Study of Testing Response in Patients with Type 2 Diabetes

Submission date	Recruitment status No longer recruiting	Prospectively registered			
08/09/2005		☐ Protocol			
Registration date	Overall study status Completed	Statistical analysis plan			
06/10/2005		[X] Results			
Last Edited	Condition category	Individual participant data			
08/11/2022	Nutritional, Metabolic, Endocrine				

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Jeffrey Johnson

Contact details

#1200, 10405 Jasper Avenue Edmonton Canada T5J 3N4

jeff.johnson@ualberta.ca

Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Study of Testing Response in Patients with Type 2 Diabetes

Acronym

STRIP-Type 2

Study objectives

The primary aim of STRIP-Type 2 is to determine the clinical impact of providing free Self-Monitoring of Blood Glucose (SMBG) supplies for people with type 2 diabetes. Secondary aims of STRIP-Type 2 are to determine the social and behavioural correlates of glycaemic control and the health behavioural impact of providing free SMBG supplies for people with type 2 diabetes.

Primary hypothesis:

Subjects with type 2 diabetes who receive free diabetes testing strips will have significantly improved HbA1c values as compared to a control group that was not supplied with the free strips.

Secondary hypotheses:

Those subjects who receive free diabetes testing strips will have significantly improved self-care activities as compared to a control group that was not supplied with the free strips, and those subjects who receive free diabetes testing strips will have a greater frequency of blood glucose tests as compared to the group that was not supplied with the free strips.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Type 2 diabetes

Interventions

We conducted a randomised controlled trial to evaluate the clinical and behavioural impact of simply providing free SMBG supplies to patients with type 2 diabetes, versus a common health care policy of patients paying out-of-pocket for their testing supplies.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Change in HbA1c over 6 months.

Key secondary outcome(s))

Our secondary outcome evaluated SMBG behaviours using the Summary of Diabetes Self-Care Activities (SDSCA). In addition, patients completed a self-administered survey at baseline and 6 month follow-up. The survey contained demographic and self-reported clinical information regarding duration of diabetes, comorbidities and complications due to diabetes, and diabetes education experience. Self-reported physical and mental health status was captured in the RAND-12.

Completion date

31/05/2003

Eligibility

Key inclusion criteria

To be included in the study, patients must:

- 1. Have had type 2 diabetes of at least one year duration
- 2. Be 30 years of age or older
- 3. Not be on insulin

Patients that controlled their diabetes by diet alone were eligible if they met the above inclusion criteria.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

262

Key exclusion criteria

We excluded pregnant patients and those with gestational diabetes, as well as patients with private insurance coverage for SMBG supplies.

Date of first enrolment

01/01/2002

Date of final enrolment

31/05/2003

Locations

Countries of recruitment

Canada

Study participating centre #1200, 10405 Jasper Avenue Edmonton Canada T5J 3N4

Sponsor information

Organisation

Institute of Health Economics (Canada)

ROR

https://ror.org/03e81x648

Funder(s)

Funder type

Industry

Funder Name

Institute of Health Economics (Canada) (ref: 148)

Funder Name

Canadian Diabetes Association (Canada) (ref: 1249)

Funder Name

Aventis Canada (Canada) (ref: 243)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Results article		01/11 /2006	08/11 /2022	Yes	No
Other publications	Association between insurance coverage for testing supplies and glycemic control	06/07 /2004		Yes	No