators, dietitians, social workers, endocrinologists, junior medical staff Description: Three phases: Phase 1 - families attend diabetes daycare centre for 2-3 consecutive days, including weekends, receive "survival skills" diabetes education; given diabetes guide and encouraged to purchase comprehensive diabetes manual; endocrinologist and diabetes registrar or fellow available 24 h/day, families given clear instructions when to contact on-call team or return to the hospital; Phase 2 - families attend 3-4 detailed "formal education" sessions. Phases 1 and 2 involve ˜16 h of education in total; Phase 3 - families attend outpatient clinic at about 4-6 weeks after diagnosis, followed by routine 3-monthly outpatient visits. Diabetes medication: starting insulin dose is 0.3-0.5 units/kg/day, divided into 2-4 daily injections depending on age and individual suitability; in first 2-4 weeks families ring diabetes educator daily for insulin doses until doses have stabilised and they become confident with insulin adjustment. Initial hospitalisation: unclear, hospitalisation data presumably refer to whole assessment period Duration: unclear, initial 2 phases within the first 4 weeks of diagnosis CONTROL (diagnosed during 9 months before daycare programme introduction) N=49 Description: hospitalisation for 4-7 days for detailed education programme given by a diabetes educator and a dietitian; families returned to a new-patient clinic within 3-6 weeks and the progressed to routine outpatient visits Duration of hospitalisation: unclear, hospitalisation data presumably refer to whole assessment period
Outcomes	1. Parental diabetes knowledge (28-item multiple choice questionnaire) 2. Parent Emotional Adjustment to Diabetes Scale (PEAD) - 16 items 3. Diabetes Responsibility and Conflict Scale - 28 items 4. HbA1c 5. Insulin dose 6. Hospital stays (no clear subdivision into main and additional outcomes) OUTCOMES MEASURED AT: baseline and 3, 6, and 12 months after diagnosis
Notes	Author contacted for missing information: 1. Does hospital length of stay data refer to the whole follow-up period or to initial admission only? Authors responded: data refer to initial admission; only 18% of the 61 children in the second cohort (after introduction of the daycare centre) were ineligible for daycare; 2. Did HbA1c and insulin requirement data include all patients or whether there were any losses to follow-up? Authors responded: data referred to all patients.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Banion 1987	Comparison groups were probably not comparable (as hospitalisation was based on acidosis, dehydration)
Bruce 1987	Including mainly adults
Duncan 1986	Not comparing outcomes in hospital and out-patient groups
Forsander 1995	Comparing traditional hospitalisation with stay in a training apartment (i.e. not home)
Hamman 1985	Comparison groups not sufficiently similar
Hatton 1994	Narrative description of practices of different centres - not a comparative study, not comparing outcomes
Kaplan 1986	Review
Kostraba 1992	Comparing different centres, not comparing outcomes
Lee 1992	Not comparing outcomes in hospital and out-patient groups
Lester 1990	Including mainly adults
Lipman 2000	Narrative review
Lowes 2000	Narrative review, not a comparative study
Lowes 2004a	Narrative review, not a comparative study
Lowes 2004b	Narrative review, not a comparative study
McEvilly 2005	Narrative review, not a comparative study
Schneider 1983	Comparison groups not similar enough
Simell 1991	Comparing short-term (about a week) with long-term (about four weeks) initial hospital stay at diagnosis
Swift 1993	Not enough data to enable a judgement on how comparable the groups were at baseline
Whitehouse 1983	Study in adults
Wilson 1986	Not a comparative study, only 17% children

DATA AND ANALYSES

Comparison 1. Out-patient/home treatment versus hospitalisation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Measures of blood glucose control			Other data	No numeric data
2 Hospitalisations			Other data	No numeric data
3 Acute diabetic complications			Other data	No numeric data
4 Psychosocial and behavioural measures			Other data	No numeric data
4.1 Diabetes knowledge			Other data	No numeric data
4.2 Treatment adherence			Other data	No numeric data
4.3 Family impact			Other data	No numeric data
4.4 Coping and stress			Other data	No numeric data
4.5 Treatment satisfaction and quality of life			Other data	No numeric data
4.6 School absences and school/work performance			Other data	No numeric data
4.7 Child behaviour and sociability			Other data	No numeric data
5 Costs			Other data	No numeric data
6 Insulin dose			Other data	No numeric data

Analysis 1.1. Comparison 1 Out-patient/home treatment versus hospitalisation, Outcome 1 Measures of blood glucose control.

		Measures of blood glucose control			
Study	Description	Out-patient/home	Hospital	p-value (test)	Notes
Chase 1992	HbA1c (%) (±SD)	1 year (N=37): 10.7±2.4	1 year (N=76): 11.0±1.8	(test unclear, t or chi squared) non-significant	values reconstructed from graph
Chase 1992		5 years (N=37): 11.5±2.1	5 years (N=76): 11.4±1.7	(test unclear, t or chi squared) non-significant	values reconstructed from graph
Dougherty 1998	HbA1c (%) (±SD)	(N=32) time 0: 10.8±2.5 1 month: 7.5±1.6	(N=31) 10.0±2.0 6.6±1.0	(t-test) N.S. N.S.	only the first two values listed here; values reconstructed from graph
Dougherty 1998		(N=32) 2 years: 6.1±1.3 3 years: 6.4±1.4	(N=31) 6.8±1.3 7.1±1.3	(t-test) p < 0.05 p < 0.02	only the last two values listed here; values reconstructed from graph
Simell 1995	HbA1c (%)	2 years (N=30): 7.6	2 years (N=30): 7.9	N.S.	
Simell 1995					
Spaulding 1976	Blood glucose (mg/dl) (±SD)	pre-insulin (N=7): 342.0±152.8	pre-insulin (N=9): 444.7±169.4	(t-test) non-significant	Values very incomplete (note N in brackets); means, standard deviations and paired t-tests calculated by CC
Spaulding 1976		2-5 weeks (N=3):	at discharge (N=8):	(t-test)	

		Measures of blood glucose control			
Study	Description	Out-patient/home	Hospital	p-value (test)	Notes
		211.7±33.3	274.3±112.4	non-significant	
Srinivasan 2004	HbA1c (%) (estimated from graph)	3 months (N=61): ~8.1, 95% CI ~6.8 to ~9.9	3 months (N=49): ~8.3, 95% CI ~7.1 to ~9.9	(t-test) non-significant	
Srinivasan 2004		6 months (N=61): ~8.0, 95% CI ~6.9 to ~9.0 12 months (N=61): ~8.3, 95% CI ~6.7 to ~9.6	6 months (N=49): ~8.0, 95% CI ~6.0 to ~9.6 12 months (N=49): ~8.3, 95% CI ~6.5 to 10.0	(t-test) non-significant	

Analysis 1.2. Comparison 1 Out-patient/home treatment versus hospitalisation, Outcome 2 Hospitalisations.

		Hospitalisations		
Study	Description	Out-patient/home	Hospital	p-value (test)
Chase 1992	Diabetes-related hospitalisations (no. of cases)	after a mean of 6.5 years (N=37): 5	after a mean of 6.6 years (N=76): 21	(chi squared) N.S.
Siminerio 1999	Emergency room visits and/or hospital (re)admissions for severe hypoglycaemia or diabetic ketoacidosis	after one month: no reported episodes of severe hypoglycaemia or ketoacidosis in either group		
Spaulding 1976	Hospital admissions	not specifically measured, but stated that none of the patients in the intervention group required hospitalisation during follow-up		
Srinivasan 2004				there were no differences between the groups in episodes of severe hypoglycaemia, readmissions for restabilisation or intercurrent illnesses

Analysis 1.3. Comparison 1 Out-patient/home treatment versus hospitalisation, Outcome 3 Acute diabetic complications.

		Acute diabetic complications			
Study	Description	Out-patient/home	Hospital	p-value (test)	Notes
Chase 1992	Severe hypoglycaemic episodes (cases)	after a mean of 6.5 years (N=37): 12	after a mean of 6.6 years (N=76): 19	(chi squared) N.S.	
Chase 1992	Diabetic ketoacidosis (cases)	after a mean of 6.5 years (N=37): 4	after a mean of 6.6 years (N=76): 18	N.S.	
Dougherty 1998	Diabetes-related adverse events	over 2 years (N=32): severe hypoglycaemia: 7 hyperglycaemia/ketosis: 2 diabetic ketoacidosis: 0 chronic hyperglycaemia: 2	over 2 years (N=31): 6 0 1 1	N.S.	
Dougherty 1998		total events: 11 no. of patients with adverse events: 9 events per patient: 0.34	8 6 0.26	N.S.	
Spaulding 1976	Diabetes score (excellent control = 0 points to poor control = 24 points)	pre-insulin (N=9): 6.8±2.4	pre-insulin (N=9): 9.3±2.1	(paired t-test) p<0.05	
Spaulding 1976		2-5 weeks (N=7): 4.7±1.7 change in scores (N=7): 2.3±2.1	at discharge (N=9): 5.6±1.8 change in scores (N=9): 3.8±3.2	(paired t-test) N.S. N.S.	change in scores between pre-insulin and at 2-5 weeks or at discharge

Analysis 1.4. Comparison 1 Out-patient/home treatment versus hospitalisation, Outcome 4 Psychosocial and behavioural measures.

Psychosocial and behavioural measures						
Study	**Description**	**Assessed by**	**Out-patient/home**	**Hospital**	**p-value (test)**	**Notes**
			Diabetes knowledge			
Dougherty 1998	Diabetes Knowledge Scale	parents adolescents (> 12 years)	1 month (N=31): 82.5%±14.0 (N=15): 71.5%±17.5	1 month (N=31): 84.5%±13.5 (N=12): 79.0%±13.0	(ANOVA) N.S. N.S.	only initial and end values listed here
Dougherty 1998	Diabetes Knowledge Scale	parents adolescents	2 years (N=30): 88.5%±13.0 (N=19): 85.0%±15.0	2 years (N=30): 84.0%±13.5 (N=16): 83.5%±11.0	N.S. N.S.	
Siminerio 1999	Test of Diabetes Knowledge	parents	no significant difference in knowledge levels at either after the initial education or at one month between the groups, no significant change in knowledge over time, knowledge levels ranged between 86% and 90%	see previous column	(paired t-test) N.S.	
Siminerio 1999						
Srinivasan 2004	Test of Diabetes Knowledge (median, range percentage correct answers)	parents	12 months (N=41): 96% (64-100%)	12 months (N=40): 96% (75-100%)	(Kruskal-Wallis test) N.S.	
Srinivasan 2004						
			Treatment adherence			
Dougherty 1998	Diabetes Regimen Adherence Questionnaire	parents adolescents (> 12 yrs)	1 month (N=31): 83.1%±9.7 (N=15): 77.9%±7.3	1 month (N=31): 85.5%±8.2 (N=12): 78.5%±11.1	(ANOVA) N.S. N.S.	only initial and end values given here; no scale ranges given for the tests
Dougherty 1998	Diabetes Regimen Adherence Questionnaire	parents adolescents	2 years (N=30): 73.9±11.1 (N=19): 73.1±10.4	2 years (N=30): 74.1±15.3 (N=16): 66.4±14.2	(ANOVA) N.S. N.S.	
Galatzer 1982	Positive adjustment in psychosocial measures as defined in table of included studies	psychologist and social worker	(N=107) compliance: 85.0%	(N=116) 65.5%	(chi squared) p < 0.001	influence of socioeconomic (SE) status: difference only in higher SE group
Galatzer 1982						
Siminerio 1999	Self-care Inventory (SCI, higher score=higher adherence)	parents	after one month (N=16): * food regulation and exercise: high compliance in both groups, no detailed data reported * blood glucose regulation: 4.47 * emergency precautions: 4.71	after one month (N=16): 4.93 4.44	(paired t-test) N.S. N.S. p < 0.01 p < 0.001	there were no significant differences in any of the measures just after the initial diabetes education
Siminerio 1999						
			Family impact			
Dougherty 1998	Impact on Family Scale	parents	1 month (N=31): 48.0±9.9	1 month (N=31): 47.7±9.2	(ANOVA) N.S.	only initial and end values listed here; scale ranges not given, but family impact approached that for other childhood chronic diseases
Dougherty 1998	Impact on Family Scale	parents	2 years (N=30): 45.2±11.4	2 years (N=30): 42.3±8.8	N.S.	only initial and end values listed here
Galatzer 1982	Positive adjustment in psychosocial mea-	psychologist and social worker	(N=107)	(N=116) 68.1%	(chi squared) p < 0.02	influence of socioeconomic (SE) status:

Study	Description	Assessed by	Out-patient/home	Hospital	p-value (test)	Notes
			Psychosocial and behavioural measures			
	sures as defined in table of included studies		familial relationship: 84.1%			difference only in higher SE group
Galatzer 1982						
Siminerio 1999	Family Assessment Device (1=high functioning to 4= low functioning)	parents	after one month (N=16): * behaviour control: 1.58 * problem solving: 1.63 * roles: 1.98 * no significant difference between groups on problem solving, communication, affective involvement, affective responsiveness and general functioning subscales	after one month (N=16): 1.68 1.79 2.13 2.31	(paired t-test) p < 0.005 N.S. p < 0.05 N.S.	there were no significant differences in any of the measures just after the initial diabetes education
Siminerio 1999	Diabetes Care Responsibilities	parents	no data reported, stated that there was no significant difference between groups		N.S.	
Srinivasan 2004	Parent Emotional Adjustment to Diabetes (range: 16 (greatest emotional impact) to 80 (least emotional impact)) (median, range)	parents	12 months (N=41): 40.3 (37.4-43.2)	12 months (N=41): 43.2 (40.4-46.0)	(Kruskal-Wallis test) N.S.	
Srinivasan 2004	Diabetes Responsibility and Conflict (range: 14 (least parental responsibility/conflict) to 70 (greatest parental responsibility/conflict)) (median, range)	parents	12 months responsibility (N=41): 46.5 (41.9-51.2) conflict (N=41): 21.4 (18.4-24.4)	12 months responsibility (N=41): 45.5 (41.0-50.0) conflict (N=36): 23.7 (21.0-26.3)	(Kruskal-Wallis test) N.S.	
			Coping and stress			
Dougherty 1998	Perceived Stress Scale	parents adolescents (> 12 yrs)	1 month (N=31): 22.4±9.3 (N=15): 22.1±7.6	1 month (N=31): 21.8±8.8 (N=12): 14.6±9.6	(ANOVA) N.S. (t-test) p < 0.05	only initial and end values listed here; scale ranges not given; stress levels after first month approached population mean
Dougherty 1998	Perceived Stress Scale	parents adolescents	2 years (N=30): 19.0±9.7 (N=19): 18.0±9.4	2 years (N=30): 19.4±7.9 (N=16): 19.4±9.2	N.S.	only initial and end values listed here
Siminerio 1999	Coping Health Inventory for Parents (lower scores=less coping)	parents	after 1 month (N=16): * maintaining family integration: 49.71 * maintaining social support: 33.57 * understanding medical situation through communication: 19.86	after 1 month (N=16): 41.75 31.63 18.38	(paired t-test) N.S. N.S. N.S.	there were no significant differences in any of the measures just after the initial diabetes education
Siminerio 1999	Coping Health Inventory for Childen (CHIC) (1=never to 5=almost always)	parents	after one month (N=16): * moody, irritable, acts out: 2.38 * no significant difference on following subscales, no detailed data given: develops competence and optimism, feels different	after one month (N=16): 2.31	(paired t-test) N.S.	there were no significant differences in any of the measures just after the initial diabetes education

Psychosocial and behavioural measures						
Study	**Description**	**Assessed by**	**Out-patient/home**	**Hospital**	**p-value (test)**	**Notes**
			and withdraws, complies with treatment, seeks support			
Treatment satisfaction and quality of life						
Dougherty 1998	Satisfaction Scale	parents adolescents (> 12 yrs)	1 month (N=31): 46.2±6.0 (N=15): 42.8±5.5	1 month (N=31): 45.5±4.6 (N=12): 46.3±3.7	(ANOVA) N.S. N.S.	only initial and end values listed here; scale ranges not given
Dougherty 1998	Satisfaction Scale	parents adolescents	2 years (N=30): 45.6±5.0 (N=19): 43.9±5.1	2 years (N=30): 46.0±3.7 (N=16): 43.9±5.7	N.S. N.S.	only initial and end values listed here
Siminerio 1999	Parental Diabetes Quality of Life (lower scores=better quality)	parents	after 1 month (N=16): * satisfaction: 1.72 * diabetes impact: 2.09 * diabetes worry: 2.77	after 1 month (N=16): 1.86 2.02 2.12	paired t-test) N.S. N.S. N.S.	there were no significant differences in any of the measures just after the initial diabetes education
Siminerio 1999						
School absences and school/work performance						
Dougherty 1998	School absences	school records	2 years (N=31): 29.7±28.7 days	2 years (N=31): 28.3±36.4 days	(ANOVA) N.S.	
Dougherty 1998						
Galatzer 1982	Positive adjustment in psychosocial measures as defined in table of included studies	psychologist and social worker	(N=107) school/work performance: 92.5%	(N=116) 86.2%	(chi squared) N.S.	
Galatzer 1982						
Child behaviour and sociability						
Dougherty 1998	Child Behaviour Checklist	parents	1 month (N=31): 51.6±11.7	1 month (N=31): 52.4±11.4	(ANOVA) N.S.	only initial and end values given here; no scale ranges given for the tests; rates of child behaviour problems within the normal range
Dougherty 1998	Child Behaviour Checklist	parents	2 years (N=27): 52.3±10.8	2 years (N=30): 53.7±14.3	(ANOVA) N.S.	
Galatzer 1982	Positive adjustment in psychosocial measures as defined in table of included studies	psychologist and social worker	(N=107) sociability: 92.5%	(N=116) 77.6%	(chi squared) p < 0.025	influence of socioeconomic (SE) status: difference only in lower SE group
Galatzer 1982						

Analysis 1.5. Comparison 1 Out-patient/home treatment versus hospitalisation, Outcome 5 Costs.

Costs				
Study	**Description**	**Out-patient/home**	**Hospital**	**p-value (test)**
Dougherty 1998	* Parental time	first month: 52.1 fewer hours than hospital group		(t-test) p < 0.001
	* Parent out-of-pocket expenses	first month: CAN$ 100.53 lower than hospital group		N.S. (p=0.06)
	* Social costs	CAN$ 48.00 higher if parent time valued at CAN$11.88 (costs lower if time valued more highly)		N.S.
Spaulding 1976	Costs, including salaries of staff, physician's fees, laboratory costs, standard bed rate	CAN$154 (N=11)	CAN$1447 (N=9)	

Analysis 1.6. Comparison 1 Out-patient/home treatment versus hospitalisation, Outcome 6 Insulin dose.

		Insulin dose			
Study	Description	Out-patient/home	Hospital	p-value (test)	Notes
Dougherty 1998	Insulin dose (IU/kg/day)	(N=32) 1 month: 0.61±0.33 2 years: 1.02±0.28	(N=31) 0.56±0.30 0.82±0.23	unclear	about 25% of difference during second year accounted for by difference in Tanner stage
Simell 1995	Insulin dose (IU/kg/day)	2 years (N=30): 0.6	2 years (N=30): 0.8	N.S.	
Srinivasan 2004	Insulin dose (IU/kg/day) (estimated from graph)	3 months (N=61): ~0.53, 95% CI ~0.2 to ~0.9 6 months (N=61): ~0.7, 95% CI ~0.4 to ~1.3 12 months (N=61): ~0.7, 95% CI ~0.5 to ~1.3	3 months (N=49): ~0.46, 95% CI ~0.3 to ~1.1 6 months (N=49): ~0.67, 95% CI ~0.3 to ~1.2 12 months (N=49): ~0.83, 95% CI ~0.5 to ~1.4	N.S.	

APPENDICES

Appendix 1. Search strategy

Search terms

Unless otherwise stated, search terms are free text terms; MesH = Medical subject heading (Medline medical index term); exp = exploded MeSH; the dollar sign ($) stands for any character(s); the question mark (?) = to substitute for one or no characters; tw = text word; pt = publication type; sh = MeSH; adj = adjacent.

Type 1 diabetes

1 explode "DIABETES-MELLITUS,-INSULIN-DEPENDENT"/ all subheadings
2 (diabet* or IDDM) in TI,AB
3 #1 or #2
4 explode "DIABETES-INSIPIDUS"/ all subheadings
5 mellitus in TI,AB
6 #4 not (#1 or #5)
7 (diabet* near (insipidus not mellitus)) in TI,AB
8 #6 or #7
9 #3 not #8

Combined with new diagnosis

10 ((new or newly or first or initial) near4 (diagnos* or onset or on-set)) in TI,AB
11 #9 and #10
12 ((new or onset or on-set or presentation) in TI,AB) near4 #9
13 #11 or #12

Combined with children

14 (child* or pediatric or paediatric or adolescen* or young) in TI,AB
15 #13 and ((AGE=ADOLESCENCE) or (AGE=CHILD) or (AGE=CHILD-PRESCHOOL) or (AGE=INFANT) or (AGE=INFANT-NEWBORN))
16 #13 and #14
17 #15 or #16

Combined with hospitalisation/out-patient care

18 (in-patient* or inpatient* or hospital* or in-hospital*) in TI,AB
19 (outpatient* or out-patient* or home*) in TI,AB

(Continued)

20 explode "Home-Care-Services"/ all subheadings
21 "Inpatients"/ all subheadings
22 "Outpatients"/ all subheadings
23 explode "Hospitalization"/ all subheadings
24 "Child-Hospitalized" / all subheadings
25 #18 or #19 or #20 or #21 or #22 or #23 or #24
26 #17 and #25

Appendix 2. Risk of bias

Criterion	Chase 1995	Dougherty 1998	Galatzer 1982	Simell 1995	Siminerio 1999	Spaulding 1976	Srinivasan 2004
Comparability at baseline	COMPARABLE WITH RESPECT TO: Age at onset of diabetes, sex, severity of diabetes, family income, parental education, occurrence of acute complications, glycaemic control (longitudinal HbA1c), time of follow-up DIFFERENCES: Use of exchange diet for in-patients and sugar-restricted diet for out-patients	COMPARABLE WITH RESPECT TO: Age, sex, socioeconomic status, HbA1c, mean insulin dosage. DIFFERENCES: More participants of greater sexual maturity in the intervention group (Tanner Stage III-IV 59% versus 32%; greater difficulty of managing diabetes in adolescence).	COMPARABLE WITH RESPECT TO: Age, sex, age at onset of diabetes, duration of diabetes, ethnic origin, socioeconomic level OMISSIONS: No information on severity of disease at onset or glycaemic control	No sociodemographic data given	COMPARABLE WITH RESPECT TO: Age, sex, ethnicity, two-parent household, income OMISSIONS: No information on glycaemic control	COMPARABLE WITH RESPECT TO: Authors tried to match for age, diabetes duration and sex (in that order), but diabetes duration was not strictly 'at diagnosis' in juveniles and only about half the patients were matched by sex DIFFERENCES: Baseline diabetes score significantly higher in hospital group, blood glucose higher but not significant	COMPARABLE WITH RESPECT TO: Age, social disadvantage risk score, education of parents, venous pH at diagnosis OMISSIONS: Sex
Randomisation procedure	No randomisation	Randomization was implemented using stratified and blocked randomization lists generated electronically and effected by calling the study research assistant once eligibility was assessed by the clinical personnel (personal correspondence)	No randomisation	Randomised, no details given	No randomisation	No randomisation	No randomisation
Allocation concealment	No	Yes	No	Unclear	No		No
Description of withdrawals and losses to follow-up	No losses to follow-up (retrospective study), although some data were incomplete - for most outcomes data were only available for 113 of 121 patients	No losses to follow-up	No losses to follow-up (retrospective study)	Not described	No losses to follow-up	No losses to follow-up (retrospective study) - although some data were very incomplete - diabetes scores missing for 2 patients at 2-5 weeks and blood glucose only available for 3 patients in the intervention group at both time points	Questionnaire data for 92% of hospital group and 74% of day-care group at 6 months, and 84% of hospital group and 67% of day-

(Continued)

						care group at 12 months; no losses of follow-up for data on HbA1c and insulin requirement	
Blinding of outcome assessment	Not mentioned	Yes (confirmed by personal correspondence); lab technicians analysing HbA1c, independent evaluation team responsible for data collection and analysis	Yes	Not mentioned	Not mentioned, probably not	Not mentioned	Not mentioned
Adequacy of length of follow-up	Yes, at least 5 years	Yes, 2 years (three for HbA1c)	Yes, outcomes measured 3-15 years after diagnosis	Yes, 2 years	No, 1 month only	No, outcomes only reported over 2-5 weeks after initiation of insulin treatment	Yes, one year

WHAT'S NEW

Date	Event	Description
4 November 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 1, 2003
Review first published: Issue 3, 2003

Date	Event	Description
30 November 2006	New search has been performed	Minor update

CONTRIBUTIONS OF AUTHORS

CHRISTINE CLAR: Protocol development, searching for trials, study selection, data extraction, quality assessment of studies, data analysis, review development.

NORMAN WAUGH: Development of review question, protocol and review development, study selection, third reviewer for resolving differences in data extraction.

SIAN THOMAS: Quality assessment of studies, data extraction.

DECLARATIONS OF INTEREST

None known. The funding from Novo Nordisk was not specifically provided for this review but had been provided to the Wessex Institute for general purposes.

SOURCES OF SUPPORT

Internal sources

- Wessex Institute for Health Research and Development, University of Southampton, UK.

External sources

- Novo Nordisk, UK.

NOTES

COSTS: costs were converted to costs in Euros with the exchange rate of 28.5.2003. This was done in an attempt to have a slightly more international representation of costs, but we are of course aware that the 2003 exchange rates do not correspond with the exchange rates as they would have been at the time the costs were calculated.

INDEX TERMS

Medical Subject Headings (MeSH)

*Ambulatory Care; *Home Care Services; *Hospitalization; Diabetes Mellitus, Type 1 [*therapy]; Randomized Controlled Trials as Topic

MeSH check words

Adolescent; Child; Humans