The cost-effectiveness of a combined group and online educational program for diabetes patients with problematic hypoglycaemia (HypoAware; in Dutch HypoBewust).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27544

Source
NTR

Health condition

Diabetes, Hypoglycemia, Hypoglycaemia, Hypoglykemie

Sponsors and support

Primary sponsor: VU university medical center (Amsterdam)
Source(s) of monetary or material Support: ZonMw, VU university medical center, Agis Achmea and Novo Nordisk.

Intervention

Outcome measures

Primary outcome

Primary health related outcome

• Frequency of severe hypoglycemia

Secondary outcome

Secondary health related outcomes

• Frequency of mild hypoglycemia

• Hypoglycemia Awareness

• Glycosylated Hemoglobin (HbA1c)

• Psychological measures: fear of hypoglycemia, diabetes-related distress, health-related quality of life, anxiety and depression, confidence in diabetes self-care

Cost-effectiveness outcomes

• Quality-adjusted life-years (QALY's)

• Health care consumption: test strip usage, outpatient visits, calls or emails, ER visits, ambulance transfers, hospital admissions

• Participation: absenteeism from paid and unpaid work

Study description

Background summary

SUMMARY

Rationale:

Hypoglycemia poses an immediate burden on the person, as well as the health care system and society. While our intervention will generate costs, we propose that we can reduce direct and indirect costs with our intervention compared to care as usual by means of reducing (severe) hypoglycemia and improving related psychosocial well-being.

Objective:

To test the cost-effectiveness of the psycho-educational intervention HypoBewust (HB) compared to care as usual.

Research questions:

1) Does HB significantly improve a) health related outcomes and b) societal costs?

2) Are the expected improvements of HB maintained from 6 to 12 months follow-up?

Study design:

Economic evaluation in a cluster RCT with measurements at baseline, 2, 4 and 6 months follow up for the intervention and control group and an additional 12 months for the intervention group to examine the possible effects over time.

Study population:

Adult insulin treated diabetes patients with severe hypoglycemia and/or impaired hypoglycemia-awareness

Intervention:

HypoAware: a 4 week blended group/online psycho-educational intervention aimed at improving patients' skills in detecting, treating, predicting, preventing and coping with hypoglycemia.

Care as usual: 1-3 extra diabetes nurse/dietician appointments and telephone/email contact aimed at reducing hypoglycemia.

Main study parameters/endpoints:

Primary health related outcome

• Frequency of severe hypoglycemia

Secondary health related outcomes

• Frequency of mild hypoglycemia

• Hypoglycemia Awareness

• Glycosylated Hemoglobin (HbA1c)

• Psychological measures: fear of hypoglycemia, diabetes-related distress, health-related quality of life, anxiety and depression, confidence in diabetes self-care

Cost-effectiveness outcomes

• Quality-adjusted life-years (QALY's)

• Health care consumption: test strip usage, outpatient visits, calls or emails, ER visits, ambulance transfers, hospital admissions

• Participation: absenteeism from paid and unpaid work

Study objective

Hypoglycemia poses an immediate burden on the person, as well as the health care system and society. While our intervention HypoAware (HA) will generate costs, we propose that we can reduce direct and indirect costs with our intervention compared to care as usual by means of reducing (severe) hypoglycemia and improving related psychosocial well-being. To test our hypothesis of superiority, we will conduct a cluster multicenter RCT with measurements at baseline and 2, 4, 6 and (for the intervention group only) 12 months follow up.

1) We expect significantly larger improvements in the HA group relative to care as usual (the control condition) at 6 months follow-up:

a) In terms of health related outcomes: a reduction in frequency of 1) severe hypoglycemia and 2) an improvement in quality of life

b) In terms of cost-effectiveness: a significant reduction in societal costs due to a reduction of sick leave and health care consumption.

2) We expect anticipated improvements in the HA group in health related outcomes and cost effectiveness to be maintained from 6 months to 12 months follow-up in the intervention group.

Study design

Measurements at baseline, 2, 4 and 6 months
follow up for the intervention and control group and an additional 12 months for the intervention group to examine the possible effects over time.

Intervention

HypoAware: a 4 week blended group/online psycho-educational intervention aimed at improving patients' skills in detecting, treating, predicting, preventing and coping with hypoglycemia.

Care as usual: 1-3 diabetes nurse/dietician appointments and telephone/email contact aimed at reducing hypoglycemia.

Contacts

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Eligibility criteria

Inclusion criteria

Patients are eligible for the study if they have had at least 1 episode of severe hypoglycemia in the past 2 years and/or have subjective impaired hypoglycemia awareness. Other inclusion criteria are: adult (18 years or older), T1DM or T2DM on Multiple Daily Injections (3 or more daily) or Continuous Subcutaneous Insulin Infusion (pump). Patients should have access to the Internet and be willing and able to actively attend the 3 group meetings.

Exclusion criteria

Exclusion criteria: insufficient in Dutch language, pregnancy, serious medical co morbidity (e.g. cancer, dialysis), major psychiatric disorder (schizophrenia, bipolar depression), drug abuse, and severe visual or cognitive impairment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2014
Enrollment:	128
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-04-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40352

Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4318
NTR-old	NTR4538
CCMO	NL47354.029.13
OMON	NL-OMON40352

Study results