LINDA: the diabetes self-management training programme for people with type 1 or type 2 diabetes

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Introduction

The education of people with diabetes mellitus (DM) has been an essential part of treatment since insulin therapy was introduced.

Group-education programmes were first used in Germany by a team from Düsseldorf University, using a system known as the Berger-Jörgens-Grüsser programmes.[1–3] Type 2 DM programmes have been simplified for use by general practitioners who treat outpatients. The type 1 DM programme – which was extensive and intended for the education of inpatients – was based on compliance and on direct patient input.

The economic impact of DM on health service providers rose rapidly in the 1990s, and diabetes education took on a new dimension. Established educational programmes were unsatisfactory; new methods of behavioural

Abstract

Background: The LINDA education programme (LIP) is a new diabetes self-management tool for people with type 1 or type 2 diabetes mellitus (DM).

Aim: To compare LIP with a standard education programme (control group, CG). Method: Clinical and behavioural data from 1109 DM patients, with mean diabetes duration of 12.6 years. A total of 374 type 2 non-insulin treated [T2]; 449 type 2 insulin-treated [T2I]; 286 type 1 [T1]) were evaluated over one year with the LIP in a randomised, controlled, three-arm study, or in a multicentre study.

Results: T2 LIP patients achieved lower mean glycosylated haemoglobin (HbA_{1c}, 6.2%) and a reduction in body mass index (BMI) of 0.8 kg/m^2. T2 CG patients reached a mean HbA_{1c} of 7% and showed an increase in BMI of 0.7 kg/m^2. Mean blood pressure (BP) improved from 145/85 mmHg to 134/80 mmHg in T2 LIP patients, and from 145/84 mmHg to 141/80 mmHg in the CG. Triglyceride and cholesterol levels decreased in both groups. T2I patients reached a mean HbA_{1c} of 6.7% in the LIP group and 7.5% in the CG. BP fell to 136/79 mmHg in LIP patients and 138/79 mmHg in the CG. Triglyceride and cholesterol levels also decreased in both groups. For T1 patients, mean HbA_{1c} fell to 6.8% LIP; mean in CG patients reached 7.4%. A quality of life (QoL) questionnaire showed improvements from 20% to 80% in people who used the LIP.

Conclusions: Patients who used the LIP achieved nearly normal values for HbA_{1c} and BP. Type 2 diabetes patients using LIP showed weight reduction and marked QoL improvement.

Eur Diabetes Nursing 2007; 4(3): 106–112.

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psychology were needed to help people with diabetes change their way of life; patients needed to acquire greater confidence in their abilities, in order to manage their disease. Therefore, the American Diabetes Association (ADA) called for diabetes self management and empowerment education programmes (SMEP)[4] to be developed, to integrate patients into the educational process. To improve quality of life (QoL) and treatment, patients needed to take responsibility for managing their diabetes.

No evaluated SMEP existed in Germany in the 1990s. Other reasons for a new programme were increasing knowledge about diabetes and the complexity of the disease. There are slim patients with insulin resistant type 2 diabetes, overweight patients with type 1 diabetes and people with type 1 and type 2 diabetes, the so called 1.5. Patients with diabetes became better informed because of information that was available through the media. These patients expected a higher standard of group education and diabetes training sessions.

Several new types of medication and insulin have recently become available; such as Incretins the latest class of drug to arrive. There are now many more therapy variations available than ever before and this provides health care professionals with the option to factor an individual strategy to every patient. Since there is no programme that meets all these demands we decided to evaluate and publish our own diabetes self-management training programme for people with type 1 or type 2 diabetes, called LINDA (**L**iving – **I**nteractive – **N**ew – **D**istinguished – **A**ctivating).

The programme conforms to the guidelines of international diabetes associations including the German Diabetes Association (DDG)[5,6] and the ADA.[7] LINDA is accredited by the German Health Board Authorities for the education of patients with type 1 and type 2 diabetes and is integrated into disease management programmes for diabetes in Germany.

This paper presents data obtained by LINDA used for patients with type 1 and type 2 diabetes, and describes the programme.

Education programme

LINDA covers all treatment options available for patients with type 1 or type 2 diabetes mellitus. It comprises seven modules. There are four basic modules for all patients covering nutrition, blood glucose self-monitoring, medication, hypoglycaemia, HbA_{1c}, podiatry, micro- and macrovascular long-term consequences, hypertension, weight reduction, sports, explanation of all items which are shown in the World Health Organization diabetes passport – a very important element of the programme. Modules five and six describe various insulin therapies. Patients learn everything about insulin injection,

to adapt insulin dosage to suit their blood glucose levels or to calculate insulin dosage according to their normal diet. They are trained to cope with diabetes in special situations such as sports participation, acute illness or hypoglycaemia unawareness. An additional module covering diabetes and pregnancy complete the programme. The course for patients with non-insulin dependent type 2 diabetes lasts for four sessions; five for conventional insulin therapy (CT), with basic insulin and tablets (BOT) and for therapy with injected incretins; six sessions for supplementary insulin(SIT) and for intensified conventional therapy (ICT); up to 12 sessions for functional insulin therapy for type 1 or type 2. Each session lasts 90–120minutes. The schedule can be adapted to suit conditions in different regions. The advantage of the modular structure is that all type 2 patients, irrespective of their therapy, can start together in the same group.

After four basic sessions patients with insulin continue with one or more additional sessions. Even patients with type 1 diabetes can also take part in the early stages of the programme. The programme is self explanatory and easy to use.

The LINDA box includes booklets for patients undergoing the course and an extensive training manual for diabetes nurses, which explains the training and gives a theoretical background to the programme. It also features timetables for the different courses. The education manual shows detailed descriptions of the sessions, outlines the aims of sessions within each module and contains detailed text and figures that support patient-specific education parameters.

The box contains 80 innovative coloured magnetic models, 50 slides and a CD for on-screen presentation. Magnetic text strips, flexible insulin graphs and ordering, sorting, question and discussion cards are provided to initiate debate.

Innovative models are used throughout the LINDA programme to illustrate the liver, intestines, pancreas, brain, heart, blood vessels and fat tissue, together with other diabetes-related items including insulin, cells and insulin resistance. The models, which are assembled by the patients, enable them to build a picture of the pathophysiological processes in DM. This facilitates explanation of
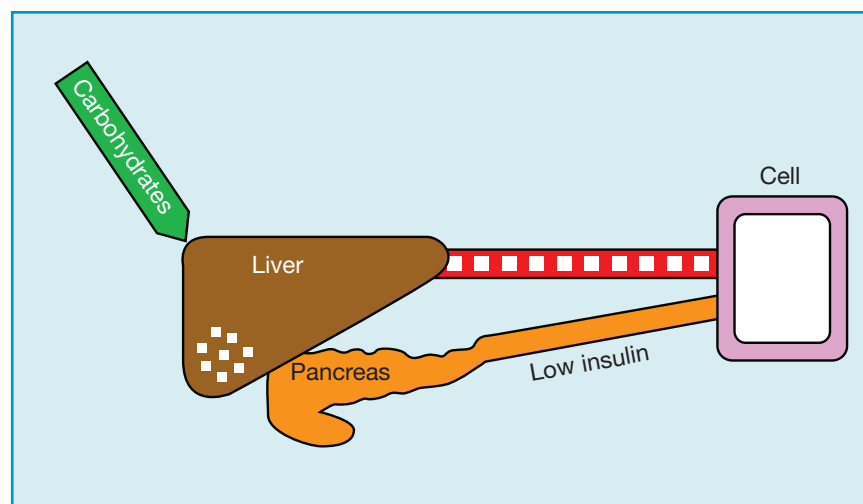

Figure 1. Models are assembled to help describe the pathophysiological processes

the many different aspects of their condition, such as the pathophysiology of type 1 or type 2 DM, the effect of alcohol, or the different target points of medication (Figures 1 and 2).

Obese people with DM often find it difficult to lose weight. Of our patients, 62% had tried to lose weight an average of 2.7 times before starting the programme. Weight gain is also clearly a problem for patients with type 1 DM: 28% of our patients are obese. Many patients see diabetes as limiting their diet and feel guilty if they cannot understand nutrition therapy or keep to therapeutic advice that they find too demanding. LINDA aims to help these people by offering a pathophysiological model that motivates them to change their lifestyle.

Because the LINDA programme helps patients to understand the metabolism of diabetes by using the models and giving information on nutrition, calories, weight loss, blood glucose and other aspects of care, the same educational information can be used for people with type 1 and type 2 diabetes. Individualised nutritional advice about obesity is not given in the basic lessons, but by taking part in the programme patients become motivated and better informed about healthy food and therapeutic options, and if they decide to reduce weight, they can get help.

The LINDA programme enables patients to manage their disease and decide for themselves what they would like to achieve. It enables overweight patients with type 1 DM, lean patients with type 2 DM or people with 'type 1.5 diabetes' to participate in education programme that deals with their particular situation. Personal weight problems are treated in single sessions.
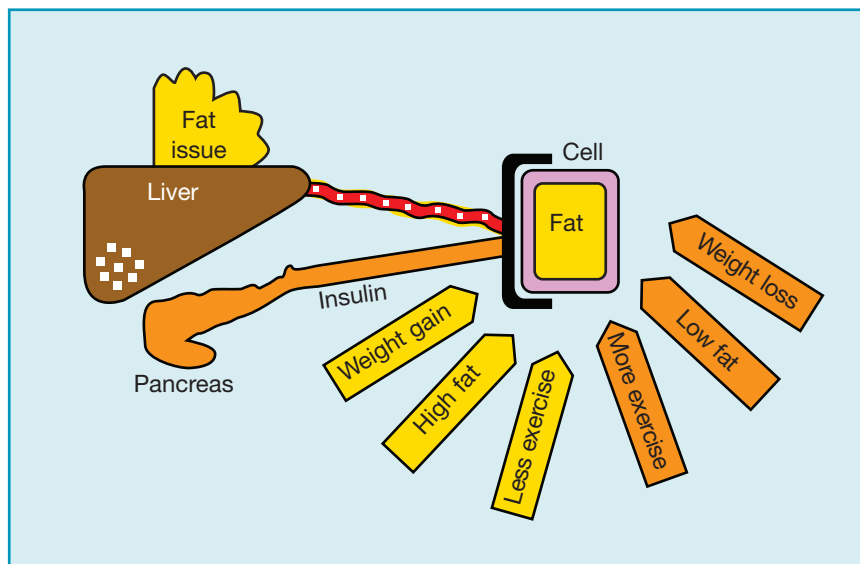

Figure 2. Models are also used to demonstrate the impact of therapy or lifestyle measures

The pedagogic and psychological structure of LINDA is based on neuroscientific research into teaching concepts. Key subjects are not merely addressed once; they are divided into smaller sections and repeated in subsequent lessons; presentations start with simple information and increase in complexity. For example, in the first lesson the blood glucose levels for hypoglycaemia and a few examples for acute therapy are shown. This information is repeated in the next session, and further details are added to explain the causes of hypoglycaemia (such as alcohol intake or low carbohydrate diet). There are further repetitions during the insulin lessons and the subject of hypoglycaemia is further enlarged when insulin dosage, adapting to glucose levels and glucagon injections are discussed.

Different media are used during the lessons, to build teamwork and discussion. The patients are at the centre of the programme: their emotions are taken into account and a positive attitude is always maintained. The LINDA training programme listens to patients' opinions, gives positive feedback and support, and enables people to deal competently with their diabetes. People learn about diabetes and gain skills for appropriate self management.

We developed the LINDA programme in the hope of achieving better results for diabetes care; our findings were published in the official journal of the DDG in 2004.[8] The evaluation was undertaken independently and no sponsorship was received. Patients in the type 2 arm continue to be followed up.

Aims

The main aim of our study was to compare the effectiveness of LINDA with that of the standard DM teaching programmes by measuring data such as glycosylated haemoglobin (HbA_{1c}), body mass index (BMI) and incidence of hypoglycaemia.

The second aim was to demonstrate the effectiveness of LINDA across several diabetes centres, according to the published guidelines of the DDG [5,6] and the ADA.[7] These guidelines require glycaemic control, with HbA_{1c}

<6.5% (DDG) or <7% (ADA) for patients with type 2 DM or <7% (ADA), where possible, for people with type 1 DM without an increase in hypoglycaemia episodes and with a clear improvement in QoL.

A third aim was to show whether patients with long-standing diabetes who had previously undertaken various educational and medication programmes, but with unsatisfactory results, reached good outcome parameters using LINDA.

Exclusion criteria were: diabetes manifestation in the past 12 months; patients with the therapy option only, free from acute signs and symptoms; patients with mental or physical disorders; or patients with decompensated DM. Such patients typically have very high HbA_{1c} levels and nearly every treatment they undergo will greatly decrease their HbA_{1c} range. Although this can imply that the results of a specific intervention seem to be very good, such findings can lead to inaccurate evaluation of the education programme.

Most of the patients who have undergone typical diabetes therapy over many years have HbA_{1c} levels ranging between 7.5% and 9%. The study aimed to show whether such patients benefited from undergoing the LINDA programme, and to establish if they not only actually showed improvement, but they reached *good* outcomes.

Patients and methods

Study methods, design and ethical criteria for DM trials in Germany are regulated by the German Diabetes Society. Our protocol was checked by Professor E Standl and his team at the Diabetes Research Centre, Munich.

The evaluation was undertaken in two parts. The first part comprised a controlled three-arm randomised study in our centre, to compare the effectiveness of LINDA with that of a standard education programme, the Jörgens-Grüsser programme, which acted as the control group (CG). The second part was a multicentre study that evaluated the effectiveness of LINDA in other education centres. All patients involved in the study were out-patients in centres with ambulant treatment only.

Randomisation was carried out according to chance. We offered several courses with either LINDA or the CG, operating at different starting times. Patients chose which to attend and did not know if they were taking part in a LINDA or a control-group course. All patients completed informed consent forms with a questionnaire that was necessary documentation to ensure health insurance reimbursement. For the first part of the evaluation, patients were randomised over 18 months to either the LINDA programme (intervention group) or the CG. They were allocated into one of three treatment arms, depending on their type of diabetes: type 2 DM arm non-insulin treated (T2), type 2 DM arm insulin-treated (T2I), and type 1 DM arm (T1). Data were collected at the start of the study (t0) and one year after the education programme (t1), although follow-up in patients in the type 2 DM is ongoing. Data collection included measures such as age, BMI, systolic (sBP) and diastolic (dBP) blood pressure, HbA_{1c}, cholesterol, triglycerides, micro-albuminuria and hypoglycaemia.

Patient knowledge and satisfaction was examined using questionnaires included in the LINDA programme. The change in QoL following the education programme was checked with a questionnaire for handling diabetes, anxiety, flexibility of life and flexibility of nutrition, containing questions including 'Do you feel that your nutrition has been affected by diabetes?' The total QoL score collectively summarised the single-item findings.

The second part of the evaluation involved patients with DM who attended 15 diabetes outdoor education centres (which were run by diabetes nurses and diabetologists) over a six-month period. The patients were separated into the arms T2, T2I and T1. Data were collected for sBP and dBP, HbA_{1c}, BMI and hypoglycaemia at the start of this phase, and one year after the education programme.

Statistical analyses

Data were collected online, using the DPV Programme of the University Ulm. Data preparation was carried out with a special education evaluation tool from the Department of Mathematics at the University of Ulm. Statistical analyses were carried out by Method Consult in Heidelberg, Germany. Paired t-tests were used for continuous variables such as sBP and BMI. Results were considered statistically significant if $p \leq 0.05$. The Satterthwaite t-test with NQUERY ADVISOR 5 was used to calculate the power of non-parametric data of equal means and unequal variances. Values over 95% were considered to be significant.

Results

For the first part of the evaluation, 805 patients were randomised to either the LINDA programme or CG; in the second part of the evaluation, 304 patients attended 15 diabetes outdoor education centres. One year after carrying out the education programme, the data for all 1109 patients were

Data	T2*		T2I		T1	
Programme	LINDA	JG 2	LINDA	JG T2I	LINDA	JG T1
Dropout, n (%)	4 (1.4)	3 (4.6)	4 (1.3)	3 (2.3)	3 (1.65)	2 (2)
Number of patients[†]	t0 t1	t0 t1	t0 t1	t0 t1	t0 t1	t0 t1
	309 305	65 62	317 313	132 129	184 181	102 100
Mean age (years)	62.5	65.4	64.8	67.3	51.6	51.8
Mean diabetes duration (years)	8.1	9.5	13.2	14.9	14.9	15.4

T2 = patients with type 2 diabetes, non-insulin treated; T2I = patients with type 2 diabetes, insulin treated; T1 = patients with type 1 diabetes
[†] t0 = start of the study; t1 = one year after the education programme

Table 1. Demographic data from patients in all arms of the study comparing LINDA, a diabetes education programme, with the Jörgens–Grüsser programme

assessed and analysed. The results are reported separately for each arm of the study.

All patients (55% women) were Caucasian. Table 1 shows the demographic data for patients in all arms of the study. The duration of diagnosed DM was 8.1–9.5 years for patients in the T2 arm, 13.2–14.9 years in the T2I arm, and 14.9–15.4 years in the T1 arm. Of the 1109 patients, 810 attended LINDA and 299 attended the with Jörgens-Grüsser (CG) programmes.

Dropout was low, affecting two to three people in each arm (range 1.3–4.6%). Due to the different types of DM, patients' age ranges varied from 62.5 to 65.4 years in the T2 arm, 64.8 to 67.3 years in the T2I arm and 51.6 to 51.8 years in the T1 arm.

The long-term consequences of diabetes were seen in many patients: 20% were diagnosed with retinopathy, 18% with microalbuminuria, 30% developed neuropathy (which was severe in 15%). Cardiac autonomic neuropathy was found in 13%, and 32% of men had erectile dysfunction.

Numerous changes in clinical data, summarised in Table 2, were found to be statistically significant. Only one severe hypoglycaemic incident occurred,

and triglyceride and cholesterol levels decreased across all groups.

In the T2 arm, LINDA patients achieved a 17.72% decrease in HbA_{1c} (p<0.0005) whereas CG patients achieved a 10.38% decrease (p<0.0005). BMI decreased in the LINDA T2 group by 2.61% (p<0.0005) and reached 29.2 after three years with the same level of glucose control. For the CG T2 patients, BMI increased by 2.24% (p<0.0005). There was a greater decrease in serum triglyceride levels in patients undergoing the LINDA programme (24.96% decrease p<0.0005) compared with the CG (15.49% decrease p<0.005). Cholesterol levels also decreased more markedly in the LINDA group (by 12.55%) compared with a 2.17% decrease in the CG (p<0.0005).

Mean systolic BP decreased in both groups, although the greatest reduction was in the LINDA group, which achieved a decrease of 7.37% (p<0.0005), falling to a value within the normal range; systolic BP decrease in the CG was only 2.85% (p<0.005). Mean diastolic BP also decreased by 5.38% in the LINDA group and 4.53% in the CG (p<0.0005). A 43.41% reduction in micro-albuminuria levels was seen in LINDA T2 patients (p<0.005) compared with a 32.33% decrease in the CG.

In the T2I arm, LINDA patients achieved a 20.46% decrease in mean HbA_{1c} levels (p<0.0005) whereas mean HbA_{1c} increased by 16.20% (p<0.0005) in the CG. BMI increased in the LINDA group by 1.21% (p<0.0005) and in the CG by 2.61% (p<0.0005). Serum triglycerides decreased by more in the LINDA group (24.76%; p<0.0005) than in the CG (14.36%; p<0.0005), as did cholesterol levels, which fell by 11.08% (p<0.0005) in the LINDA group and 7.04% (p<0.0005) in the CG.

Mean systolic BP also fell in both groups, reaching normal values (5.45%; p<0.0005 decrease in the LINDA group and 5.15%; p<0.0005 decrease in the CG). Diastolic BP reached normal values, falling by 4.03% (p<0.0005) in the LINDA group and 4.82% (p<0.0005) in the CG. This arm also showed a 39.8% (p<0.0005) decrease in microalbuminuria levels in LINDA T2I patients compared with a 37.8% (p<0.0005) decrease in the CG.

In the T1 arm, LINDA patients achieved a 19.38% (p<0.0005) decrease in HbA_{1c} and CG patients had a 9.61% (p<0.0005) decrease in HbA_{1c}. BMI increased slightly in this arm, by 1.43% (p<0.0005) in LINDA patients and 2.62% (p<0.0005) in the CG.

Serum triglyceride levels decreased in both groups in the

Type	T2				T2I				T1			
Programme	LINDA		JG 2		LINDA		JG T2I		LINDA		JG T1	
HbA_{1c} (%)	7.5	6.2	7.9	7.0	8.5	6.7	9.0	7.5	8.4	6.8	8.2	7.4
BMI (kg/m^2)	31.2	30.4	31.2	31.9	31.5	31.8	32.2	33.1	26.9	27.3	26.7	27.4
Triglycerides (mg %)	105	78	247	209	120	90	217	186	91	65	179	142
Cholesterol (mg%)	111	98	222	217	114	101	226	210	105	98	204	199
BP systolic (mmHg)	145	134	145	141	144	136	146	138	137	130	135	133
BP diastolic (mmHg)	85	80	84	80	82	79	83	79	81	77	79	78
Microalbuminuria (mg %)	6	4	14	9	11	7	25	16	6	3	15	11
Severe hypoglycaemia (%)	0.003	0	0	0	0.023	0	0.078	0	0.058	0	0.06	0.01

T2 = patients with type 2 diabetes non-insulin treated; T2I = patients with type 2 diabetes, insulin treated; T1 = patients with type 1 diabetes; HbA_{1c} = glycosylated haemoglobin; BMI = body mass index; BP = blood pressure

Table 2. Mean clinical results from participants in the evaluation study of the LINDA and Jörgens–Grüsser (JG) diabetes education programmes

T1 arm, by 28.78% (p<0.0005) in the LINDA group and 20.63% (NS) in the CG. Cholesterol levels also fell, by approximately 6.65% (p<0.005) in the LINDA group and 2.27% (p<0.005) in the CG.

Mean BP levels were normalised after one year in both type 1 groups (129.75/76.5 mmHg or -5.12/-5.15%; p<0.0005 in the LINDA group and 133/78 mmHg or -2.27/-1.41%; NS in the CG). The T1 arm also showed decreases in microalbuminuria levels in the LINDA group of 45.67% compared with 24.66% (NS) in the CG.

In the year before the study, four severe cases of hypoglycaemia were reported in people who went on to participate in LINDA programmes, and seven cases occurred in future CG participants. During the study there was one case of severe hypoglycaemia, in one patient in the T1 CG.

Evaluation of the knowledge test in the study centres showed that 89.3% of patients scored more correct answers, 8.7% reached the same score as before, and 2% gave fewer correct answers. When asked about satisfaction with the LINDA programme, 75.6% of patients were very satisfied, 23.7% were satisfied, and only 0.7% of patients were less satisfied.

The QoL scores showed a marked reduction in the percentage of patients whose QoL was affected by diabetes (Table 3).

Discussion

Norris *et al* examined 72 studies involving diabetes education programmes for their effectiveness in generating self-management.[9] They realised that programmes which actively involve patients in the educational process seem to be more successful than teaching programmes that focus on imparting knowledge. The evaluation of effectiveness of the empowerment in those studies is unsatisfactory, however, because no existing standards are available to measure empowerment and self-management:[3] in addition to patient questionnaires, there are only indirect indicators of QoL, such as the incidence of hypoglycaemia or days of inpatient treatment.

However, better QoL in diabetes care is achieved by better quality of treatment, which leads to improved glucose control. Thus, we believe HbA_{1c} levels are also suitable indicators for QoL and SMEP evaluations.

There may always be doubts about evaluating the data in educational programmes. Nevertheless, numerous significant improvements in data parameters for people enrolled in the LINDA group were shown when we compared results with those from the control group, on the one hand, and with the published guidelines of the DDG and ADA on the other.

People with type 2 DM who participated in the LINDA programme reached nearly normal long-term glucose control and maintained their weight loss even after three years. In T2I patients, glucose control was improved, and a smaller mean weight gain was reported in LINDA participants than in the control group. In another study of an education programme, the BMI only increased by approximately 0.4 kg/m^2, HbA_{1c} decreased to 8.4%, hypoglycaemia rate slightly increased and the dropout rate was relatively high.[10]

The improved outcome parameters, the positive reaction of patients, the small dropout rate, and the achievement of a high degree of knowledge and self-management skills indicate that LINDA significantly improved diabetes treatment and QoL, thus our study aims were achieved. The

Cause of affection	t0 (%)	t1 (%)	Improvement
Restricted diet	85	25	-60
Restricted daily life	60	35	-25
Anxiety about the long term	70	20	-50
Insecurity about dealing with diabetes	70	5	-65
Total rate of affection	71	21	-50

Table 3. Percentage of all patients following the LINDA programme whose quality of life was affected by diabetes

LINDA programme also shows that diabetes self-management education is considerably more effective when carried out in a team as part of a comprehensive treatment plan.[11] This should involve DM health care professionals who have special training in teaching methods,[4] such as diabetes nurses.[5]

But what makes LINDA different compared with other education programmes? They all contain media material, they all have an educational content, and most of them try to fulfil the SMEP suggestions and obey the guidelines of diabetes associations. However, the results of other programmes have been less than satisfactory.[9]

We believe that the overall programme of patient empowerment achieved by group work, interactive exercises, repetitive questionnaires, positive motivation, the use of the LINDA models and finally, a special psychology and philosophy enable this approach to be more successful.

A precise description of the primary and secondary aims of the education plan allows the connection between different items to be understood. Gradually increasing the complexity of instruction and repetition in exercises helps to develop the educational process. Motivation is achieved through games, which are enjoyed. According to Zimbardo, such methods help the memory process.[12]

Knowledge is increased by activating different senses, such as hearing and sight. Additionally, visualising processes in three dimensions, as is done with the LINDA models, may have a strong influence on memory, as described in the Berlin intelligence model.[13] Finally, the sense of touch aids our memory[14] and is used widely in the LINDA programme by getting participants to touch and build the models. Together, these elements combine to provide exceptional education. Nevertheless, acceptance by patients of the way in which they need to manage their diabetes is necessary, both during the educational programmes and afterwards, because issues relating to long-term health and management in DM continue forever.

Acknowledgements
We thank the study centres for their free co-operation with the LINDA project.

Conflict of interest statement:
None

Further information:
The LINDA programme is available commercially.

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