



**JAWATANKUASA ETIKA PERUBATAN  
PUSAT PERUBATAN UNIVERSITI MALAYA  
(MEDICAL ETHICS COMMITTEE)**

**Protokol Kajian (Study Protocol)**

**Version No.: 1**

**Version Date: 24/1/2019**

**1.0 Tajuk Projek (Project Title)**

The Values in Shared Interactions Tool (VISIT) for integrating patient agendas into consultations: A single-center block-randomization trial

**2.0 Latar Belakang, Bahan-Bahan Semakan, dan Rationale yang berkaitan dengan Projek ini**  
*(Background, Literature Reference and Rationale for this Project).*

An effective doctor-patient relationship is built on adequate two-way communication where the doctor shares their clinical expertise and the patient voices their concerns and expectations (Charles et al 1997). However, there are considerable challenges to the elicitation of patient perspectives in medical consultations. These barriers include doctors' lack of skills on how to discuss patient perspectives, prevailing attitudes such as paternalism (where the doctor decides what is best for the patient), time factors (short consultation times) and a lack of patient empowerment to participate in consultations (Legare et al 2008). Indeed there is often a 'silent misdiagnosis of patient preferences' whereby clinicians often make an assumption about their patient's preferred options (Mulley, Trimble & Elwyn 2012).

If barriers to patient involvement are present, patients become passive, uninvolved agents in the consultation. A passive patient role has negative impact on both patient outcomes and resource utilization. Passive patients (patients who are not actively involved in consultations) have been shown to have higher decisional regret (Hack et al 2006). Patients who do not have the skills to manage their health care incur costs that are up to 21 percent higher than patients who are highly engaged in their care (James 2013).

A prototype of the VISIT (Values in Shared Interactions Tool) website has been developed by the researcher (LYK) to facilitate value-based consultations by asking patients to enter information on their concerns and health-related values (e.g. family, career, religion) (Lee et al 2013) which would be displayed on the doctor's EMR (Electronic Medical Records) screen. This prototype has been pilot-tested on eight consultations with promising preliminary results (Lee et al 2015).

The study that is currently being proposed is to further refine the VISIT website, by using only relevant items and on a larger pool of participants, in the hopes that it can potentially increase the efficiency and satisfaction of medical consultations.

## References:

- Charles C, Gafni A, Whelan T. Shared Decision-Making in the Medical Encounter: What Does it Mean? (Or it Takes at Least Two to Tango). Soc Sci Med. 1997; 44(5):681-92.
- Hack TF, Degner LF, Watson P, Sinha L. Do patients benefit from participating in medical decision making? Longitudinal follow-up of women with breast cancer. Psychooncology. 2006 Jan; 15(1):9-19.
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- Lee YK, Low WY, Ng CJ. Exploring patient values in medical decision making: a qualitative study. PLoS One. 2013; 8(11): e80051.
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- Legare F, Ratte S, Gravel K, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions. Patient Educ Couns. 2008 Dec; 73(3):526-35.
- Mulley AG, Trimble C, Elwyn G. Stop the silent misdiagnosis: patients' preferences matter. BMJ. [Review]. 2012; 345:e6572

### 3.0 Tujuan-Tujuan Projek (*Objectives of the Project*).

This project aims to conduct a block-randomized trial to determine the effect of using the VISIT tool in consultations versus regular primary care consultations on patient and physician satisfaction, agenda items and length of consultation.

### 4.0 Methodologi/Kaedah yang Dicapai (*Proposed Methodology*).

**Design:** Cluster randomized trial with embedded qualitative component

**Duration:** 24 months

**Participant Inclusion Criteria:** For doctors, we will be recruiting year 3 and 4 family medicine trainees in the clinic. For patients, those who are on follow-up visits for long-term chronic conditions, and have smartphones and mobile data.

**Sample Size:** The sample size is estimated to be 200 patients (100 in each arm) based on a power of 80% to detect an effect size of OR 2.667 for a difference in patients' perceptions that the doctor addressed issues that were important to them (Early et al 2015). In order to compensate for the clustering effect and to retain equivalent power, the sample size will be increased to 272 with the design effect of 1.36. The study will involve all year 3 and 4 family medicine trainees in the clinic (approximately 30 doctors) who will be randomized into either the intervention or control group.

**Setting:** University Malaya Medical Centre

## Methods

### Doctor recruitment

- All year 3 & 4 family medicine trainees in the clinic will be approached to join the study
- A participant information sheet will be distributed and written consent will be taken from those who agree to participate

### Randomization

- Doctors will be randomized into two clusters; the control arm and intervention arm, using computer generated numbers.

- Intervention group doctors will be trained on how to use the VISIT tab in the EMR. Due to the behavioural nature of the study, blinding of researchers and participants is not possible
- A daily patient list will be generated from the appointments in the EMR system and will be sorted into the intervention and control arms

#### **Patient recruitment**

- Patients who come for their appointments will be approached at the waiting area and will be briefed on the study
- Patients will be given a patient information sheet and consent will be taken if they agree to participate

#### **Cluster trial procedure**

- Patients will then be asked to fill in a demographic data sheet & a mobile device proficiency questionnaire
- Patients who will be seeing doctors in the intervention arm will be asked to fill in their agenda on the VISIT website prior to their consultation, whereas patients in the control arm will see their doctors as usual
- Agenda items from VISIT will appear as a tab in the intervention group doctors' EMR screen before the consultation
- Once the consultation is over, patients will be asked to complete a post-consultation questionnaire

#### **Embedded qualitative study**

- 10 consultations in each arm will be audio-recorded to capture the consultation process for VISIT versus usual consultations
- 15 doctors will also be interviewed by research team members who are trained in qualitative methodology, to explore the acceptability and feasibility of VISIT

#### **Outcome measures:**

The following outcome measures will be taken after each consultation: a single-item 'My doctor discussed the issues that were important to me' rated on a four-point scale (strongly disagree/disagree/agree/strongly agree) (Early et al 2015), a patient satisfaction scale for primary care, the total number of agenda items discussed (average items discussed per consultation), and the length of consultation time (average length of time per consultation).

#### **Analysis:**

##### **Quantitative data**

All data will be analysed at the individual patient level and the analysis will be adjusted for clustering effect. Categorical data will be analysed using Chi-square test to compare proportions between intervention and control groups. Continuous data will be analysed using a student-t test.

##### **Qualitative data**

A qualitative analysis will be conducted on within the sample using audio-recorded consultation to explore how the use of VISIT affects the process of aligning the doctor and patient agendas versus a normal consultation. Linguistic analysis of alignment via discourse-pragmatic analysis will be conducted on 10 randomly selected control and intervention consultations each.

## **5.0 Jadual waktu bagi Projek (Time frame for project)**

### **Gantt Chart of Research Activities**

Activity	2019												2020								
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sept
<b>Phase 1: Pilot</b>																					
RA/ Masters recruited	█																				
Pilot testing			█																		
<b>Phase 2: Trial</b>																					
Dr recruitment			█																		
Randomization			█																		
Doctor training			█	█																	
Trial in RUKA					█	█	█	█	█												
Data analysis										█	█										
<b>Phase 3: Dissemination</b>																					
Article writing												█	█	█							
Training														█	█	█	█	█	█	█	
Implementation															█	█	█	█	█	█	

**END**