## AstraZeneca

### ASTRAZENECA PHARMACEUTICALS

#### FINISHED PRODUCT: Patient Education Material for Improvement in Doctor Patient Communication ACTIVE INGREDIENT: None

### ACTIVE INOREDIENT: NO

### **Study No: NCT00879736**

A Multi-centre, Randomised Trial in Ontario to Evaluate the Efficacy of **Talking Health Together**T.M. (T.H.T. in Practice), a Communication Education Intervention for Primary Care Patients With Chronic Disease.

**Developmental Phase:** Non-phase, non-drug, interventional study **Study Completion Date: December 2010 Date of Report:** Publication in the form of poster: June 2011

### **OBJECTIVES:**

Primary: To evaluate the impact, compared to Usual Care, of training interventions on patients with chronic disease on patient participation in primary care encounters assessed after intervention.

Secondary:

- physician satisfaction and sense of partnership with the doctor-patient encounter
- patient perception of quality of doctor-patient communication and relationship and patient confidence in own ability to communicate effectively with their doctor
- patient perception of the management of their chronic disease(s); and patient recall of discussions of lifestyle recommendations and chronic disease medications discussed during the encounter.

### **METHODS:**

- 1. prospective, multi-centre, randomised, three-arm, parallel group study
- 2. patients were each randomized to one of three intervention arms:
  - T.H.T. e-Learning module alone (eL);
  - T.H.T. e-Learning module followed by T.H.T. nurse-led workshop (eL+W); and,
  - Control Group Usual Care (no T.H.T. intervention or other intervention) (UC).
- 3. T.H.T. workshop was an incremental intervention after the T.H.T. e-Learning module was chosen so that the added value of the T.H.T. workshop could be assessed.

Audiotape of doctor patient encounter was recorded. These audio recordings were coded according to RIAS and MEDICODE systems and then statistically analyzed to determine differences between the three intervention arms.

# Sociodemographic and clinical characteristics of patients at study entry

	Study Intervention Group				
Characteristic	UC (n=106)	eL (n=74)	eL+W (n=41)	F Test	р
	Mean or %	Mean or %	Mean or %	Value	value
Sociodemographics					
Average age (Years)	58.2	56.9	60.5	1.994	.139
Gender (% Men)	63.2%	54.1%	53.7%	1.963	.375
Education (% High school or more)	72.4%	71.6%	73.2%	0.033	.984
Clinical characteristics					
Length of relationship (% >5 years)	75.5%	68.9%	70.7%	2.315	.678
Nb visits in past year (% ≥4 visits)	72.6%	64.9%	58.5%	4.094	.393
Functional status					
Physical component score	41.8	40.8	42.0	0.187	.830
Mental component score	46.1	47.0	50.4	1.600	.204
Chronic Care survey (PACIC)					
PACIC Global score (1-5)	3.33	3.07	3.44	2.018	.136
PACIC Patient activation (1-5)	3.68	3.25*	3.72	3.975	.02

#### (n=221 Completed intervention)

\*post hoc tests : p=.029 between UC and eL groups; p=.071 between eL and eL+W groups

## **Primary Outcome Measures**

To evaluate the impact, compared to Usual Care, of training interventions on patients with chronic disease on patient participation in primary care encounters assessed after intervention.

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	Study Intervention Grou	p		
Usual Care (n=106)	eLearning (n=74)	eL+Workshop (n=41)		
Usual Care (n=106) % (SD)	eLearning (n=74) %(SD)	eL+Workshop (n=41) %(SD)	F	Sig.

## Secondary Outcome Measures

\* physician satisfaction and sense of partnership with the doctorpatient encounter;

	Visit 2, Q12,	Score 0-7		
	Study Intervention Grou	ıp		
Usual Care (n=96)	eLearning (n=69)	eL+Workshop (n=38)		
Mean (SD)	Mean (SD)	Mean (SD)	F	Sig.

### Secondary Outcome Measures

\* patient perception of quality of doctor-patient communication and relationship and patient confidence in own ability to communicate effectively with their doctor;

\	/isit 2, Q9, items 3	to 10, Score 1-7		
	Study Intervention Grou	p		
Usual Care (n=67)	eLearning (n=49)	eL+Workshop (n=26)		
			-	0:-
Mean (SD)	Mean (SD)	Mean (SD)	F	Sig.

## Secondary Outcome Measures

\* patient perception of the management of their chronic disease(s); and patient recall of discussions of lifestyle recommendations and chronic disease medications discussed during the encounter.

Visit 2, Section 11,	Cholesterol medi	cations during the e tions 2, 14 and 26 cc ent Analysis	ncounter	·- É	
Usual Care (n=89) Mean (SD)	eLearning (n=63) Mean (SD)	eL+Workshop (n=34) Mean (SD)	F	Sig.	
0.64 (0.40)	0.69(0.38)	0.64 (0.44)	.226	.798	-

AZ Synopsis Template 2010 June 4