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Efficacy of the Talking Health Together™ communication education intervention for primary care patients with chronic disease

Submission date	Recruitment status	[ ] Prospectively registered
01/04/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/05/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/05/2009	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A multicentre, randomised trial in Ontario to evaluate the efficacy of Talking Health Together™ (THT in Practice), a communication education intervention for primary care patients with chronic disease

Acronym
THT In Practice

Study objectives
We hypothesise that both Prepare, Ask, Check and Express (PACE) Talking Health Together™ (THT) education approaches compared to usual care will improve patient participation in medical encounters with their primary care physician. We also hypothesise that the combined THT e-Learning followed by workshop approach compared to the THT e-Learning alone approach will be more efficacious in improving patient participation in medical encounters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board Services gave approval on the 9th January 2009

Study design
Prospective multicentre randomised three-arm parallel group study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Type II diabetes mellitus, hypertension, hypercholesterolaemia

Interventions
The three intervention arms are as follows:
1. THT e-Learning module alone
2. THT e-Learning module followed by THT nurse-led workshop
3. Control Group - wsual care (no THT intervention or other intervention)

Total duration of treatment is the length of time it takes to complete the on-line training for the e-Learning arm (approximately 45 minutes to 1 hour) and the length of time it takes to do the workshop (approximately 3 hours). For the third arm that gets usual care, there is no intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Evaluate the impact, compared to usual care, of a PACE training intervention of patients with chronic disease using one of two THT education approaches (either e-Learning only or e-Learning followed by a workshop) on patients' participation in primary care encounters assessed after intervention. We also will compare the impact of the THT e-Learning only approach to the THT e-Learning followed by workshop approach in the same way. This will be assessed by coding and analysis of audio-taped dialogue between the patient and the doctor at second of two doctor visits. Two published methodologies will be used: RIAS and MEDICODE.

Secondary outcome measures
1. Physician satisfaction with the doctor-patient encounter
2. Physician sense of partnership with patients
3. Patient perception of quality of doctor-patient communication and relationship
4. Patient confidence in own ability to communicate effectively with their doctor
5. Patient perception of the management of their chronic disease(s)
6. Patient recall of discussions of lifestyle recommendations and chronic disease medications discussed during the encounter

Assessed by questionnaires filled out by both patients and physicians at both visit 1 and visit 2.

Overall study start date
15/03/2009

Completion date
06/07/2010

Eligibility

Key inclusion criteria
To be eligible to participate in the study, male or female patients of participating physicians must:
1. Be aged 40 years of age or greater
2. Have clinical documentation of diagnosis of at least one of the following pharmacologically-treated chronic conditions for which standard disease measures are considered to not be to target:
2.1. Type II diabetes mellitus as defined by the Canadian Diabetes Association Clinical Practice Guidelines (haemoglobin A1C greater than 7.0)
2.2. Hypertension defined as either resting office diastolic blood pressure of greater than 90 mmHg or resting office systolic blood pressure of greater than 140 mmHg and for diabetics:

either resting office diastolic blood pressure of greater than 80 mmHg or resting office systolic blood pressure of greater than 130 mmHg as per Canadian Hypertension Education Program (CHEP) Guidelines
2.3. Hypercholesterolaemia as defined by the Hyperlipidaemia Canadian Consensus Guidelines (Low risk patients: low density lipoprotein [LDL] greater than or equal to 5.0 mmol/l or total cholesterol [TC]/high density lipoprotein [HDL] greater than or equal to 6 mmol/l, and high risk patients: LDL greater than 2 mmol/l or TC/HDL greater than 4 mmol/l)
3. Receive a prescribed medication for the chronic disease for which they were included in the study (i.e., hypertension, diabetes and hypercholesterolaemia)
4. Fill their prescriptions for the chronic disease for which they were included in the study at a pharmacy where the prescription information is available in the RxCanada® Inc. database
5. Have a routine clinic follow-up visit scheduled within three to six months of study enrolment

All participating patients will complete an informed consent form before initiation of any study related procedures.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
360

Key exclusion criteria
1. Patients in the active phase of cancer treatment (i.e. chemotherapy or radiotherapy at time of this study)
2. Previous enrolment in the present study
3. Pregnant or lactating women
4. Involvement in the planning and conduct of the study (applies to both AstraZeneca staff or staff at the study site)
5. Involvement in any other clinical study or adherence program
6. Inability to read or write in English
7. Inability to carry out the encounter with their physician in English without need of assistance
8. Uncomfortable using a computer for routine activities such as regular access to the web and e-mail

Date of first enrolment
15/03/2009

Date of final enrolment
06/07/2010

Locations

Countries of recruitment

Canada

Study participating centre
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Canada
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Sponsor information

Organisation
AstraZeneca Inc. (Canada)

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Sponsor type
Industry

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ROR
https://ror.org/04n8fbz89

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca Inc. (Canada)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration