

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

**Submission date**  
01/04/2009

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
27/05/2009

**Overall study status**  
Completed

☐ Statistical analysis plan

☐ Results

**Last Edited**  
27/05/2009

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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 - usual 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**  
**4400 Earnscliffe**  
Montreal  
Canada  
H4A 3E8

## Sponsor information

**Organisation**  
AstraZeneca Inc. (Canada)

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**Sponsor type**  
Industry

**Website**  
<http://www.astrazeneca.com/>

**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