



ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA
DIPARTIMENTO DI SCIENZE
MEDICHE E CHIRURGICHE - DIMEC

Em* società italiana medicina
d'emergenza-urgenza

CONVEGNO HYPOTHESIS

HYPOglycemia Treatment
in the Hospital Emergency System



BOLOGNA, 28 novembre 2013

Aula Stabat Mater - Palazzo dell'Archiginnasio

15:50 Ipoglicemia ed educazione
A.V. Ciardullo

DIABETES AND DRIVING

Some general remarks

- Public safety (crash prevention) is the primary goal, but individual mobility rights should not be violated if there is no special risk for public safety
- A person with diabetes is an individual. There is a lot of heterogeneity in the group of diabetics (type of treatment, level of stabilisation, presence of complications, duration of the disease, active personal involvement with the disease, level of diabetes education, frequency of hypoglycaemia, etc....)
Ideally, these should be taken into account when assessing fitness to drive.
- In the evaluation of the driving ability, there should be equal attention paid to the preventive measures that the patient can take (eg level of diabetes education and diabetes control, frequency of self blood glucose monitoring, etc) as to the medical condition per se.
- More emphasis should be given to the implementation of the rules.
The more the rules are restrictive and difficult in their implementation (eg administratively complex), the less they will be followed. This problem of compliance to the regulations (with frequent under reporting in many Member States) is not only mentioned in this WG, but is a problem noted for a number of medical conditions.

Hypoglycemia & driving

Che fare?

Prevention

A well-informed person with the ability and willingness to take charge of his or her diabetes is key to successful glycaemic control, including the prevention of hypoglycaemia.

Therefore, patient education and empowerment, frequent self-monitoring of BG, flexible insulin and other drug regimens, individualised glycaemic goals, and ongoing professional guidance are crucial factors in the prevention of hypoglycaemia.

For example, one study found that patients did not report 50% of episodes that occurred during driving, presumably due to concerns about driving privileges. This means that diabetes educators should query patients directly about episodes of hypoglycemia, and their impact on FoH and diabetes management.

Che fare?

Educational points for diabetes and driving.

The following items are important for each driver with diabetes, treated with insulin or oral hypoglycaemic drugs:

- understand the interaction between food-insulin-activity
- have rapid absorbable carbohydrate available in the car and have a BG meter available in the car to measure BG before and during long trips
- inject insulin at regular times
- do not skip meals
- anticipate any abnormal physical activities (eg loading/unloading a car)
- do not drive between injection and meal
- if HYPOGLYCAEMIA OCCURS: stop as soon as possible, take carbohydrates
wait 15-30 min before driving again

Ipoglicemia e educazione

Recenti evidenze scientifiche

EVIDENCE SYNTHESIS

Experience of hypoglycaemia and strategies used for its management by community-dwelling adults with diabetes mellitus: a systematic review

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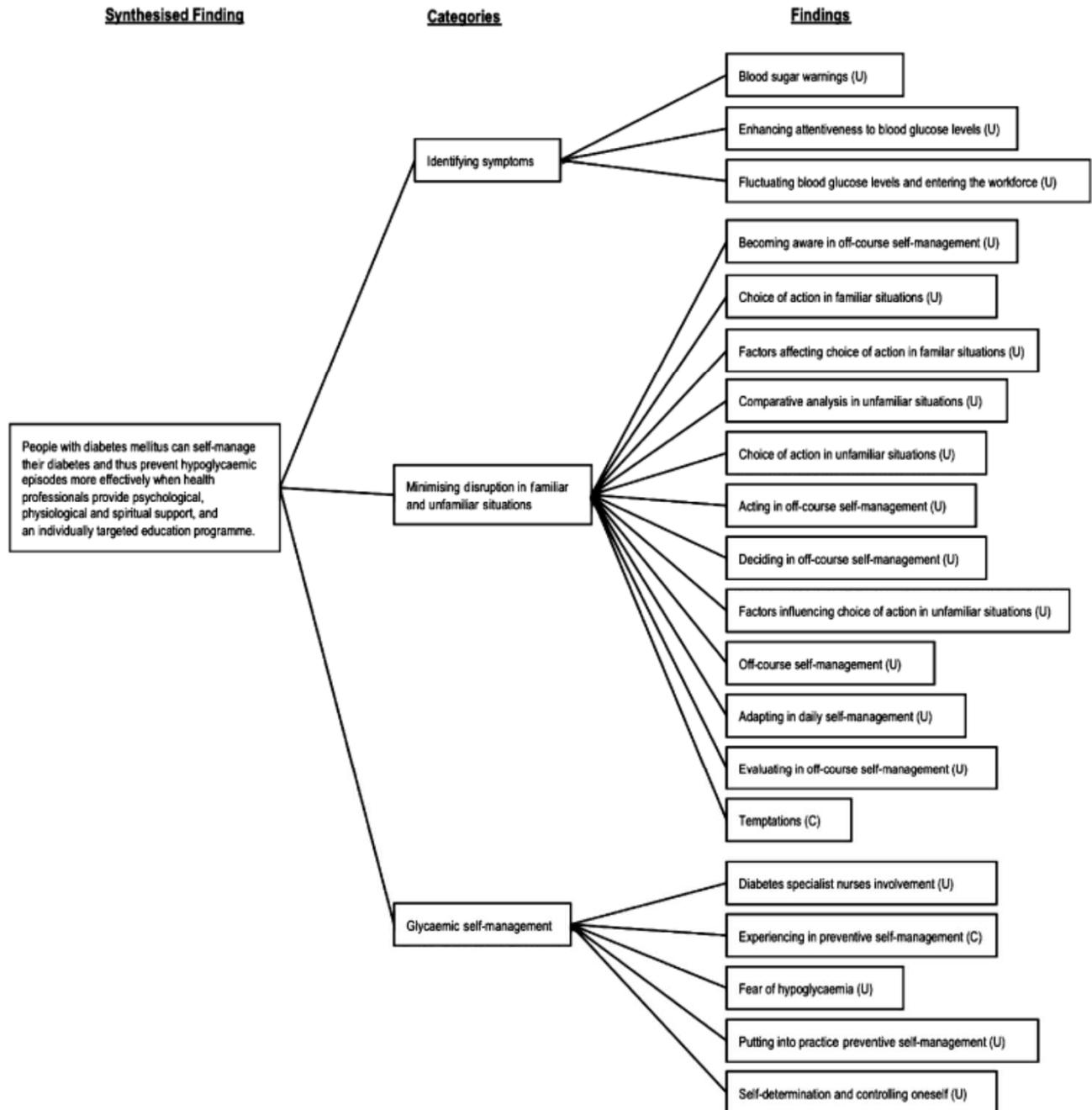


Figure 2 Synthesised finding, categories and findings. U, unequivocal; C, credible

Recognize:

- the symptoms of hypoglycemia
- the hypoglycemia unawareness or hypoglycemia related problems
- the HAAF

Review

A critical review of the literature on fear of hypoglycemia in diabetes:
Implications for diabetes management and patient education

Diane Wild^{a,*}, Robyn von Maltzahn^a, Elaine Brohan^a, Torsten Christensen^b,
Per Clauson^b, Linda Gonder-Frederick^c

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Practice implications: There is some evidence to suggest that interventions including BG awareness training and cognitive behavioral therapy can reduce levels of fear and improve disease management. While many aspects of FoH require further well-designed research, it is evident that this phenomenon can have a major impact on diabetes management and needs to be specifically addressed in patient education programs.

Evaluation of a self-management-based patient education program for the treatment and prevention of hypoglycemia-related problems in type 1 diabetes

Thomas Kubiak^{a,*}, Norbert Hermanns^b, Hans-Jürgen Schreckling^c,
Bernhard Kulzer^{b,c}, Thomas Haak^{b,c}

Curriculum and contents of the new program

Lesson 1: goal-setting, prior experiences with hypoglycemia, initial problem analysis and introduction of self-monitoring techniques

Lesson 2: individual problem analysis and building up motivation to change

Lesson 3: model of hypoglycemia perception and “circulus vitiosus” of impaired hypoglycemia awareness

Lesson 4: individual glycemetic goals, fear of hypoglycemia and diabetic complications

Lesson 5: hypoglycemia in social context and coping with hypoglycemia in daily life

Lesson 6: goal attainment, feedback and strategies for maintaining behavior change

3.3.2. Hypoglycemia awareness

Hypoglycemia awareness remained constant in IG, whereas some deterioration was observed in CG (Table 5).

In this observational controlled pre-post study, the effects of a self-management-based intervention program on hypoglycaemia-related problems were compared with standard patient education. A benefit of the self-management-based intervention could be observed with regards to the target criteria severe hypoglycemia and hypoglycemia-related problems without a deterioration of glycemetic control observable. These results are in line with the results published on Blood Glucose Awareness Training [20,22].

Dossier: Diabetes: Basic Research and Clinical Approach

Hypoglycemia in type 2 diabetes: a critical review

Glen H. Murata^{a,b,*}, William C. Duckworth^{c,d}, Richard M. Hoffman^{a,b},
Christopher S. Wendel^e, M. Jane Mohler^{e,f}, Jayendra H. Shah^{d,e}

Comparison of patients with no, low-, and high-frequency hypoglycemia

	No hypoglycemia Group 0 (n = 168)	Low frequency Group 1 (n = 92)	High frequency Group 2 (n = 84)	P-value
Median number of events/year (inter-quartile range)	0	2.0 (1.2–3.6)	16.0 (8.8–27.4)	
Duration of diabetes (years)	13.2 ± 9.3	14.8 ± 9.6	17.4 ± 10.7	0.013 ^a
Diabetes knowledge score (% correct)	62.5 ± 15.3	64.0 ± 14.4	69.3 ± 15.4	0.003
BMI (kg/m ²)	32.7 ± 6.1	31.9 ± 6.0	29.9 ± 6.2	0.003
Use of an oral hypoglycemic agent	40.5%	40.2%	19.0%	0.044
Number of preparations	0.58 ± 0.79	0.54 ± 0.73	0.23 ± 0.49	0.001 ^a
Use of glyburide	24.6%	21.7%	7.1%	0.004
Dosing times per day	0.82 ± 1.04	0.80 ± 1.04	0.32 ± 0.72	<0.001
Number of insulin preparations	1.33 ± 0.50	1.45 ± 0.52	1.58 ± 0.58	0.002 ^a

Polychotomous logistic model for the hypoglycemia risk categories

	Coefficient	Standard error	Odds ratio (OR)	95% CI for OR
Duration of insulin treatment (in decades)	0.388	0.147	1.5	1.1–2.0
Diabetes knowledge score (in deciles)	0.287	0.083	1.3	1.1–1.6
Mini-Mental State score	–0.122	0.048	0.88	0.81–0.97
BMI (kg/m ²)	–0.461	0.192	0.95	0.92–0.99
HbA1c (%)	–0.145	0.069	0.87	0.76–0.99
Number of oral hypoglycemic agents	–0.292	0.173	0.75	0.53–1.00
Number of daily insulin injections	0.502	0.204	1.7	1.1–2.5

Evaluation of a Structured Outpatient Group Education Program for Intensive Insulin Therapy

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 WOLFGANG J. SCHNEDL, MD

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 PETER KAUFMANN, MD
 GUENTER J. KREJS, MD

Table 2—Clinical data for the 201 patients with complete follow-up at baseline and after 3 years

	Baseline	Follow-up	Difference (95% CI)	P value
HbA _{1c} (%)	8.7 ± 2.0	7.5 ± 1.2	-1.2 (0.9-1.5)	0.001
Severe hypoglycemia (episodes/patient-year)	0.46 ± 1.37	0.13 ± 0.40	-0.33 (0.06-0.60)	0.001
Patients with history of severe hypoglycemia (%)	77 (38)	82 (41)	5 (3)	NS
Body mass index (kg/m ²)	23.3 ± 3.0	23.8 ± 3.0	0.5 (0.2-0.8)	0.001
Systolic blood pressure (mmHg)	127 ± 21	130 ± 19	3 (-2-8)	NS
Diastolic blood pressure (mmHg)	78 ± 13	80 ± 9	2 (-3-7)	NS
Patients receiving antihypertensive treatment	16 (8)	35 (17)	19 (9)	0.001
Hospitalization				
Acute metabolic (days/patient-year)	4.5 ± 11.1	1.4 ± 6.7	-3.1 (1.0-5.2)	0.001
Other (days/patient-year)	5.6 ± 14.5	6.2 ± 9.5	0.6 (-6.6-7.2)	NS

CONCLUSIONS — A structured outpatient DTTP as used in this study is able to improve overall metabolic control and decrease the frequency of severe hypoglycemia in patients with IDDM.

The structured DTTP lasted from Monday to Friday and included 24 h of group teaching. The overall goal of the DTTP was to aim for (near-) normoglycemia and to avoid hypoglycemia. Intensive insulin therapy was introduced on the 2nd day during the DTTP. Patients were advised to regularly perform four blood glucose measurements per day before main meals and at bedtime and to record the results in a log book.

CONCLUSIONS— This study demonstrates

the beneficial effects of a structured outpatient DTTP on overall metabolic control in patients with IDDM. After DTTP we found a significant decrease in HbA1c levels and in frequency of severe hypoglycemia. This was also reflected by a decreased need for hospital admission due to acute metabolic disturbances. From previous observations it is known that only very few patients are able to achieve or maintain normal HbA1c levels over a longer period of time (1,11). In our study we found 15% of patients with normal HbA1c at follow-up compared with 4% before DTTP.

Effect of Structured Group Education on Glycemic Control and Hypoglycemia in Insulin-Treated Patients

We investigated the effect of a structured group diabetes education program (1) on insulin-treated patients who had received individual counseling (at the time of diagnosis and insulin initiation). A total of 1,369 type 1 and insulin-treated type 2 diabetic patients with mean disease duration of 11.7 and 13.7 years, respectively, were allocated to receive or not receive structured group education, which was delivered in 10 45-min sessions over 3–5 days.

Baseline GHb levels of type 1 diabetic patients were 9.3% for the education group and 9.13% for the control group and decreased at 6 months by -0.82 and -0.22% , respectively ($P = 0.0005$). The number of injections per day and self-monitoring increased, while the total insulin dose remained unchanged. The incidence of severe hypoglycemia was reduced by 0.18 events/6 months in the ed-

ucation group, whereas it increased by 0.03 events/6 months in the control group ($P = 0.003$).

In type 2 diabetic patients, baseline GHb was 9.1% in the education and 8.7% in the control group, with a significant difference in the changes after 6 months in favor of the education group: -0.48 vs. 0.17% , respectively ($P = 0.0005$). A trend of reduced incidence of hypoglycemic episodes was observed.

Education for people with diabetes is a prerequisite for an understanding and acceptance of their condition and its successful self-management (2). A recent study found that group education was as effective as individual tuition in achieving improvements in glycemic control (3). In our study, structured group education after initial individual counseling at diagnosis and insulin initiation resulted in improved glycemic control and reduction of hypoglycemia. This observation is in line with results from previous publications (4,5). These improvements could be attributed to better self-care (increased frequency of self-monitoring in both type 1 and insulin-treated type 2 diabetic patients) and the increase in the number of insulin injections (in type 1 diabetic patients). It should be noted that there was not a significant difference in the mean insulin doses at the 6-month follow-up visit compared with baseline in both type 1 and type 2 diabetic patients; therefore, it was not the amount of injected insulin but the educational intervention that contributed to the improved glycemic control.

It can be suggested that a group education program following individual counseling could be an effective tool in diabetes management.

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Improved Biomedical and Psychological Outcomes 1 Year After Structured Education in Flexible Insulin Therapy for People With Type 1 Diabetes

The U.K. DAFNE experience

Diabetes Care 35:1638–1642, 2012

Table 3—Changes in measures of psychological well-being/distress

	Baseline		1 year post-DAFNE		P value
	Mean	SD	Mean	SD	
EQ-5D	0.84	0.16	0.84	0.18	NS
EQ-5D VAS	71.2	20.8	75.1	18.4	0.002
PAID	25.2	17.4	16.7	14.1	<0.001
HADS (anxiety)	5.3	3.7	4.6	3.5	<0.001
HADS (depression)	4.8	3.2	4.2	3.1	<0.001

DAFNE

Clinical Care/Education/Nutrition/Psychosocial Research

ORIGINAL ARTICLE

Improved Biomedical and Psychological Outcomes 1 Year After Structured Education in Flexible Insulin Therapy for People With Type 1 Diabetes

The U.K. DAFNE experience
One-year outcomes of structured education in type 1 diabetes

Table 2—Hypoglycemia awareness status and severe hypoglycemia rates at enrollment and 1 year post-DAFNE

Baseline	n	Status at 1 year			SH pre-DAFNE		SH post-DAFNE	
		Aware	Impaired	No data	Mean	SD	Mean	SD
Aware	324	202 (62)	81 (25)	41 (13)	0.87	3.99	0.35*	1.63
Impaired awareness	215	92 (43)	97 (45)	26 (12)	3.6	13.6	1.3*	5.9
All	539	294 (54)	178 (33)	67 (12)	1.7	8.5	0.6*	3.7

Data are n (%) of people in each category at baseline and follow-up, together with self-reported mean number of severe hypoglycemic (SH) episodes per subject for the year preceding DAFNE attendance and for 1st year post-DAFNE. * $P < 0.05$ for comparison of pre- and post-DAFNE mean data.

CONCLUSIONS—A structured education program delivered in routine clinical practice not only improves HbA_{1c} while reducing severe hypoglycemia rate and restoring hypoglycemia awareness but also reduces psychological distress and improves perceived well-being.

setting translate into routine clinical practice, we have conducted a retrospective audit of biomedical and psychological outcomes at baseline (enrollment in the program) and at 1 year posttraining, in-

Effectiveness of Self-Management Training in Type 2 Diabetes

A systematic review of randomized controlled trials

Table 7—Conclusions of a review of randomized, controlled trials of the effectiveness of self-management training in type 2 diabetes

A. Effectiveness of interventions

1. In the short term (<6 months), knowledge levels, SMBG skills, and self-reported dietary habits improve.
2. In the short term, improvements in glycemic control, knowledge, and diet are more readily demonstrated than improvements in weight and physical activity levels.
3. Improved glycemic control does not correspond to measured changes in knowledge or SMBG skills.
4. Weight loss can be demonstrated with repetitive interventions or with short-term follow-up (<6 months).
5. Physical activity levels are variably affected by interventions.
6. Effects on lipids and blood pressure are variable and more likely to be positive with interactive or individualized, repetitive interventions.
7. Studies with short-term follow-up are more likely to demonstrate positive effects on glycemic control and behavioral outcomes than studies with longer follow-up intervals.
8. Interventions with regular reinforcement are more effective than one-time or short-term education.
9. Interventions that involve patient participation and collaboration seem to produce somewhat more favorable effects on glycemic control, weight loss, and lipid profiles than didactic ones.
10. Group education is more effective for lifestyle interventions and seems to be equally effective for interventions focusing on knowledge and SMBG.
11. The focus of the current literature has been on knowledge and glycemic control outcomes; there is little literature measuring quality of life and long-term clinical outcomes.

CONCLUSIONS — Evidence supports the effectiveness of self-management training in type 2 diabetes, particularly in the short term. Further research is needed to assess the effectiveness of self-management interventions on sustained glycemic control, cardiovascular disease risk factors, and ultimately, microvascular and cardiovascular disease and quality of life.

The objective of this study was to systematically review reports of published randomized controlled trials to ascertain the effectiveness of self-management training in type 2 diabetes, to provide summary information to guide diabetes self-management programs and future

EVIDENCE SYNTHESIS

Effect of educational components and strategies associated with insulin pump therapy: a systematic review

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Type of outcomes

The outcomes of interest were:

- Glycaemic control measured by glycated haemoglobin concentration (HbA1c-level) and/or fasting plasma glucose level
- Continuous blood glucose monitoring
- Body mass index and weight
- Episode of diabetic ketoacidosis (DKA)
- Frequency and severity of hypoglycaemia
- Frequency of admission/presentation/contact with healthcare professionals for blood glucose level problems
- Frequency of site complications (including infection)
- Insulin pump knowledge

- 1 Education and training is important for successful initiation of IPT (Level III).
- 2 Multidisciplinary teams that comprised of doctors, nurses, dieticians and diabetes educators may be an effective team for delivering IPT education and training (Level III).
- 3 There is no one educational method that appears significantly more effective than any other method. However, the mixture of group and individual teaching may be effective for delivering IPT education and training (Level III).
- 4 The provision of materials for use in education and training and for patients to take home (e.g. training pump) may be considered useful and valued by patients (Level III).
- 5 Blood glucose monitoring, carbohydrate counting, adjustment of insulin dose (initial basal rates and premeal boluses), practical aspect of insulin pump including identification of malfunctions, prevention and management of acute complications (e.g. DKA), and lifestyle changes are the major components of IPT education and training programs (Level III).
- 6 Longer-term training with multiple sessions may be more effective than short session training (Level III).
- 7 The duration and frequency of follow up for optimal self-management of IPT may be adapted to individual needs (Level III).



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LETTER TO THE EDITOR

**Bolus calculator improves long-term metabolic control
and reduces glucose variability in pump-treated
patients with Type 1 diabetes**

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Table 1 Pre-prandial, post-prandial and bedtime capillary blood glucose levels (mean \pm SD of three days), measures of glycemic variability and time spent with blood glucose levels <70 mg/dl (determined by the analysis of interstitial glucose concentration measured continuously over 72 h), and frequency of severe hypoglycemia during the year before and the year after the use of bolus calculator in 30 Type 1 diabetic patients.

	Period without bolus calculator	Period with bolus calculator	<i>P</i>
Blood glucose values (mmol/l)			
Pre-breakfast	8.92 \pm 4.94	8.76 \pm 4.43	0.644
2 h post-breakfast	9.25 \pm 3.46	9.04 \pm 3.52	0.521
Pre-lunch	8.08 \pm 3.1	8.01 \pm 3.07	0.868
2 h post-lunch	9.54 \pm 4.38	8.77 \pm 4.11	0.022
Pre-dinner	8.44 \pm 3.97	8.37 \pm 3.56	0.876
2 h post-lunch	9.80 \pm 4.12	8.88 \pm 3.66	0.047
At bedtime	8.77 \pm 3.86	8.52 \pm 3.37	0.517
Measures of glycemic variability (mmol/l)			
CONGA 4/day	5.45 \pm 3.57	4.97 \pm 3.33	0.005
CONGA 4/night	4.44 \pm 3.09	4.42 \pm 2.93	0.832
CONGA 2/ day	4.67 \pm 2.79	3.89 \pm 2.02	0.002
CONGA 2/night	4.03 \pm 2.01	3.95 \pm 1.91	0.321
MODD	2.78 \pm 1.61	2.66 \pm 1.29	0.769
<i>Time spent with glucose levels <70 mg/dl during CGM (min/day)</i>	37 \pm 22	35 \pm 24	0.503
<i>Frequency of severe hypoglycemia (episodes/patient year)</i>	0.066 \pm 0.253	0.066 \pm 0.253	1

Self-monitoring of blood glucose in type 2 diabetes: systematic review

C Clar, K Barnard, E Cummins, P Royle
and N Waugh for the Aberdeen Health

Technology Assessment Group

Tabella 8

Raccomandazioni sull'uso e la periodicità dell'autocontrollo

Health Technology Assessment 2010; Vol. 14: No. 12

Si individuano le seguenti classi di pazienti in funzione della terapia:

- 1) Terapia insulinica intensiva
- 2) Terapia insulinica convenzionale o mista
- 3) Terapia ipoglicemizzante orale con farmaci secretagoghi
- 4) Terapia dietetica e/o con farmaci insulino-sensibilizzanti

RACCOMANDAZIONI IN RELAZIONE ALLE CLASSI SU ESPOSTE

Classe 1	a) di regola 4 controlli/die in condizioni routinarie b) numero illimitato in condizioni di squilibrio glicemico o malattie intercorrenti, per periodi limitati alla risoluzione del fatto
Classe 2	a) numero di controlli quotidiani pari al numero di iniezioni + 20% in routine b) numero illimitato in condizioni di squilibrio glicemico o malattie intercorrenti, per periodi limitati alla risoluzione del fatto
Classe 3	a) numero di controlli pari a un profilo settimanale su 4 punti in routine b) fino a 2 controlli/die in presenza di rischio elevato di ipoglicemia o conseguenze potenzialmente gravi dell'ipoglicemia (coronaropatia, vasculopatia cerebrale, retinopatia proliferante) c) numero illimitato in condizioni di squilibrio glicemico o malattie intercorrenti, per periodi limitati alla risoluzione del fatto
Classe 4	L'efficacia dell'autocontrollo della glicemia in questa classe di pazienti non è a tutt'oggi dimostrata. Fa eccezione a quanto sopra il diabete gestazionale in cui è indicato l'autocontrollo domiciliare della glicemia per decidere quando iniziare la terapia insulinica; la frequenza dei controlli deve essere decisa dal diabetologo in relazione alle singole situazioni cliniche. Glucometri: sono da considerarsi indispensabili per l'effettuazione dell'autocontrollo domiciliare. Aghi pungidito, in numero uguale al numero dei controlli previsti, e pungidito a scatto sono ugualmente da considerarsi indispensabili.

RACCOMANDAZIONI SULLE VERIFICHE

- Verificare la tecnica del monitoraggio a intervalli regolari
- Verificare l'accuratezza dei risultati
- Verificare le capacità di utilizzo dei risultati da parte del paziente

C. EDUCAZIONE TERAPEUTICA

RACCOMANDAZIONI

- ▶ Le persone affette da diabete devono ricevere un'educazione all'autogestione del diabete al momento della diagnosi, mantenuta in seguito per ottenere il maggior beneficio. **(Livello della prova I, Forza della raccomandazione A)**
- ▶ L'educazione è più efficace se pianificata e organizzata per piccoli gruppi di pazienti. **(Livello della prova I, Forza della raccomandazione A)**
- ▶ L'educazione all'autogestione del diabete va garantita, all'interno del team da parte delle diverse figure professionali (medico, infermiere, dietista, educatore sociosanitario) specificamente qualificate sulla base di una formazione professionale continua all'attività educativa. **(Livello della prova I, Forza della raccomandazione A)**
- ▶ Nel lavoro di team è importante che la pianificazione e la conduzione dell'attività educativa siano svolte mediante metodologie basate sui principi dell'educazione dell'adulto, che tengano conto dell'esperienza di vita della persona e della sua personale motivazione al cambiamento. **(Livello della prova IV, Forza della raccomandazione B)**
- ▶ L'educazione all'autogestione del diabete va rivolta anche ai problemi psicosociali, poiché il benessere emotivo è fortemente associato con gli esiti positivi per il diabete. **(Livello della prova III, Forza della raccomandazione B)**
- ▶ L'educazione all'autogestione del diabete deve essere adeguatamente riconosciuta e remunerata nell'ambito delle prestazioni fornite dal SSN, nell'ambito di un sistema integrato di interventi. **(Livello della prova VI, Forza della raccomandazione B)**



STANDARD ITALIANI PER LA CURA DEL DIABETE MELLITO TIPO 2



Group based training for self-management strategies in people with type 2 diabetes mellitus (Review)

Deakin TA, McShane CE, Cade JE, Williams R



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Group based training for self-management strategies in people with type 2 diabetes mellitus (Review)

Comparison 1. Group-based diabetes education programme versus individual routine treatment				
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Death	3	525	Odds Ratio (M-H, Random, 95% CI)	1.24 [0.28, 5.56]
2 Reduction in diabetes medication	5	654	Odds Ratio (M-H, Random, 95% CI)	11.79 [5.17, 26.90]
3 Glycated haemoglobin (4-6 months)	3	395	Mean Difference (IV, Random, 95% CI)	-1.35 [-1.93, -0.78]
4 Glycated haemoglobin (12-14 months)	7	1044	Mean Difference (IV, Random, 95% CI)	-0.82 [-0.99, -0.65]
5 Glycated haemoglobin (2 years)	2	333	Mean Difference (IV, Random, 95% CI)	-0.97 [-1.40, -0.54]
6 Fasting blood glucose (12-14 months)	4	641	Mean Difference (IV, Random, 95% CI)	-1.17 [-1.63, -0.72]
7 Weight (4-6 months)	4	566	Mean Difference (IV, Random, 95% CI)	-2.13 [-4.71, 0.45]
8 Weight (12-14 months)	5	591	Mean Difference (IV, Random, 95% CI)	-1.61 [-2.97, -0.25]
9 Body Mass Index (4-6 months)	4	718	Mean Difference (IV, Random, 95% CI)	-0.16 [-1.00, 0.68]
10 Body Mass Index (12-14 months)	4	751	Mean Difference (IV, Random, 95% CI)	0.45 [-0.32, 1.23]
11 Diabetes knowledge (12-14 months)	3	432	Std. Mean Difference (IV, Random, 95% CI)	0.95 [0.72, 1.18]
12 Systolic blood pressure (4-6 months)	2	399	Mean Difference (IV, Random, 95% CI)	-5.37 [-9.53, -1.21]
13 Diastolic blood pressure (4-6 months)	2	399	Mean Difference (IV, Random, 95% CI)	-2.65 [-5.57, 0.28]
14 Systolic blood pressure (12-14 months)	2	327	Mean Difference (IV, Random, 95% CI)	-2.61 [-6.74, 1.52]
15 Total cholesterol (12-14 months)	3	552	Mean Difference (IV, Random, 95% CI)	0.09 [-0.09, 0.26]
16 Triglycerides (4-6 months)	3	628	Mean Difference (IV, Random, 95% CI)	-0.24 [-0.52, 0.04]
17 Triglycerides (12-14 months)	4	652	Mean Difference (IV, Random, 95% CI)	0.14 [-0.13, 0.41]

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Group based training for self-management strategies in people with type 2 diabetes mellitus (Review)

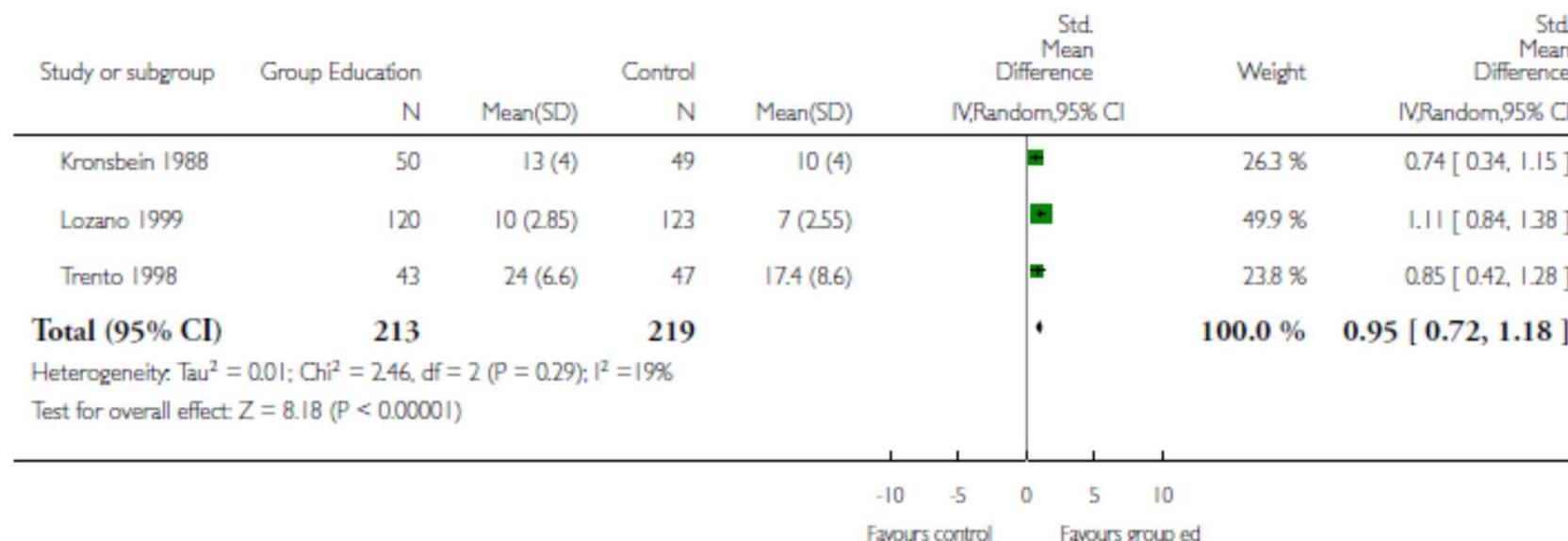
Deakin TA, McShane CE, Cade JE, Williams R

Analysis 1.11. Comparison 1 Group-based diabetes education programme versus individual routine treatment, Outcome 11 Diabetes knowledge (12-14 months).

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 1 Group-based diabetes education programme versus individual routine treatment

Outcome: 11 Diabetes knowledge (12-14 months)



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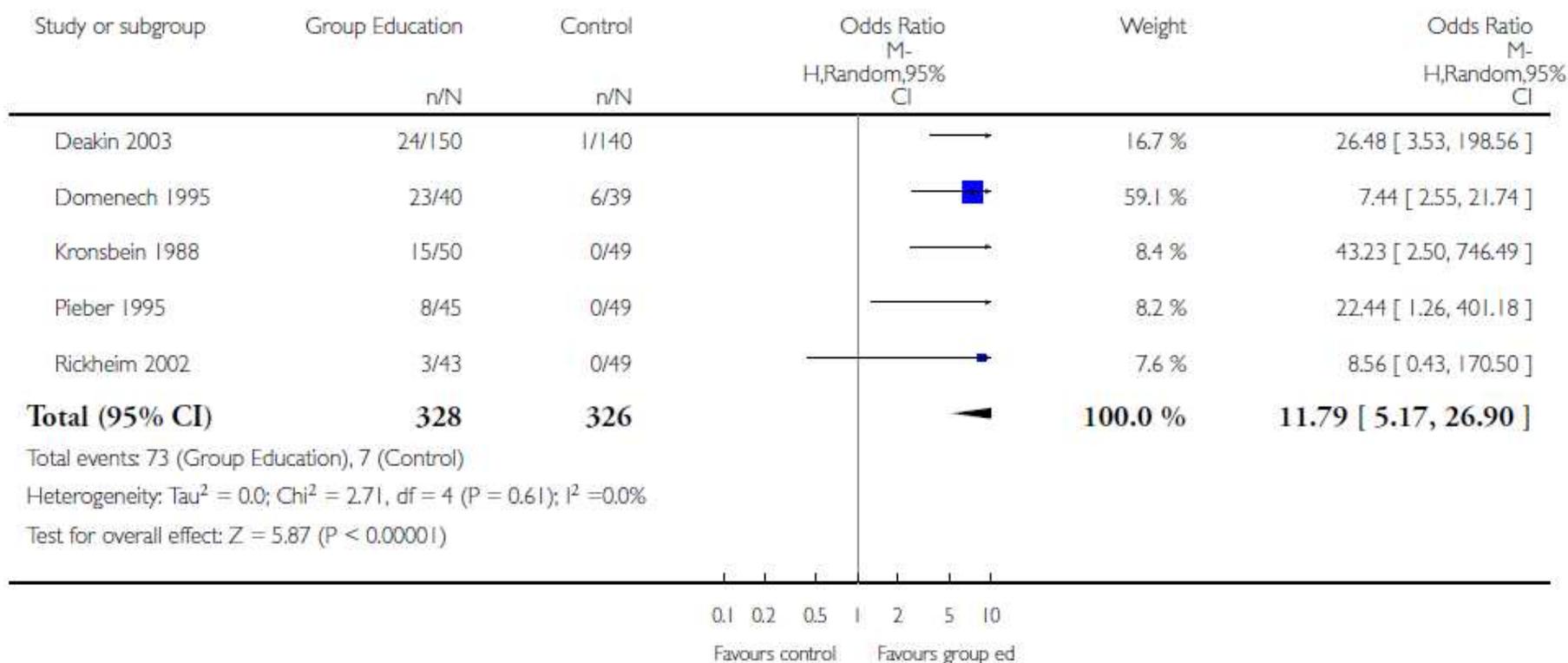
Group based training for self-management strategies in people with type 2 diabetes mellitus (Review)

Analysis 1.2. Comparison 1 Group-based diabetes education programme versus individual routine treatment, Outcome 2 Reduction in diabetes medication.

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 1 Group-based diabetes education programme versus individual routine treatment

Outcome: 2 Reduction in diabetes medication



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Group based training for self-management strategies in people with type 2 diabetes mellitus (Review)

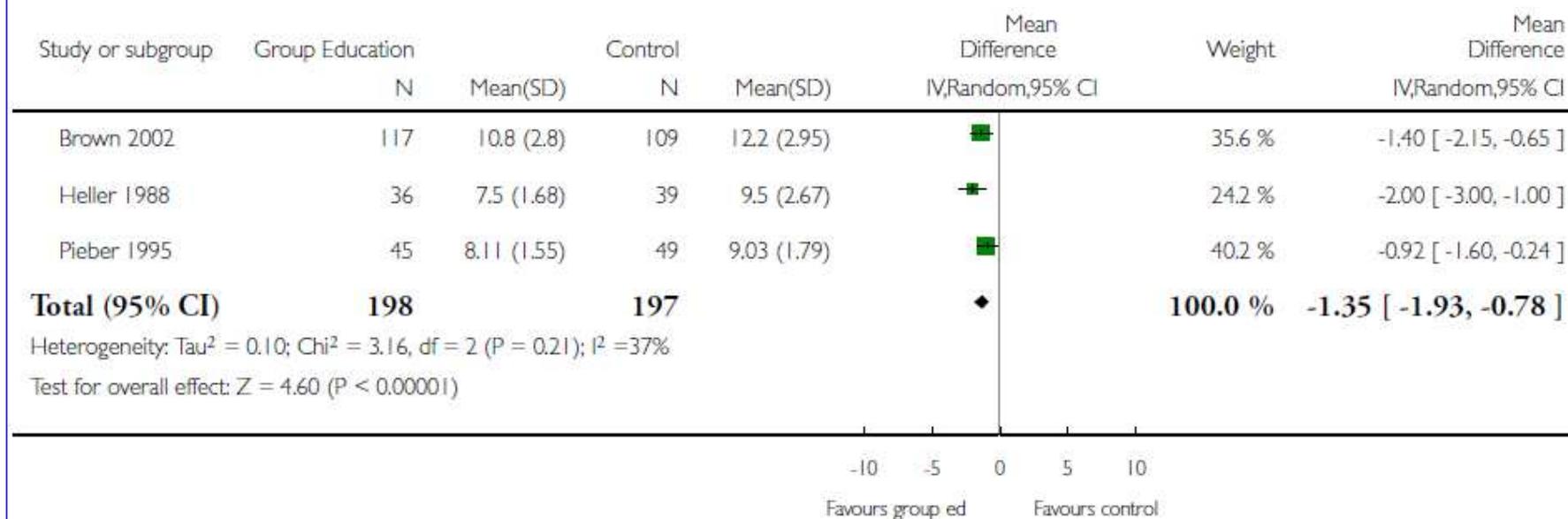
Deakin TA, McShane CE, Cade JE, Williams R

Analysis 1.3. Comparison 1 Group-based diabetes education programme versus individual routine treatment, Outcome 3 Glycated haemoglobin (4-6 months).

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 1 Group-based diabetes education programme versus individual routine treatment

Outcome: 3 Glycated haemoglobin (4-6 months)



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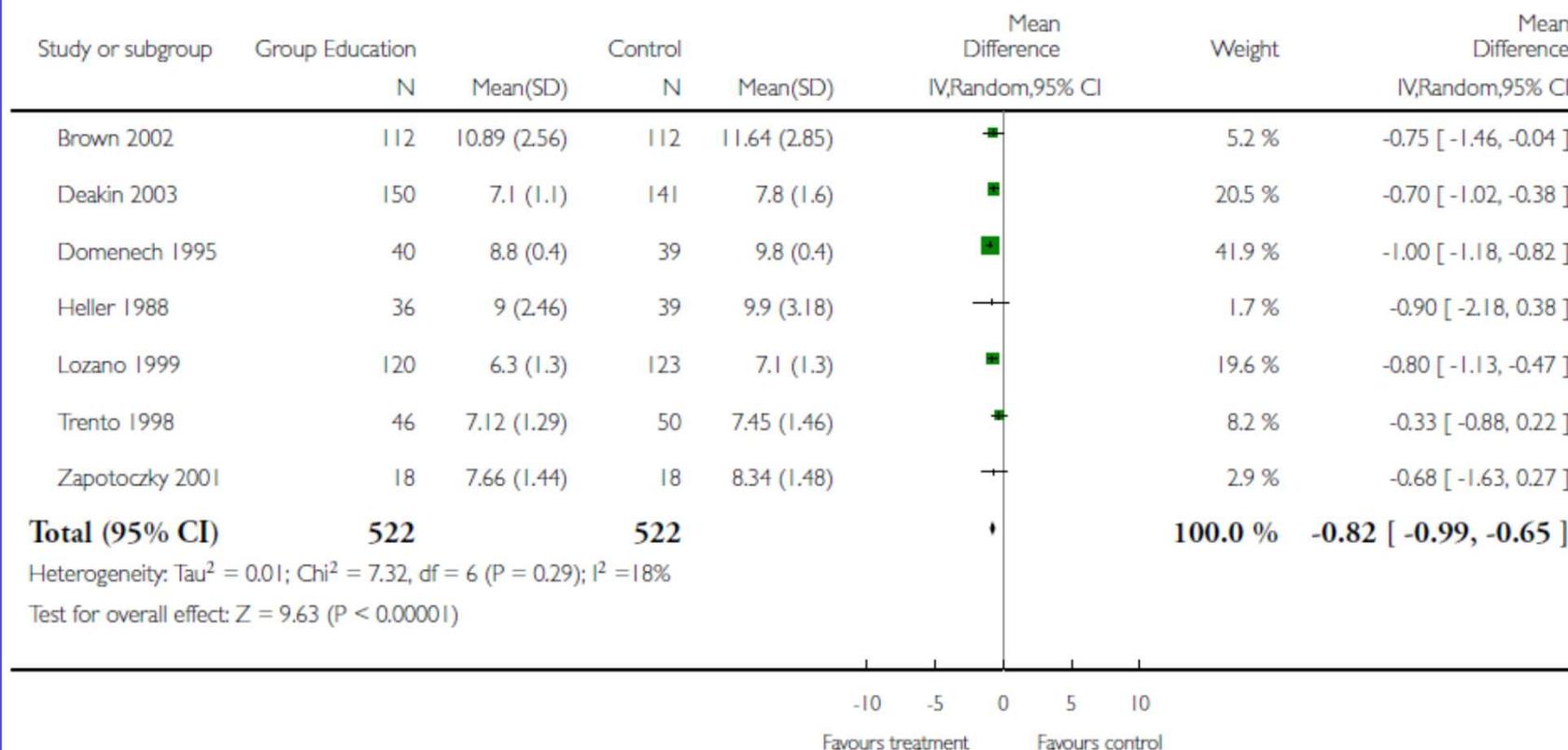
Group based training for self-management strategies in people with type 2 diabetes mellitus (Review)

Analysis 1.4. Comparison 1 Group-based diabetes education programme versus individual routine treatment, Outcome 4 Glycated haemoglobin (12-14 months).

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 1 Group-based diabetes education programme versus individual routine treatment

Outcome: 4 Glycated haemoglobin (12-14 months)



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Group based training for self-management strategies in people with type 2 diabetes mellitus (Review)

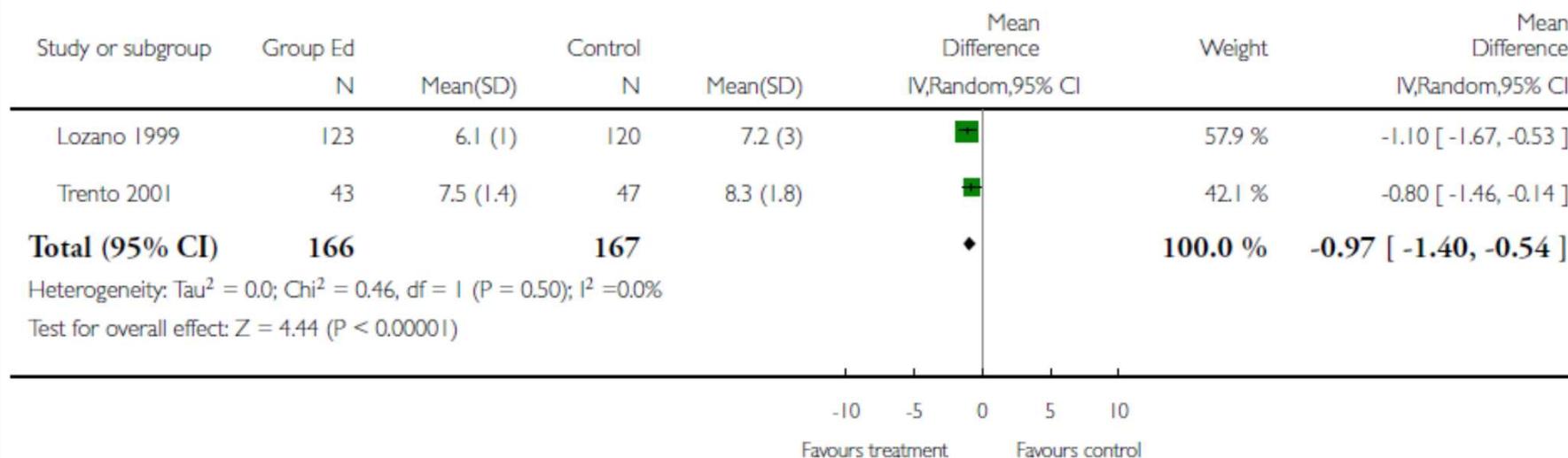
Deakin TA, McShane CE, Cade JE, Williams R

Analysis 1.5. Comparison 1 Group-based diabetes education programme versus individual routine treatment, Outcome 5 Glycated haemoglobin (2 years).

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 1 Group-based diabetes education programme versus individual routine treatment

Outcome: 5 Glycated haemoglobin (2 years)



Group based training for self-management strategies in people with type 2 diabetes mellitus (Review)

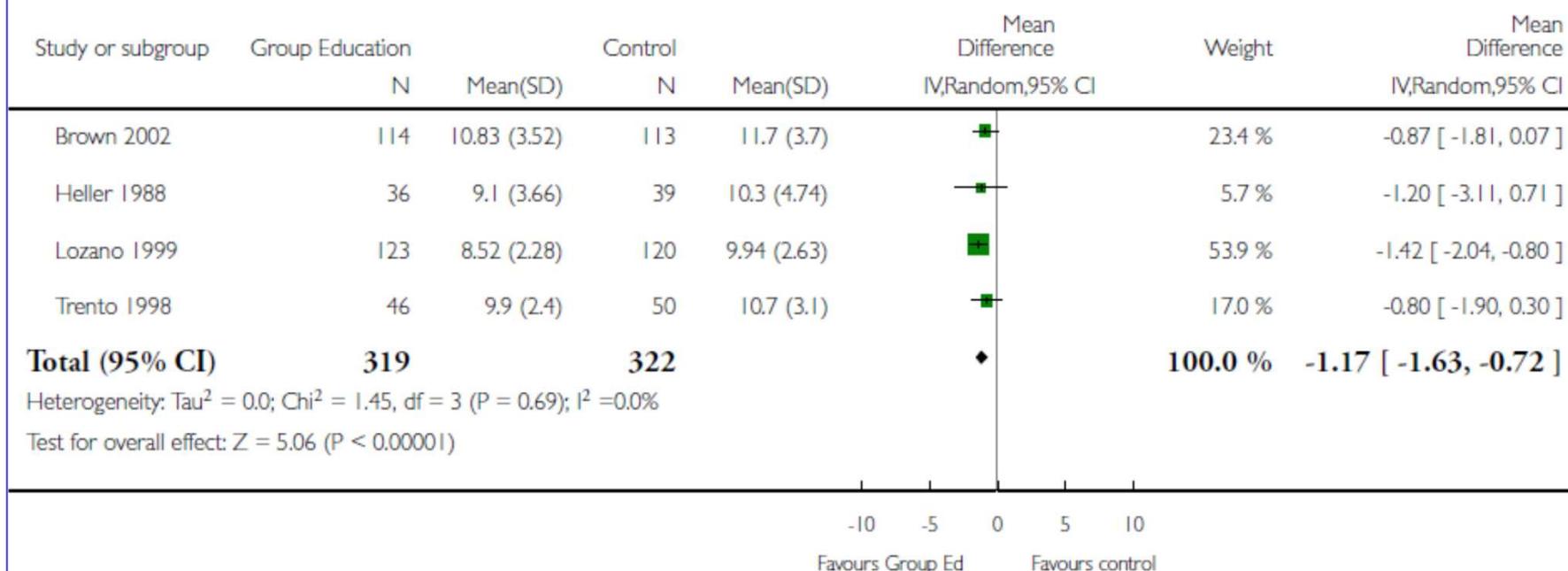
Deakin TA, McShane CE, Cade JE, Williams R

Analysis 1.6. Comparison 1 Group-based diabetes education programme versus individual routine treatment, Outcome 6 Fasting blood glucose (12-14 months).

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 1 Group-based diabetes education programme versus individual routine treatment

Outcome: 6 Fasting blood glucose (12-14 months)



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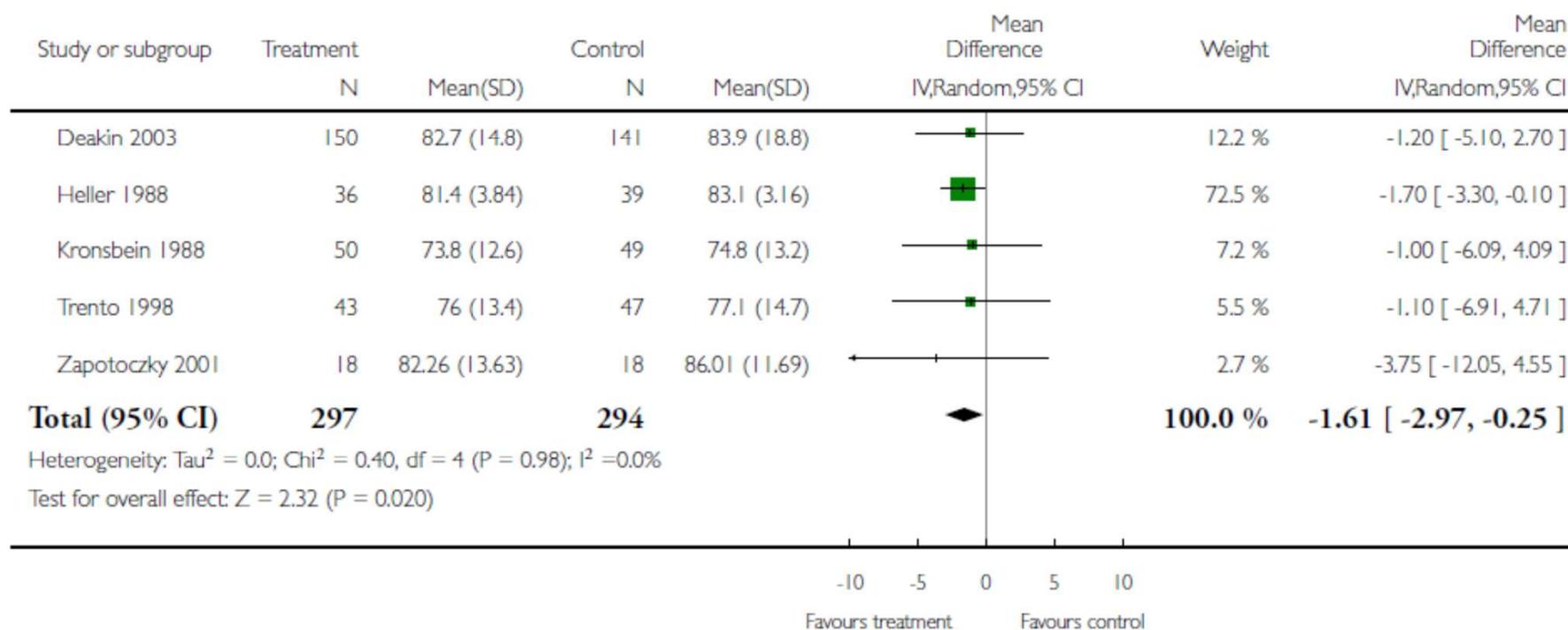
Group based training for self-management strategies in people with type 2 diabetes mellitus (Review)

Analysis 1.8. Comparison 1 Group-based diabetes education programme versus individual routine treatment, Outcome 8 Weight (12-14 months).

Review: Group based training for self-management strategies in people with type 2 diabetes mellitus

Comparison: 1 Group-based diabetes education programme versus individual routine treatment

Outcome: 8 Weight (12-14 months)



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Diabetes Interactive Diary: A New Telemedicine System Enabling Flexible Diet and Insulin Therapy While Improving Quality of Life

An open-label, international, multicenter, randomized study

Interventions

Patients randomly assigned to the experimental group attended a course on the use of DID lasting up to 2 weeks. The course was provided as an outpatient program of three encounters with the physician and/or dietitian.

Patients randomly assigned to the control group received the standard educational approach usually used in the center, lasting up to 3 months. Before the start of the study, an investigators' meeting was organized to establish some fundamental rules in the educational training and in the prescription of carbohydrate-to-insulin ratio and the correction factor.

Impact of the “Diabetes Interactive Diary” Telemedicine System on Metabolic Control, Risk of Hypoglycemia, and Quality of Life: A Randomized Clinical Trial in Type 1 Diabetes



Maria Chiara Rossi, MSc Pharm Chem,¹ Antonio Nicolucci, MD,¹ Giuseppe Lucisano, MSc Stat,¹ Fabio Pellegrini, MSc Stat,¹ Paolo Di Bartolo, MD,² Valerio Miselli, MD,³ Roberto Anichini, MD,⁴ and Giacomo Vespasiani, MD,⁵ on behalf of the DID Study Group*

TABLE 4. AVERAGE NUMBER OF HYPOGLYCEMIC EPISODES PER PATIENT PER YEAR BY RANDOMIZATION ARM AND RISK OF HYPOGLYCEMIA IN THE DIABETES INTERACTIVE DIARY GROUP COMPARED WITH THE STANDARD GROUP

<i>Hypoglycemic episodes</i>	<i>IR (95% CI)</i>		<i>IRR (95% CI)</i>
	<i>DID group (n=63)</i>	<i>Standard group (n=64)</i>	
Grade 1	49.2 (46.7–51.9)	45.6 (43.2–48.1)	1.08 (1.00–1.16)
Grade 2	0.33 (0.17–0.63)	2.29 (1.80–2.91)	0.14 (0.07–0.29)

CI, confidence interval; DID, Diabetes Interactive Diary; IR, incidence rate; IRR, incidence rate ratio.

TABLE 1. STUDY PROCEDURES

<i>Visit</i>	<i>Time</i>	<i>Group A (DID)</i>	<i>Group B (standard care)</i>
-1	15 days before randomization	<ul style="list-style-type: none"> • Check of eligibility • Blood sample for HbA1c, fasting blood glucose, and lipid profile • Diary of insulin doses and blood glucose self-monitoring measurements • Prescription of three 7-point glycemic profiles • Instructions for identification, management, and treatment of hypoglycemia 	<ul style="list-style-type: none"> • Check of eligibility • Blood sample for HbA1c, fasting blood glucose, and lipid profile • Diary of insulin doses and blood glucose self-monitoring measurements • Prescription of three 7-point glycemic profiles • Instructions for identification, management, and treatment of hypoglycemia
0	Randomization	<ul style="list-style-type: none"> • Informed consent • Randomization • Clinical data collection • Download of blood glucose self-monitoring • Diary of insulin doses and blood glucose self-monitoring measurements • QOL questionnaire • Education on DID 	<ul style="list-style-type: none"> • Informed consent • Randomization • Clinical data collection • Download of blood glucose self-monitoring • Diary of insulin doses and blood glucose self-monitoring measurements • QOL questionnaire • Standard education
1	3 months after randomization	<ul style="list-style-type: none"> • Clinical data collection • Blood sample for HbA1c and fasting glucose • Download of blood glucose self-monitoring and data stored on DID • Diary of insulin doses and blood glucose self-monitoring measurements 	<ul style="list-style-type: none"> • Clinical data collection • Blood sample for HbA1c and fasting glucose • Download of blood glucose self-monitoring • Diary of insulin doses and blood glucose self-monitoring measurements
2	6 months after randomization	<ul style="list-style-type: none"> • Clinical data collection • Blood sample for HbA1c and fasting glucose • Download of blood glucose self-monitoring and data stored on DID • Diary of insulin doses and blood glucose self-monitoring measurements • QOL questionnaire 	<ul style="list-style-type: none"> • Clinical data collection • Blood sample for HbA1c and fasting glucose • Download of blood glucose self-monitoring • Diary of insulin doses and blood glucose self-monitoring measurements • QOL questionnaire

DID, Diabetes Interactive Diary; HbA1c, hemoglobin A1c; QOL, quality of life.

Prediction of Severe Hypoglycemia

DANIEL J. COX
LINDA GONDER
LEE RITTERBAN

OBJECTIVE —
accurately anticipate
using blood glu

RESEARCH DESIGN —
were followed for
4 months. Data
were stored on

about occurrence of SH. Respective demographics for the two groups were age 40.7 and 50.2 years, duration of diabetes 20.0 and 12.2 years, A1C 7.6 and 8.8%, and male sex 43 and 39%, respectively.

RESULTS — Relative risk for SH, quantified by the ratio of an individual's low blood glucose index (LBGI) based on the previous 150 SMBG readings to the LBGI based on recent SMBG readings, increased significantly in the 24 h before SH episodes in individuals with type 1 and type 2 diabetes ($t = 10.3$, $P < 0.0001$, and $t = 4.2$, $P < 0.001$, respectively). A sliding algorithm detected 58% of imminent (within 24 h) SH episodes in the type 1 diabetic group and 60% of those in the type 2 diabetic group when three SMBG readings were available in the 24 h before an episode. Detection increased to 63 and 75%, respectively, if five SMBG readings were available in the 24 h before an episode.

CONCLUSIONS — SH often follows a specific blood glucose fluctuation pattern that is identifiable from SMBG. Thus, partial prediction of imminent SH is possible, providing a potential tool to trigger self-regulatory prevention of significant hypoglycemia.

dent risk factors. Finally, a prospective study [33] showed that the LBGI rose, mean blood glucose declined, and blood glucose variance increased in the 24 h prior to a hypoglycemic episode. These parameters normalized within 48 h. It has subsequently been shown that the LBGI is valid for type 2 patients as well.

blood glucose index (LBGI; a measure of the frequency and extent of low self-monitored blood glucose [SMBG] readings) accounts for 40–55% of future (within 6 months) SH episodes (13–16).

Hypoglycemia may lead to a “vicious cycle” of recurrent hypoglycemic episodes (17–21). According to the concept of hypoglycemia-associated autonomic failure (22), recent antecedent hypoglycemia causes defective counterregulation and hypoglycemic unawareness. Hypoglycemia-associated autonomic failure is observed in both type 1 (22) and advanced type 2 (23) diabetes. Considering this, it is reasonable to expect that SH episodes are pre-

Prediction of Severe Hypoglycemia

DANIEL J. COX, PHD¹
LINDA GONDER-FREDERICK, PHD¹
LEE RITTERBAND, PHD¹

WILLIAM CLARKE, MD²
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ited to assessment of long-term risk. The Diabetes Control and Complications Trial concluded that only ~8% of the variance of future (within several months) SH episodes could be ac-

Table 2—Prediction of upcoming (within 24 h) SH and mild hypoglycemia

	Minimum number of SMBG readings in the 24 h preceding the episode	Percent predicted SH episodes
Accuracy in type 1 diabetes	3	58
	4	60
	5	60
Accuracy in type 2 diabetes	3	60
	4	64
	5	73

CONCLUSIONS— SH often follows a specific blood glucose fluctuation pattern that is identifiable from SMBG. Thus, partial prediction of imminent SH is possible, providing a potential tool to trigger self-regulatory prevention of significant hypoglycemia.

ness. Hypoglycemia-associated autonomic failure is observed in both type 1 (22) and advanced type 2 (23) diabetes. Considering this, it is reasonable to expect that SH episodes are pre-

Che fare?

Hypoglicemia?



Il Diabete Settembre 2013

“I pazienti hanno imparato a difendersi dalla ipoglicemia medico-indotta prima che noi ci accorgessimo di questo”

Hypoglycemia and Diabetes: A Report of a Workgroup of the American Diabetes Association and The Endocrine Society

Elizabeth R. Seaquist, John Anderson, Belinda Childs, Philip Cryer, Samuel Dagogo-Jack, Lisa Fish, Simon R. Heller, Henry Rodriguez, James Rosenzweig, and Robert Vigersky*

Table 2. Hypoglycemia Patient Questionnaire

Name _____
 First _____ Middle _____ Last _____
 Today's date _____

1. To what extent can you tell by your symptoms that your blood glucose is LOW?
 ___ Never ___ Rarely ___ Sometimes ___ Often ___ Always

2. In a typical week, how many times will your blood glucose go below 70 mg/dL?
 _____ a week

3. When your blood glucose goes below 70 mg/dL, what is the usual reason for this?

4. How many times have you had a severe hypoglycemic episode (where you needed someone's help and were unable to treat yourself)?
 Since the last visit _____ times
 In the last year _____ times

5. How many times have you had a moderate hypoglycemic episode (where you could not think clearly, properly control your body, had to stop what you were doing, but you were still able to treat yourself)?
 Since the last visit _____ times
 In the last year _____ times

6. How often do you carry a snack or glucose tablets (or gel) with you to treat low blood glucose?
 Check one of the following:
 Never ___ Rarely ___ Sometimes ___ Often ___ Almost always ___

7. How LOW does your blood glucose need to go before you think you should treat it?
 Less than _____mg/dL

8. What and how much food or drink do you usually treat low blood glucose with?

9. Do you check your blood glucose before driving? Check one of the following:
 Yes, always ___ Yes, sometimes ___ No ___

10. How LOW does your blood glucose need to go before you think you should not drive?
 _____mg/dL

11. How many times have you had your blood glucose below 70 mg/dL while driving?
 Since the last visit _____ times
 In the last year _____ times

12. If you take insulin, do you have a glucagon emergency kit?
 Yes ___/ No ___

13. Does a spouse, relative, or other person close to you know how to administer glucagon?
 Yes ___/ No ___

1. How should hypoglycemia in diabetes be defined and reported?
2. What are the implications of hypoglycemia on both short- and long-term outcomes in people with diabetes?
3. What are the implications of hypoglycemia on treatment targets for patients with diabetes?
4. What strategies are known to prevent hypoglycemia, and what are the clinical recommendations for those at risk for hypoglycemia?
5. What are the current knowledge gaps in our understanding of hypoglycemia, and what research is necessary to fill these gaps?

Figura 1 Questionario di screening per le ipoglicemie

Nome del paziente

Data

1	Con che frequenza riferisci di avere crisi ipoglicemiche? <input type="checkbox"/> Mai <input type="checkbox"/> Raramente <input type="checkbox"/> Qualche volta <input type="checkbox"/> Spesso <input type="checkbox"/> Sempre
2	Generalmente, in una settimana, quante volte riscontri il valore della glicemia più basso di 70 mg/dL? N. volte:
3	Quando riscontri un valore di glicemia inferiore a 70 mg/dL, di solito conosci la causa?
4	Quante volte hai avuto episodi di ipoglicemia severa (che hanno necessitato dell'aiuto di altre persone)? Dall'ultima visita, n. Nell'ultimo anno, n.
5	Quante volte hai avuto episodi di ipoglicemia moderata (episodi in cui avevi difficoltà a concentrarti, difficoltà a controllare il tuo corpo, difficoltà a continuare a svolgere quello che stavi facendo, continuando tuttavia a gestire da solo la situazione)? Dall'ultima visita, n. Nell'ultimo anno, n.
6	Quante volte porti con te snack, zucchero (o altro) che possano servire per gestire un'ipoglicemia? <input type="checkbox"/> Mai <input type="checkbox"/> Raramente <input type="checkbox"/> Qualche volta <input type="checkbox"/> Spesso <input type="checkbox"/> Sempre
7	Quanto deve essere basso il valore della glicemia prima che tu pensi che si debba trattare o intervenire? Meno di mg/dL
8	Quale cibo/bevanda e in che quantità normalmente utilizzi per trattare un'ipoglicemia?
9	Controlli la tua glicemia prima di metterti alla guida? <input type="checkbox"/> Sì, sempre <input type="checkbox"/> Sì, qualche volta <input type="checkbox"/> Mai
10	Quanto deve essere bassa la glicemia affinché tu possa pensare/decidere di non metterti alla guida? mg/dL
11	Quante volte hai avuto la glicemia più bassa di 70 mg/dL mentre eri alla guida? Dall'ultima visita, n. Nell'ultimo anno, n.
12	Se sei in trattamento con insulina, possiedi anche un kit di emergenza con glucagone? <input type="checkbox"/> Sì <input type="checkbox"/> No
13	Ci sono persone prossime a te (coniuge/familiari) che conoscono le modalità di somministrazione del glucagone? <input type="checkbox"/> Sì <input type="checkbox"/> No

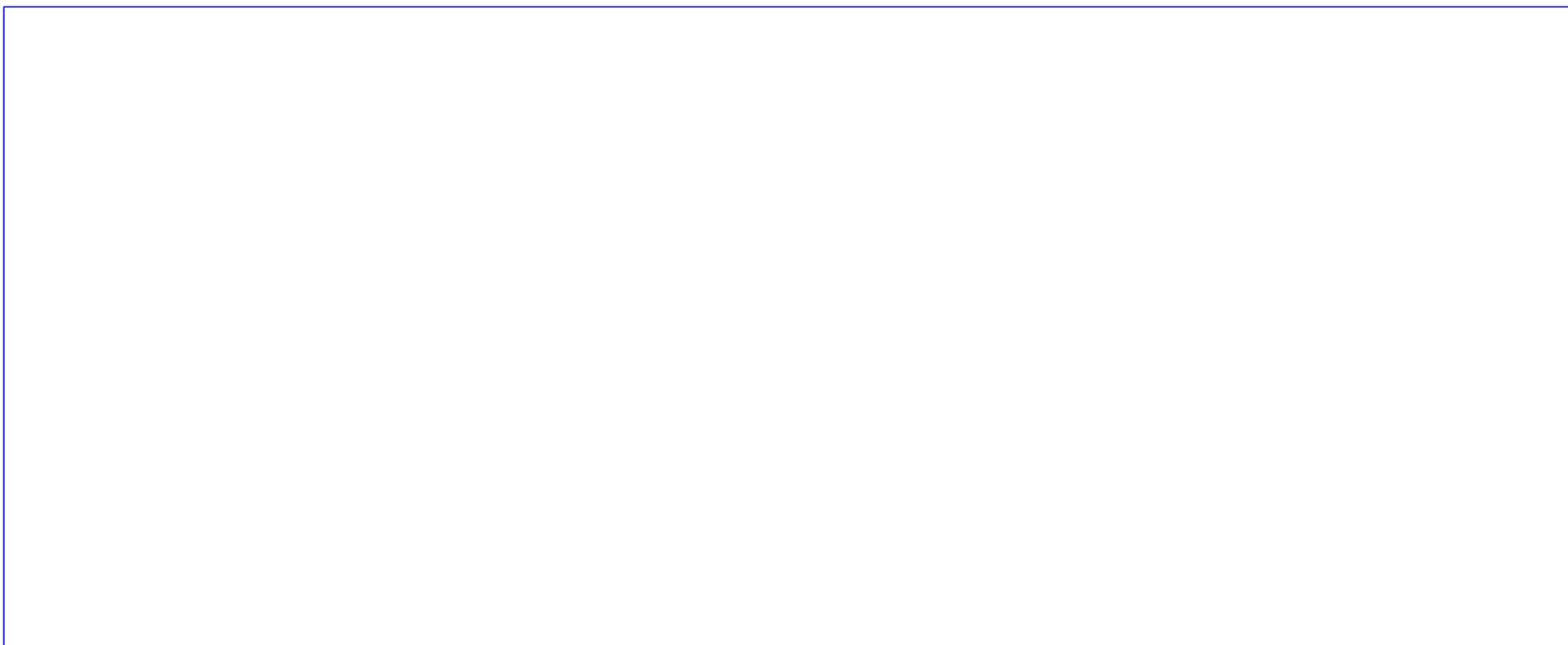
Il questionario avrebbe lo scopo di intervistare il paziente durante il soggiorno in sala di attesa prima di ogni visita diabetologica. Il medico diabetologo, tramite l'ausilio dello stesso, potrebbe analizzare il reale rischio di ipoglicemie del paziente. Sulla base di questi risultati si potrebbe intervenire, fornendo al paziente educazione e supporto, al fine di evitare il verificarsi e il perpetuarsi delle crisi. Mod. da (3, 4)

- 1 Healthcare professionals should provide sufficient support to ensure they empower people with diabetes mellitus to self-manage their disease so that it has minimal impact on their daily life (Level 1 evidence).
- 2 To cope with and lessen fear, healthcare professionals should assess the need for emotional support especially for people who have experienced severe hypoglycaemia (Level 1 evidence).
- 3 Healthcare professionals should discuss and assess the knowledge and awareness of hypoglycaemia with patients. This can facilitate the identification of reasons for hypoglycaemia unawareness and allow them to provide advice accordingly (Level 1 evidence).
- 4 Healthcare professionals should be mindful that hypoglycaemic symptoms could vary between individuals. Therefore, healthcare professionals should explore possible symptoms relating to hypoglycaemia together with patients during consultations (Level 1 evidence).

Hypoglycemia and Diabetes: A Report of a Workgroup of the American Diabetes Association and The Endocrine Society

Table 1. Approach to Restore Recognition of Hypoglycemia in Patients With HAAF

Monitoring and goal setting
Encourage SMBG before meals, at bedtime, and during suggestive symptoms
Encourage SMBG between 2 A.M. and 5 A.M. at least three times weekly
Set targets for preprandial blood glucose levels at 100–150 mg/dL
Patient education
Educate patients on hypoglycemic symptoms and the role of recurrent hypoglycemia in the etiology of hypoglycemia unawareness
Reassure patients that hypoglycemia unawareness is reversible through avoidance of hypoglycemia
Train patients to recognize and respond promptly to early neuroglycopenic symptoms
Dietary intervention
Ensure adequate caloric intake
Recommend interprandial and bedtime snacks
Ensure access to readily absorbable carbohydrates at all times
Consider moderate amounts of xanthine beverages, if tolerated
Exercise counseling
Encourage SMBG before, during, and after exercise
Advise preexercise caloric intake if blood glucose is <140 mg/dL
Advise consumption of additional calories during and after exercise if blood glucose is <140 mg/dL
Medication adjustment
Adjust insulin regimen to achieve and maintain target glucose levels
Use rapid-acting insulin analogs (lispro, aspart, glulisine) to decrease the risk of interprandial hypoglycemia
Use basal insulin analogs (glargine, detemir) to decrease the risk of nocturnal hypoglycemia
Consider a continuous subcutaneous insulin infusion pump, as appropriate
Consider a CGM device



Patient-physician interactions in diabetes management: consistencies and variation in the structure and content of two consultations

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Received 8 November 1994; revised 3 March 1995; accepted 21 March 1995

	Physician				<i>r</i>	Patient				<i>r</i>
	First		Second			First		Second		
	Mean	S.D.	Mean	S.D.		Mean	S.D.	Mean	S.D.	
Gives information	0.41	0.12	0.44	0.15	0.24	0.50	0.14	0.47	0.13	0.47**
Positive talk	0.32	0.12	0.34	0.12	0.55**	0.32	0.13	0.34	0.13	0.58**
Asks questions	0.11	0.06	0.10	0.05	0.23	0.04	0.03	0.05	0.04	0.52**
Diet talk	0.09	0.09	0.08	0.09	0.20	0.10	0.08	0.10	0.09	0.39**
Social conversation	0.05	0.06	0.04	0.06	0.13	0.05	0.05	0.04	0.06	0.17
Partnership building	0.01	0.01	0.01	0.01	-0.18					

	% of visits discussed			Extent topic discussed ^a		<i>r</i> ^b
	First visit	Second visit	Either visit	First visit	Second visit	
Diet/weight loss	95.5	90.9	100.0	1.80 (1.88, 42)	1.93 (2.13, 40)	0.15
Blood glucose monitoring	88.6	75.0	97.7	1.21 (1.36, 39)	1.36 (1.82, 33)	0.21
Timing/combination	65.9	63.6	84.1	0.80 (1.21, 29)	0.73 (1.14, 28)	0.24
Exercise	61.4	59.1	75.0	0.71 (1.15, 27)	0.68 (1.15, 26)	0.27
Medication	50.0	43.2	75.0	0.86 (1.73, 22)	0.77 (1.79, 19)	-0.07
Stress	29.5	20.5	36.3	0.39 (1.31, 13)	0.34 (1.67, 9)	0.31*
Foot care	13.6	15.9	20.5	0.23 (1.67, 6)	0.30 (1.86, 7)	0.25
Smoking habits	13.6	9.1	18.1	0.14 (1.00, 6)	0.11 (1.25, 4)	0.40**
Alcohol consumption	4.5	0.0	4.5	0.05 (1.00, 2)	0.00 (—, —)	N/A

“Senza un intervento politico strutturale rivolto al diabete e alla gestione del diabete molti dei nostri pensieri rischiano di NON tradursi in realtà.....Ogni medico diabetologo dovrà vigilare sui pazienti a rischio di ipoglicemia e ad ogni incontro dovrà richiedere esplicitamente se si sono verificati episodi.”

ISPAD Clinical Practice Consensus Guidelines 2009 Compendium

Diabetes education in children and adolescents

Education is the keystone of diabetes care and structured self-management education is the key to a successful outcome. Adapted from (1)