S2 Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Evidence from the First Shared Medical Appointments (SMAs) Randomised Controlled Trial in India: SMAs Increase the Satisfaction, Knowledge, and Medication Compliance of Patients with Glaucoma
This supplement contains the following items:

1. Original protocol, ethics approval letters, amendments, case report form, patient information sheet and informed consent form in English and Tamil.
## Contents

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Section 1 – Protocol
Title of the Project
Shared Medical Appointments Randomized Trial (SMART)

Project Duration
Duration: June 1, 2016 through December 31, 2017.
Enrollment period of 6 months: June 1, 2016 to December 31, 2016
Follow-up period of 12 months: Ending December 31, 2017
(Data from 4 pre-trial and 4 post-trial follow up will be collected from the patient’s case records)

Principal Investigator (with designation)
Dr S. Kavitha, Senior Glaucoma Specialist, Aravind Eye Hospital, Pondicherry

Co-investigators (with designation)
Ryan Buell, Assistant Professor of Business Administration, Harvard Business School
Kamalini Ramdas, Professor of Management Science & Operations, Deloitte Chair in Innovation & Entrepreneurship and Academic Director, Deloitte Institute of Innovation & Entrepreneurship, London Business School
Dr R. Venkatesh, Chief Medical Officer, Aravind Eye Hospital, Pondicherry

Collaborator with designation and affiliation
Nazli Sonmez, PhD student, London Business School

Funding agency
The costs for this research project will be funded through research budgets at London Business School and Harvard Business School, in addition to possible outside funding.
Budget
Funding will be used for the following activities:

New Study Administrator Position: The researchers will fund a new study administrator position at Aravind Eye Hospital to administer the study for the entire duration of the project. The salary of this administrator will total approximately £200 per month or less. This administrator will be hired by the Aravind Pondicherry Glaucoma Clinic.

Video recording: We intend to video record the final examination stage of the appointments for patients in the treatment and the control group, using wall mounted video cameras. Cost is estimated as a maximum of £500 per camera and equipment, maximum £2,000 total for four cameras.

Video transcription: As described below, we also intend to create de-identified transcripts of the videos to facilitate in-depth analysis of drivers of patient behaviour. Cost is estimated as a maximum of £14,000.

Background
The most fundamental vehicle of healthcare delivery – the doctor-patient interaction – has remained unchanged for millennia. All over the world, the most common and often the only way to meet a physician for non-urgent care is through a one-on-one appointment. An alternative to the one-on-one doctor visit has been practiced successfully by a few providers in the US for over 15 years. In a shared medical appointment (SMA) a group of 5-8 patients with similar chronic conditions – such as diabetes – meet with a doctor simultaneously. Each patient in turn receives full one-on-one attention including diagnosis and prescription, while the others listen.
Patients in an SMA have similar chronic conditions so the doctor need not repeat common advice – which is a large part of most one-on-one appointments. As SMAs substitute for one-on-one appointments, doctors can use the time saved in SMAs to provide better individual medical attention and forge patient relationships. Any remaining time contributes to productivity gains. Although doctors engaged in SMAs often spend less time with each patient on average due to the batch processing, patients in an SMA spend more total time with the doctor and are exposed to more information. In an SMA, patients with similar conditions learn from one another and from the doctor’s responses to other patients’ questions. A shared appointment in effect brings a support group into the doctor’s office. Patients’ realization that they are not alone in their difficulties can reduce anxiety. A desire to conform or excel in a group may spur them to adhere to the doctor's instructions. Thus SMAs for chronic diseases have the potential to serve as a catalyst for patient behavior change.

SMAs have been implemented for diabetes, cardiac preventive care, asthma and other chronic diseases. Clinics that offer shared appointments have noted improved patient outcomes, greater rates of compliance and adherence, and increases in capacity (Bronson and Maxwell 2004). SMAs often prove to be successful where adopted, but their benefits have not been rigorously and scientifically documented. In their recent review paper, Edelman et al. (2012) note that the evidence base on SMAs is very scant. Furthermore, the existing research has focused mainly on medical outcomes rather than behaviors that may impact outcomes. Even more importantly, no one has examined the underlying mechanisms by which SMAs may induce behavior change.
**Major Objectives**

The primary objectives of this research project are to examine how SMAs for the final examination stage of a glaucoma appointment affect the level of patient knowledge and follow-up rates in glaucoma care provision. Understanding the nature of glaucoma, the implications of following the course of treatment, and persisting with the treatment regime, are important precursors to improved medical outcomes.

In support of these primary objectives, to understand what is driving any observed change in knowledge levels and patient follow-up rates, we will measure the extent of peer-to-peer learning and exposure to information. This will improve our understanding of how the design of an SMA – such as patient mix in terms of disease progression levels, education levels, and other measures of patient diversity – impacts knowledge levels, follow-up rates, and in turn, outcomes.

We also intend to examine changes in underlying patient behaviors as well as patients’ satisfaction with care provided, that may link increased knowledge levels and follow-up rates engendered by SMAs to changes in medical outcomes. Behavioral outcomes include propensity to adhere to prescribed medicines and courses of treatment. To assess the links between these behaviors and medical outcomes, we will explore how SMAs and these intermediate behaviors impact vision and intra-ocular pressure over the course of the study.

Finally, we intend to examine the efficiency of SMAs, with respect to operational and financial outcomes. Operational outcomes include the average amount of time the doctor spends per patient, and the amount of waiting time. Financial outcomes
include estimates of the potential cost savings and/or revenue gains that can accrue from being able to treat more patients in the same time.

**Methodology**

We propose conducting a randomized control trial (RCT) at Aravind Eye Hospital’s Glaucoma Clinic, in Pondicherry, India, from June 1, 2016 through December 31, 2017. We will analyse the data collected using quantitative and qualitative research methods. We propose an enrollment period of 6 months (June 1, 2016 to December 31, 2016) and a follow-up period of 12 months for each enrolled patient, to capture changes in patient prognosis over three follow-up visits, each spaced four months apart. We will collect study data continuously over this period, so that preliminary outcomes can be examined prior to the official end of the study.

Based on prior research (Edelman, et al. 2012) and a power analysis we conducted with pre-pilot study data comparing the knowledge levels and follow-up rates among patients who experienced SMAs and traditional appointments, we propose an initial target sample size of 1,000 (with 500 patients in each condition). We calculate that such a sample size will ensure a study with 90% power ($\beta=0.01$) and the ability to calculate differences among sample means with 99% confidence ($\alpha=0.01$). We propose to conduct additional power analyses based on data collected from from June 1, 2016 to June 30, 2016, to further calibrate the sample size (Ahn, et al. 2014; Altman 1980; Chow, et al. 2007; Schultz and Grimes 2005).

*Flow of qualified patients during the enrolment period:* During SMA clinic days (Tuesday – Friday during the period of enrolment), when qualified patients arrive who have not yet been enrolled in the study, they will follow a typical patient flow:
1. Patient is registered
2. Patient’s case record is retrieved
3. Patient is transported to the glaucoma clinic
4. The patient will undergo all or a subset of the processes below:
   a. Vision check/ Refraction
   b. Take history and check eye pressure
   c. Preliminary doctor visit
   d. Additional testing - HFA
5. During the waiting time between steps listed in #4 above, the study coordinator will review the informed consent material with the pre-qualified patient, and if the patient agrees to the terms, he or she will be enrolled in the study. De-identified data will be collected on which patients choose not to participate.
6. The patient undergoes dilatation
7. Groups of five enrolled patients will be formed in the order of their arrival at the clinic. Groups will randomly be assigned to the treatment (SMA) or control (individual appointment) conditions.
8. Patient will undergo OCT if advised in a previous visit
9. Patient will experience SMA or individual appointment
10. Patient will receive follow-up survey
11. Patient will undergo any additional typical process steps, which may include meeting the study coordinator for counseling and/or scheduling a follow-up appointment on a day when SMAs are conducted (Tuesday – Friday, at specified times during the morning).
12. Any cross reference to other departments will be done once the patient completes the above steps
Flow of enrolled patients during follow-up appointments: Several days in advance of an enrolled patient’s follow-up appointment, the study coordinator will contact the patient by telephone to remind the patient about their appointment and confirm their availability. If the patient will not be available to attend their appointment at their scheduled time, the appointment will be rescheduled on a day when SMAs are conducted (Tuesday – Friday, at specified times during the morning).

During SMA clinic days (Tuesday – Friday, at specified times during the morning, throughout the period of the study), when enrolled patients arrive for follow-up appointments, they will follow a typical patient flow:

1. to 4. Same as above
5. The patient undergoes dilatation
6. The Patient will undergo OCT if advised in a previous visit.
7. Patients who have been assigned to the treatment condition will be routed to experience an SMA, and patients who have been assigned to the control condition will be routed to experience an individual appointment. Depending on the number of patients in the treatment condition who are scheduled to come to the glaucoma clinic for a follow-up appointment on a given day, the appropriate number of SMA sessions will be chosen, such that patients will be assigned to an SMA with approximately five people. However, we recognize that the number of patients per SMA will vary based on patient arrivals.
8. Patient will receive follow-up survey as detailed below
9. Patient will undergo any additional typical process steps, which may include meeting the study coordinator for counseling and/or scheduling a follow-up appointment.

_Treatment Procedure:_ Patients in the treatment condition will experience an SMA – an appointment shared with other patients. We will target five patients per SMA during this study, though the number will vary based on patient arrivals.

_Control Procedure:_ Patients in the control condition will experience an individual appointment – a one-on-one consultation with the physician.

_Dropouts:_ Any patient who voluntarily drops out of the study will be dis-enrolled from the study and returned to the regular patient stream. The fact that the patient dropped out of the study will be recorded in the study data.

**Measures and Sample Collection**

**Measures**

We propose collecting a variety of measures to quantify the efficiency and efficacy of SMAs relative to individual appointments, and to understand the mechanisms through which SMAs affect outcomes.

Efficacy Measures will include medical outcomes (e.g. vision and intra ocular pressure) and behavioral outcomes (e.g. propensity to follow up and propensity to adhere to medications.)

Efficiency Measures will include actual duration of each appointment, number of patients in each appointment, and time stamp data on patient waiting time at each stage in the glaucoma clinic process.
To the extent that they are available, these efficacy measures will be collected for each patient during the four sessions included during the study period, as well as the four sessions preceding and the four sessions following the study period. Collecting data prior to the study will facilitate a pre-period trends analysis, to ascertain whether participants in the treatment and control groups were on similar trajectories in terms of their medical prognosis, engagement in their treatment, and propensity to follow-up, prior to the introduction of shared medical appointments for treated patients. Collecting data from after the study will facilitate understanding whether the introduction of shared medical appointments had lasting effects beyond the period of the study. To the extent that shared medical appointments may reframe the patients’ relationship with glaucoma and with their doctor, their introduction may have a lasting effect of behavior that is measurable even after the treatment subsides.

Mechanisms measures will include assessment of patients’ knowledge about glaucoma (e.g. what it is, what causes it, how to treat it, etc.), patients’ perceptions about quality of care provided during an appointment, and the extent of factors such as peer-to-peer learning and exposure to new information.

*Sample Collection*
The study coordinator will be responsible for sample data collection. The study coordinator will create a unique identifier for each appointment (so that we can identify which patient was in which appointment), a participant ID number in the study which can be linked to Medical Record Number, and de-identified coding of which doctor conducted each appointment.
Surveys: All patients in the treatment and control groups will respond to a survey at the end of the final examination stage in each of their appointments during the trial. These surveys will contain questions to assess patient knowledge and patient perceptions about quality of care. In the final follow up appointment of the trial, patients will in addition be administered an exit survey in which they will be asked questions regarding factors that influence their propensity to follow up and their propensity to adhere to medications. Treatment group patients will in addition be asked about their interest in continuing SMAs, their propensity to recommend SMAs to others, and the reasons they may have preferred / not preferred SMAs to one-on-one appointments that they have experienced in the past.

Video recording: We propose that the individual appointments and SMAs of patients who are enrolled in the study will be video recorded, so that the sessions can be transcribed and analyzed at a later time. The video recordings will be kept securely, maintaining patient confidentiality. The recording process will be described fully in the informed consent materials. We propose taking the following steps to protect patient confidentiality with regard to video recordings:

1. Video recordings will be transcribed by a professional transcription service within India, and the transcribers will have access to no information about the patients apart from the contents of the videos.

2. Transcriptions will include the full spoken text of the session, but patient names will be removed. Transcribers will be asked to codify specified behaviors, such as: a) The degree to which patients in the session appeared attentive. b) The number of questions patients in the session asked. c) The
duration of the session. This information will help the researchers identify mechanisms of impact, such as peer-to-peer learning, and the amount of information shared in each session.

3. Transcripts will be indexed by an appointment identifier, which will link to the participant ID in a database maintained by the study coordinator at Aravind Eye Hospital. As such, the researchers will not have access to the videos, nor any identifiable information in the transcripts that will be used for the analysis.

4. Following transcription, the videotapes will be retained securely for a period of six years, to allow sufficient time for the peer-review publication process and to facilitate the transcription of additional moderators as necessary, following the procedure outlined above. After six years, the videotapes will be destroyed, to protect patient confidentiality. However, the de-identified codified behaviors, as well as the de-identified text transcriptions will be made available to the researchers for textual analysis.

Data from charts: In addition, during each appointment, the study coordinator will collect information on medical outcomes from the patients’ charts, and will ensure measurement of operational outcomes such as time taken for each appointment and patient waiting times, using time stamps. Combined with hospital data on staff costs and patient revenues this information can be used to examine impact on financial outcomes.

Demographics and patient history: The study coordinator will also collect data on all relevant control variables. Demographics will include gender, age, literacy
level, income proxies, rural vs. urban, etc. History will include patient comorbidities, years of glaucoma, and family history.

**Inclusion/Exclusion Criteria:** Pre-qualification and Inclusion Criteria: During the enrolment period of the study, the study administrator will contact patients in advance of their appointments to confirm the date and time of their appointments, and to pre-qualify patients to participate in the study. And also patients who have come on a non-appointment basis, if they satisfy the inclusion criteria will also be recruited if they are willing to participate. De-identified data will be collected on which patients choose not to participate. Patients who are willing to participate in a Shared Medical Appointment (SMA), and who meet the inclusion criteria specified below, will be considered pre-qualified for the study. The inclusion criteria are:

1. The patient must be a primary glaucoma patient,
2. The patient must not have had more than one surgery in one eye in the past,
3. The patient must not have undergone a tube shunt surgery,
4. The patient must not be monocular,
5. The patient should not require surgical intervention in the near future,
6. The patient must not wish to interact with a specific doctor,
7. It is believed that the patient will interact effectively in a group setting,
8. The patient should not be a part of any other existing trial, and;
9. The patient should not have any vision threatening condition other than glaucoma.
Exclusion Criteria:
1. Any primary glaucoma patient who does not meet the inclusion criteria
2. Any glaucoma other than primary glaucoma

Risk & Benefits

Patient Risks and Ethical Approval
We plan to obtain data in a de-identified form and believe that the study does not pose any direct or indirect risk to patients' health. We do not plan to publish any data on individual patients. We will apply for IRB approval through the Aravind, London Business School and Harvard Business School processes. London Business School and Harvard Business School have already granted ethical approval for this project (approval form attached).

Project Risks
We do not foresee any major risks to the completion of the project and obtaining insights as envisaged above. However, the success of the project depends heavily on the ability to obtain high quality data required to conduct the statistical analysis as highlighted earlier. This will be ensured through the study coordinator.

Benefits
The direct benefits of this project include a better understanding of how SMAs impact medical, behavioral, operational and financial outcomes. This study will also throw light on the mechanisms through which SMAs may impact outcomes – e.g. peer-to-peer learning and patients’ access to greater information. This study will also lay the foundation for future research at Aravind that can examine the long term benefits of SMAs for glaucoma and other eye diseases.
**Expected Outcome**

As described above, we believe that this study will enable us to examine the extent to which SMAs impact medical outcomes for glaucoma (vision and intraocular pressure in particular). In addition, it will generate fundamental insights regarding patient behaviours, knowledge and satisfaction that drive the observed changes in medical outcomes. We expect that these insights will be published in top academic journals in operations management (such as Management Science) and in top medical journals.

**References:**


Section 2 – Ethics Approval Letters
Institutional Ethics Committee

Date 27.05.2016

To

Dr. S. Kavitha,
Medical Consultant,
Glaucoma Services,
Aravind Eye Hospital, Pondicherry.

Ref: The study No. AEH/PDY/EC/OA/15/2016 entitled "Shared Medical Appointments Randomized Trial (SMART)".

Investigators

1. Dr. S. Kavitha, Senior Glaucoma Specialist, Aravind Eye Hospital, Pondicherry
2. Ryan Buell, Assistant Professor of Business Administration, Harvard Business School
4. Dr. R. Venkatesh, Chief Medical Officer, Aravind Eye Hospital, Pondicherry
5. Nazli Sonmez, PhD student, London Business School

Dear Dr. S. Kavitha,

The Meeting of the Institutional Ethics Committee (IEC) was held on 04.05.2016 at Aravind Eye Hospital, in the Conference Hall with Dr. Tioumouougane Serane as Chairperson.
09 members attended the meeting. The list of members who attended the meeting is as follows:

<table>
<thead>
<tr>
<th>Name of Members</th>
<th>Position in IEC</th>
<th>Designation</th>
<th>Gender</th>
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<tbody>
<tr>
<td>Dr. V. Tiroumourougane</td>
<td>Chairperson</td>
<td>Consultant Neonatologist</td>
<td>M</td>
</tr>
<tr>
<td>Serane</td>
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<tr>
<td>Mr. S. Sankaralingam</td>
<td>Legal Expert</td>
<td>Advocate</td>
<td>M</td>
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<tr>
<td>Mr. Ram Sehgal</td>
<td>Lay Person</td>
<td>Journalist</td>
<td>M</td>
</tr>
<tr>
<td>Mr. V. C. Raam Sukaesh</td>
<td>Lay Person</td>
<td>C.E.O, Vinbros and Co</td>
<td>M</td>
</tr>
<tr>
<td>Mr. K. Senthil Kumar</td>
<td>Social Scientist</td>
<td>Director, SARPAM, Sri Aurobindo Society</td>
<td>M</td>
</tr>
<tr>
<td>Dr. Kartik J. Salwe</td>
<td>Basic Scientist</td>
<td>Associate Professor, Dept of Pharmacology</td>
<td>M</td>
</tr>
<tr>
<td>(Pharmacology)</td>
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<tr>
<td>Dr. Sharbari Basu</td>
<td>Basic Scientist</td>
<td>HOD, Dept of Biochemistry</td>
<td>F</td>
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<tr>
<td>(Biochemistry)</td>
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<tr>
<td>Dr. R. Jayagathri</td>
<td>Clinician</td>
<td>Medical Consultant in Orbit &amp; Oculoplasty</td>
<td>M</td>
</tr>
<tr>
<td>Dr. N. Shivananda</td>
<td>Clinician</td>
<td>Senior Medical Consultant in Cornea</td>
<td>M</td>
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</tbody>
</table>

**GENERAL OPHTHALMOLOGY**
- Dr. S. Josephine Christy
- Dr. Indevar V. Mishra
- Dr. Sahil Bhandari
- Dr. Rajesh V.
- Dr. Priya S.
- Dr. Annamalai O.
- Dr. Balamuruganandaraj D.

**RETINA – VITREOUS**
- Dr. Pankaja Dhoble
- Dr. Manavi D. Sindal
- Dr. Sabysachi Sengupta
- Dr. Prabu Baskaran

**CATARACT**
- Dr. Manas Nath
- Dr. Prasanth Gireesh

**CORNEA**
- Dr. K. Tiruvengada Krishnan
- Dr. N. Shivananda
- Dr. Seema Ramakrishnan
- Dr. Smitha Krishnamurthy

**PAEDIATRIC OPHTHALMOLOGY**
- Dr. K. Venna
- Dr. Marie Frederic Mottappra
- Dr. Shelke Vijayal Appara

**GLAUCOMA**
- Dr. R. Venkatsh
- Dr. S. Kaviha
- Dr. Swati Upadhya
- Dr. Debasish Dash
- Dr. Pavan Kumar M.G.

**ORBIT & OCULOPLASTY**
- Dr. S. Bala Murugan

**NEURO-OPHTHALMOLOGY**
- Dr. K. Nirmala Devy
It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The IEC has reviewed and approved the following documents submitted for the above-mentioned clinical study at the meeting.

1. Form A, Form B
2. Protocol
3. Informed Consent Documents

The IEC hereby approves the proposal entitled, “Shared Medical Appointments Randomized Trial (SMART)”.

It is understood that the study will be conducted under your direction, in a total of 1000 research participants, at Dept. of Glaucoma, Aravind Eye Hospital, Pondicherry as per the submitted protocol.

This approval is valid for the entire duration of the study.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to the IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval) on or before 04.04.2017.

A copy of the final report should be submitted to the IEC for review.

The IEC functions in accordance with ICH GCP, Schedule Y, ICMR guidelines and other applicable regulatory requirements.

Sincerely yours,

Signature of Chairperson

Date of Approval of the study: 27.05.2016
On 3/16/2016, the Institutional Review Board (IRB) of the Harvard University-Area approved this Initial Study. **Please note that the approval for this protocol will lapse on 3/15/2017.**

The documents that were finalized for this submission may be accessed through the IRB electronic submission management system at the following link: [Shared Medical Appointments](http://cuhs.harvard.edu).

The IRB made the following determinations:
- Special Populations: None
- Waivers: None
- Risk Determination: No greater than minimal risk
- Research Information Security Level: The research is classified, using Harvard’s Data Security Policy, as Level 3 Data.

Please contact me if you have any questions at 617-496-9952 or twegner@hbs.edu.

Sincerely,

Toni Wegner
Coordinator, Protection of Research Participants, HBS
Harvard University-Area  
Committee on the Use of Human Subjects  
1414 Massachusetts Avenue, 2nd Floor  
Cambridge, MA 02138  
IRB Registration - IRB00000109  
Federal Wide Assurance - FWA00004837

Notification of Continuing Review Approval

February 15, 2017

Ryan Buell  
rbuell@hbs.edu

Protocol Title: Shared Medical Appointments Randomized Trial (SMART)  
Principal Investigator: Ryan Buell  
Protocol #: IRB16-0213  
Submission #: CR16-0213-01  
Funding Source: Check listing  
Review Date: 2/15/2017  
CR Effective Date: 3/16/2017  
Expiration Date: 3/15/2018  
IRB Review Type: Expedited  
IRB Review Action: Approved

The Institutional Review Board (IRB) of the Harvard University-Area has approved this Continuing Review. Please note that the approval for this protocol will lapse on 3/15/2018.

The documents that were finalized for this submission may be accessed through the IRB electronic submission management system at the following link: IRB16-0213.

The IRB made the following determinations:
• Special Populations: None  
• Waivers: None  
• Risk Determination: No greater than minimal risk  
• Research Information Security Level: The research is classified, using Harvard’s Data Security Policy, as Level 3 Data.

Please contact me at 6174966348 or abonacossa@hbs.edu with any questions.

Sincerely,

Alain Bonacossa,  
Director, Research Administration
March 9, 2018

Ryan Buell
rbuell@hbs.edu

Protocol Title: Shared Medical Appointments Randomized Trial (SMART)
Principal Investigator: Ryan Buell
Protocol #: IRB16-0213
Submission #: CR16-0213-02
Funding Source: None
Review Date: 3/9/2018
CR Effective Date: 3/16/2018
Expiration Date: 3/15/2019
IRB Review Type: Expedited
IRB Review Action: Approved

The Institutional Review Board (IRB) of the Harvard University-Area has approved this Continuing Review. **Please note that the approval for this protocol will lapse on 3/15/2019.**

The documents that were finalized for this submission may be accessed through the IRB electronic submission management system at the following link: IRB16-0213.

The IRB made the following determinations:
- Special Populations: None
- Waivers: None
- Risk Determination: No greater than minimal risk
- Research Information Security Level: The research is classified, using Harvard’s Data Security Policy, as Level 3 Data.

Please contact me at 6174966348 or abonacossa@hbs.edu with any questions.

Sincerely,

Alain Bonacossa,
Senior Director for Research Administration and Behavioral Research Services
Harvard University-Area  
Committee on the Use of Human Subjects  
Smith Campus Center, Suite 935  
1350 Massachusetts Ave.  
Cambridge, MA 02138  
IRB Registration - IRB00000109  
Federal Wide Assurance - FWA00004837

Notification of Continuing Review Approval

March 17, 2019

Ryan Buell  
rbuell@hbs.edu

Protocol Title: Shared Medical Appointments Randomized Trial (SMART)  
Principal Investigator: Ryan Buell  
Protocol #: IRB16-0213  
Submission #: CR16-0213-03  
Funding Source: None  
Review Date: 3/17/2019  
CR Effective Date: 3/17/2019  
Expiration Date: 3/16/2020  
IRB Review Type: Expedited  
IRB Review Action: Approved

The Institutional Review Board (IRB) of the Harvard University-Area has approved this Continuing Review. **Please note that the approval for this protocol will lapse on 3/16/2020.**

The documents that were finalized for this submission may be accessed through the IRB electronic submission management system at the following link: [IRB16-0213](http://cuhs.harvard.edu).

The IRB made the following determinations:  
• Risk Determination: No greater than minimal risk  
• Research Information Security Level: The research is classified, using Harvard’s Data Security Policy, as Level 3 Data.

Please contact me at 6174966348 or abonacossa@hbs.edu with any questions.

Sincerely,

Alain Bonacossa  
Senior Director for Research Administration
Harvard University-Area
Committee on the Use of Human Subjects
44-R Brattle, Suite 200 (2nd floor)
Cambridge, MA 02138
IRB Registration - IRB00000109
Federal Wide Assurance - FWA00004837

Notification of Study Closure

April 17, 2020
Ryan Buell
rbuell@hbs.edu

Protocol Title: Shared Medical Appointments Randomized Trial (SMART)
Principal Investigator: Ryan Buell
Protocol #: IRB16-0213
Submission #: CR16-0213-04
Funding Source: None
IRB Review Date: 4/17/2020
IRB Review Action: Closed

The Institutional Review Board (IRB) of the Harvard University-Area closed this study.

As part of this action:
• The protocol is permanently closed to enrollment.
• All subjects have completed all protocol-related interventions.
• Collection of private identifiable information is completed.
• Analysis of private identifiable information is completed.

Investigators must maintain human research records, including signed and dated consent documents, for at least seven years after study closure. The IRB retains protocol files for the same duration.

If the human research is sponsored, please contact the sponsor before disposing of any records as there may be specific policies related to record retention.

Please contact me at 6174966348 or abonacossa@hbs.edu regarding this protocol or with any questions.

Sincerely,

Alain Bonacossa
Senior Director for Research Administration
22nd December 2015

Project Title: Shared Medical Appointments

Dear Kamalini,

Thank you for completing the attached ethical review form for the above proposed research project to the Economic and Social Sciences Research Council (ESRC). Please proceed with your application. Should your proposal be successful, given the nature of the project further ethical consideration should be given as required by the funding body. Please do submit any relevant documentation to ethics@london.edu, prior to any work commencing on the project.

A copy of the attached ethical approval application will be retained in the Research & Faculty Office for their records.

Yours sincerely,

Emre Ozdenoren
Chair, Research Ethics Committee
Section 3 – Amendments
Protocol / Protocol related documents Amendment Request and Assessment Form

<table>
<thead>
<tr>
<th>IEC Protocol Number:</th>
<th>AEH/PDY/EC/OA/15/2016</th>
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</thead>
<tbody>
<tr>
<td>Protocol Title:</td>
<td>Shared Medical Appointments Randomized Trial (SMART)</td>
</tr>
<tr>
<td>Principal Investigator and Department:</td>
<td>Dr.S.Kavitha, Glaucoma Services</td>
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<tr>
<td>Approved date:</td>
<td>27.05.2016</td>
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<td>No. of amendment:</td>
<td>01</td>
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</table>

State/describe the amendment : type of document/ part of document amended

Extension of Study Recruitment Period from Jan 16 to December 2017.

Reasons for the amendment

Could not complete inclusion targets.

Impact of your amendment on your present study at this site: (modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of the amendment or any other)

Have the changes modifications in the amended versions been highlighted/ underlined?

Yes [ ] No [x]

If yes, please submit Annexure – AX 06/SOP 06/V1

With these amendments, do you have any conflicts of interest (financial / non-financial/others) to declare

Yes [ ] No [x]

Name of Principal Investigator: Dr.S.Kavitha

Signature with Date: [Signature] 24/01/2017
**Type of review:** (Decision by the Chairperson/ Member Secretary)

- Review by Member Secretary/ Chairperson  
- by designated IEC members  
- Full Board discussion and review

**Comments of the reviewer:**


**Decision:**

- [ ] Approved
- [ ] Suggested Recommendation(s)
- [ ] Disapproved
- [ ] Next full board discussion

**Name of IEC Member / Member Secretary / Chairperson reviewing the project:**

Signature with Date:

**Final Decision:** Approved  Yes  No

If disapproved, reasons for disapproval:

Further revision or modification required:

Any Other:

**Signature of the Chairperson/Member Secretary:**

[Signature]

Date: 09/02/17
## Protocol / Protocol related documents Amendment Request and Assessment Form

<table>
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**State/describe the amendment : type of document/ part of document amended**

Questionnaire- Need to add few more questions to the existing exit survey

**Reasons for the amendment**

Adding these questions to the final survey will help us to understand the patients’ perception on shared medical appointment in a better way.

**Impact of your amendment on your present study at this site: (modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of the amendment or any other)**

Nil

Have the changes modifications in the amended versions been highlighted/ underlined?

Yes [ ] No [ ]

If yes, please submit Annexure – AX 06/SOP 06/V1

**With these amendments, do you have any conflicts of interest (financial / non-financial/others) to declare**

Yes [ ] No [ X ]

**Name of Principal Investigator: Dr. S. Kavitha**

**Signature with Date:**

[Signature]

[Date] 3/17
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Additional Question We Would Like to Add to the Survey after Trial Appointments 1, 2, 3, 4:

1. (For Both SMA and One on One Patients) How satisfied were you with the length of your waiting time before the final exam stage of your appointment?
   a. Very satisfied
   b. Satisfied
   c. Neutral
   d. Dissatisfied
   e. Very dissatisfied

Exit Survey

The questions below refer to your glaucoma appointments over the past year.

1. (For Both SMA and One on One Patients) How much at ease did you feel during the interactions?
   1  2  3  4  5
   1: Very much at ease
   5: Not at all at ease

2. (For Both SMA and One on One Patients) To what extent do you agree that your doctor has been fair in his or her dealings with you.
   a. Much more than expected
   b. More than expected
   c. As much as expected
   d. Less than expected
   e. Much less than expected

3. (For Both SMA and One on One Patients) How caring was the doctor towards you?
   a. Much more than expected
   b. More than expected
   c. As much as expected
   d. Less than expected
   e. Much less than expected

4. (For Both SMA and One on One Patients) During your appointment, how caring was the doctor towards the other patients?
   a. Much more than expected
   b. More than expected
   c. As much as expected
   d. Less than expected
   e. Much less than expected
5. (For Both SMA and One on One Patients) During your appointment, how caring was the nurse towards you?
   a. Much more than expected
   b. More than expected
   c. As much as expected
   d. Less than expected
   e. Much less than expected

6. (For Both SMA and One on One Patients) Did you spend enough time with Dr. Kavitha / Dr. Venkatesh relative to your expectations?
   a. Much more than expected
   b. More than expected
   c. As much as expected
   d. Less than expected
   e. Much less than expected

7. (For Both SMA and One on One Patients) How Many Minutes of Individual Attention Did You Get from the Doctor in the Final Exam Stage in Each Visit?

8. (For Both SMA and One on One Patients) (Essay) How would you describe your appointment with Dr Kavitha / Venkatesh today?

9. (For Both SMA and One on One Patients) (Essay) What were the best and worst parts of your final examination with Dr. Kavitha/Dr. Venkatesh?

10. (SMA patients only) Over the past year, how often did you interact outside the hospital with people that you met during your shared appointments?
    a. Very frequently
    b. Frequently
    c. Occasionally
    d. Rarely
    e. Very rarely

11. (For Both SMA and One on One Patients) Over the past Year, to what extent did you coordinate with other patients in your SMA group to determine the date for your follow up appointments?
    a. Very frequently
    b. Frequently
    c. Occasionally
    d. Rarely
    e. Very rarely
12. (SMA patients only) How satisfied were you with the level of confidentiality?

a. Very satisfied
b. Satisfied
c. Neutral
d. Dissatisfied
e. Very dissatisfied

13. (SMA patients only) How much of what you learned about glaucoma during the final examination came from the doctor?

a. All of what I learned
b. Most of what I learned
c. About half of what I learned
d. Some of what I learned
e. None of what I learned
1. (பாதி எடுத்துக்கொள்ள பகிர்வால் முழுமையான விளக்கம் பதிக்கவுள்ள, கணக்கெடுப்பு முறையியல்) பொருளாதார முறையியல் பயிற்சிகளாக இருந்து பொருளாதார முறையியல் விளக்கம் பதிக்கும் பாதி எடுத்துக்கொள்ளல் எப்படி?  

☐ முதல் தீவெடுப்பு  
☐ முறையியல்  
☐ பொருளாதார  
☐ முறையியல் பின்புறம்  
☐ முறையியல் பின்புறம்

அப்படி படிகை விளக்கங்கள் முறையியல்

ஆக்குத்தான் எடுத்துக்கொள்ள கண்டு அறிவு எடுத்துக்கொள்ள பகிர்வால் விளக்கங்களை செயல்படுத்த வேண்டும்?

1. (பாதி எடுத்துக்கொள்ள பகிர்வால் முழுமையான விளக்கம் பதிக்கவுள்ள, கணக்கெடுப்பு முறையியல்) எடுத்துக்கொள்ள பகிர்வால்

| பகிர்வால் எடுத்துக்கொள்ள பகிர்வால் எடுத்துக்கொள்ள பகிர்வால் | எடுத்துக்கொள்ள பகிர்வால் எடுத்துக்கொள்ள பகிர்வால் |
|----------------|----------------|----------------|----------------|----------------|----------------|
| 1              | 2              | 3              | 4              | 5              | எடுத்துக்கொள்ள பகிர்வால் |

1: புதிதியில் குறுக்கியை எடுத்துக்கொள்ள
5: புதிதியில் குறுக்கியை

2. (பாதி எடுத்துக்கொள்ள பகிர்வால் முழுமையான விளக்கம் பதிக்கவுள்ள, கணக்கெடுப்பு முறையியல்) எடுத்துக்கொள்ள பகிர்வால்

☐ பகிர்வால் எடுத்துக்கொள்ள பகிர்வால்
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3. (பாதி எடுத்துக்கொள்ள பகிர்வால் முழுமையான விளக்கம் பதிக்கவுள்ள, கணக்கெடுப்பு முறையியல்) எடுத்துக்கொள்ள பகிர்வால்

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☐ பகிர்வால் எடுத்துக்கொள்ள பகிர்வால்
4. (மாணிக்கால பொருட்கள் வருமதி நீர் மற்றும் பொருட்கள்) என்றுக்கும் இருந்து பொருட்களை வெப்பந்திருப்பது நீர், பொருட்கள் என்று அல்லது அத்லையும் பொருட்கள்/நீர் இருந்து வெப்பந்திருப்பது என்று சொல்லப்பட்டால் என்கிறேற்றும்?

☐ அத்லையும் பொருட்கள்
☐ நீர்
☐ அத்லையும் பொருட்கள்
☐ அத்லையும் பொருட்கள்
☐ நீர்
☐ அத்லையும் பொருட்கள்

5. (மாணிக்கால பொருட்கள் வருமதி நீர் மற்றும் பொருட்கள்) என்றுக்கும் இருந்து பொருட்களை வெப்பந்திருப்பது நீர், பொருட்கள் என்று அல்லது அத்லையும் பொருட்கள்/நீர் இருந்து வெப்பந்திருப்பது என்று சொல்லப்பட்டால் என்கிறேற்றும்?

☐ அத்லையும் பொருட்கள்
☐ நீர்
☐ அத்லையும் பொருட்கள்
☐ அத்லையும் பொருட்கள்
☐ நீர்
☐ அத்லையும் பொருட்கள்

6. (மாணிக்கால பொருட்கள் வருமதி நீர் மற்றும் பொருட்கள்) என்றுக்கும் இருந்து நீர் பொருட்கள் என்று அல்லது பொருட்கள் என்று அல்லது அத்லையும் பொருட்கள்/நீர் இருந்து வெப்பந்திருப்பது என்கிறேற்றும்?

☐ அத்லையும் பொருட்கள்
☐ நீர்
☐ அத்லையும் பொருட்கள்
☐ அத்லையும் பொருட்கள்
☐ நீர்
☐ அத்லையும் பொருட்கள்

7. (மாணிக்கால பொருட்கள் வருமதி நீர் மற்றும் பொருட்கள்) என்று குறிப்பிட்டு அத்லையும் பொருட்கள்/நீர் வெப்பந்திருப்பது என்று அத்லையும் பொருட்கள்/நீர் இருந்து வெப்பந்திருப்பது என்கிறேற்றும்?

8. (மாணிக்கால பொருட்கள் வருமதி நீர் மற்றும் பொருட்கள்) சிறுவர் பொருட்களை யார், குறிப்பிட்டு நீர் அத்லையும் பொருட்கள்/நீர் இருந்து வெப்பந்திருப்பது என்கிறேற்றும்?

9. (மாணிக்கால பொருட்கள் வருமதி நீர் மற்றும் பொருட்கள்) என்று குறிப்பிட்டு அத்லையும் பொருட்கள்/நீர் இருந்து வெப்பந்திருப்பது என்கிறேற்றும்?
10. (பாலியல் பரிச்சாசலா சிேப்பு) குறுக்கும் மறுவர் சேவைகள் பாலியல் பரிச்சாசலாவின் பாலியல் சேவைகள் என்று பரிச்சாசலாவின் அமைப்பு உள்ளது (சுருக்கிப் பதிவு/பாலியல்)

☐ பெருமை அதிகார
☐ அறுக்கள்
☐ நூற்றாண்டுக் காலமுடி
☐ அகழ்வார்
☐ நிலையை அதிகார

11. (பாலியல் பரிச்சாசலா சிேப்பு குறியீட்டு) குறுக்கும் மறுவர் சேவைகள் பாலியல் பரிச்சாசலாவின் பாலியல் சேவைகள் என்று பரிச்சாசலாவின் அமைப்பு உள்ளது (சுருக்கிப் பதிவு/பாலியல்)

☐ பெருமை அதிகார
☐ அறுக்கள்
☐ நூற்றாண்டுக் காலமுடி
☐ அகழ்வார்
☐ நிலையை அதிகார

12. (பாலியல் பரிச்சாசலா சிேப்பு) குறுக்கு சேவைகள் என்று அதிகார தீர்மானம் அடைகிறது?

☐ பெருமை தீர்மானம்
☐ குறிப்பிட்டில்
☐ துள்ளுகை
☐ குறிப்பிட்டில் தினை
☐ நிலையை தினை தினை

13. (பாலியல் பரிச்சாசலா சிேப்பு) குறுக்கு முயற்சிகள் பாலியல் பரிச்சாசலாவின், குறுக்கு அமைதியின் பரிச்சாசலா உள்ளது என்று நல்லை நோக்கினால் பரிச்சாசலா என்று அறிந்திருக்கிறது?

☐ பெருமைத் தீர்மானம்
☐ குறிப்பிட்டில் நல்லை தீர்மானம் நல்லை
☐ நல்லை தீர்மானம் வார்த்தை
☐ நல்லை தீர்மானம்
☐ நல்லை தினை
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State/describe the amendment: type of document/ part of document amended

Reasons for the amendment
Extension of study recruitment period (to July 2018) as we could not yet achieve the Sample size

Impact of your amendment on your present study at this site: (modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of the amendment or any other)

Nil

Have the changes modifications in the amended versions been highlighted/ underlined?

Yes ☐ No ☐ N/A
If yes, please submit Annexure – AX 06/SOP 06/V1

With these amendments, do you have any conflicts of interest (financial / non-financial/others) to declare

Yes ☐ No ☐

Name of Principal Investigator: Dr.S.Kavitha

Signature with Date: [Signature] 16/13/18
Type of review :- (Decision by the Chairperson/ Member Secretary)
Review by Member Secretary/ Chairperson
Review by designated IEC members
Full Board discussion and review
Comments of the reviewer :-

Decision:
☐ Approved       ☐ Suggested Recommendation(s)
☐ Rejected       ☐ Next full board discussion

Name of IEC Member / Member Secretary /
Chairperson reviewing the project:

Signature with Date: ____________________________

Final Decision: Approved       Yes ☑ Yes ☑ No ☐
If disapproved, reasons for disapproval

Further revision or modification required:

Any Other:

Signature of the Chairperson/Member Secretary: ____________________________

Date: 16/3/18
Section 4 – Case Report Form
CASE REPORT FORM

Aravind Eye Care System,
Cuddalore Main Road,
Thavalakuppam,
Pondicherry, India
<table>
<thead>
<tr>
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<th>Actual Date</th>
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<tr>
<td>Pre-Trial Visit-2</td>
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<td>Pre-Trial Visit-3</td>
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<td>Post-Trial Visit-4</td>
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ELIGIBILITY WORK SHEET

INCLUSION CRITERIA:

I01. The patient must be a primary glaucoma patient

I02. The patient must not have had more than one surgery in one eye in the past

I03. The patient must not have undergone a tube/shunt surgery

I04. The patient must not be monocular

I05. The patient should not require surgical intervention in the near future

I06. The patient must not wish to interact with a specific doctor

I07. It is believed that the patient will interact effectively in a group setting

I08. The patient should not be a part of any other existing trial

I09. The patient should not have any vision threatening condition other than glaucoma

EXCLUSION CRITERIA:

E01. The patient who is not primary glaucoma patient.

E02. The patient who has had more than one surgery in one eye in the past

E03. The patient who has undergone a tube shunt surgery

E04. Monocular patients

E05. The patient who requires surgical intervention in the near future

E06. The patient who wishes to interact with a specific doctor

E07. The patient who won’t interact effectively in a group setting

E08. The patient who is a part of another trial.

E09. The patient who has any vision threatening condition other than glaucoma.
### BASIC DEMOGRAPHIC DETAILS

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<th>Others (Specify if any)</th>
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Pre-Trial Visit-1

DATE: ____________

Arrival Time in the Glaucoma Clinic ..........................

Departure Time from the Glaucoma Clinic ..........................

OBJECTIVE MEASURES:

Number of Years the Patient Has Had Glaucoma .........................

Best corrected visual acuity:  RE ......................... LE .........................

Intra Ocular Pressure:  RE ......................... LE .........................

Number of Medications:  RE ......................... LE .........................

Details of Medication:

  RE ................. LE.........................

  1.Beta blocker
  2. Alpha agonist
  3.Pilocarpine
  4. CAI
  5.PG Analogues

Has the patient complied with the prescribed protocol since the last visit?

(Yes or No): ..........................

Optic Nerve Head Examination:  RE ......................... LE .........................

Other Ocular Co-morbidities:  RE ......................... LE .........................

1. Yes 2. No

If Yes, Please mention:  RE ......................... LE .........................

CONTROL VARIABLES:

Name and Affiliation of the Examining Doctor

...............................
Pre-Trial Visit-2

DATE: ____________________________

Arrival Time in the Glaucoma Clinic ........................................

Departure Time from the Glaucoma Clinic .................................

OBJECTIVE MEASURES:

Number of Years the Patient Has Had Glaucoma .........................

Best corrected visual acuity: RE .............................. LE ........

Intra Ocular Pressure: RE .............................. LE ........

Number of Medications: RE .............................. LE ........

Details of Medication:

RE ........................ LE....................

1. Beta blocker
2. Alpha agonist
3. Pilocarpine
4. CAI
5. PG Analogues

Has the patient complied with the prescribed protocol since the last visit?

(Yes or No): .................................

Optic Nerve Head Examination: RE .............................. LE ........

Other Ocular Co-morbidities: RE .............................. LE ........

1. Yes 2. No

If Yes, Please mention: RE .............................. LE ........

CONTROL VARIABLES:

Name and Affiliation of the Examining Doctor

........................................
Pre-Trial Visit-3

DATE: ___________ ___________ ___________

Arrival Time in the Glaucoma Clinic ..........................

Departure Time from the Glaucoma Clinic .....................

OBJECTIVE MEASURES:

Number of Years the Patient Has Had Glaucoma ..................

Best corrected visual acuity:  RE ..........................  LE ..........................

Intra Ocular Pressure:  RE ..........................  LE ..........................

Number of Medications:  RE ..........................  LE ..........................

Details of Medication:

RE ..........................  LE..........................

1. Beta blocker
2. Alpha agonist
3. Pilocarpine
4. CAI
5. PG Analogues

Has the patient complied with the prescribed protocol since the last visit?

(Yes or No): ..........................

Optic Nerve Head Examination:  RE ..........................  LE ..........................

Other Ocular Co-morbidities:  RE ..........................  LE ..........................

1. Yes 2. No

If Yes, Please mention:  RE ..........................  LE ..........................

CONTROL VARIABLES:

Name and Affiliation of the Examining Doctor

..........................
Pre-Trial Visit-4

DATE: 

Arrival Time in the Glaucoma Clinic ……………………………

Departure Time from the Glaucoma Clinic ……………………………

OBJECTIVE MEASURES:

Number of Years the Patient Has Had Glaucoma ……………………..

Best corrected visual acuity:  RE ………………… LE ……………………..

Intra Ocular Pressure:  RE ………………… LE ……………………..

Number of Medications:  RE ………………… LE ……………………..

Details of Medication:

RE ………………… LE…………………………

1. Beta blocker
2. Alpha agonist
3. Pilocarpine
4. CAI
5. PG Analogues

Has the patient complied with the prescribed protocol since the last visit?

(Yes or No): ……………………………

Optic Nerve Head Examination:  RE ………………… LE ……………………..

Other Ocular Co-morbidities:  RE ………………… LE ……………………..

1. Yes 2. No

If Yes, Please mention:  RE ………………… LE ……………………..

CONTROL VARIABLES:

Name and Affiliation of the Examining Doctor

……………………………………
Trial Visit-1

DATE: 

Unique Identity of the Appointment: ........................................

One-on-one or SMA (by randomization): ..............................

Number of the Patients in the Appointment: ............................

Arrival Time in the Glaucoma Clinic: ......................................

Start Time of Registration: ..............................................

Time of Entry to the Glaucoma Department: ............................

Start Time of Vision Check/Refraction: .................................

End Time of Vision Check/Refraction: .................................

Start Time for Taking History and Checking Eye Pressure: ..........

End Time for Taking History and Checking Eye Pressure: ............

Start Time for the Preliminary Examination: ..........................

End Time for the Preliminary Examination: ............................
Start Time for HFA: .................................

End Time for HFA: .................................

Start Time for Dilatation: ..............................

End Time for Dilatation: ..............................

Start Time of OCT: .................................

End Time of OCT: .................................

Start Time for Final Examination: ..............................

End Time for Final Examination: ..............................

Duration of the Entire Appointment: ..............................

(From Start of Registration to the End of Final Examination)

**Start and End Times for Follow-Up Steps**

Start Time for Meeting with Study Coordinator

For Counselling and/or Scheduling a Follow-up  : ..............................

Appointment

End Time for Meeting with Study Coordinator

For Counselling and/or scheduling a Follow-up  : ..............................

Appointment

Next Appointment On: ..............................
EFFICACY MEASURES

Patient Perceptions: Administer a brief survey following each appointment, which includes the questions below. Knowledge assessment questions will be used during the pilot period to conduct a sample size calculation, as described in the protocol, and will also be asked throughout the study:

1. Knowledge assessment: Glaucoma is:
   a. Contagious disease
   b. Hereditary
   c. Both
   d. None of the above

2. Knowledge assessment: What causes glaucoma?
   a. Diabetes
   b. Age related
   c. Trauma
   d. All of the above

3. Knowledge assessment: Glaucoma causes:
   a. Loss of visual field/side vision
   b. Loss of central vision
   c. Eye pain
   d. Headache

4. Knowledge assessment: Treatment for glaucoma:
   a. Eye drops
   b. Laser therapy
   c. Surgery
   d. All of the above.
5. Knowledge assessment: Glaucoma leads to:
   a. High intra-ocular pressure
   b. Loss of visual field
   c. Optic nerve damage
   d. All of the above

6. How satisfied were you with today’s appointment:
   a. Very satisfied
   b. Satisfied
   c. Neutral
   d. Dissatisfied
   e. Very dissatisfied

7. To what extent were your doubts addressed during today’s appointment?
   a. Fully
   b. Almost fully
   c. Somewhat
   d. Not very well
   e. Not at all

8. Relative to your expectations, how much did you learn about glaucoma during today’s appointment?
   a. Much more than expected
   b. More than expected
   c. As much as expected
   d. Less than expected
   e. Much less than expected
9. How well did you understand the doctor’s instructions?
   a. Fully
   b. Almost fully
   c. Somewhat
   d. Not very well
   e. Not at all

10. How likely are you to return for your next appointment?
    a. Very likely
    b. Likely
    c. Somewhat likely
    d. Not likely
    e. Very unlikely

**OBJECTIVE MEASURES:**

Best corrected visual acuity: RE ..................... LE ......................
Intra Ocular Pressure: RE ..................... LE ......................
Number of Medications: RE ..................... LE ......................

Details of Medication:

    RE ..................... LE ......................

    1. Beta blocker
    2. Alpha agonist
    3. Pilocarpine
    4. CAI
    5. PG Analogues

Has the patient complied with the prescribed protocol since the last visit?

(Yes or No): .........................
Optic Nerve Head Examination:  RE ..........................  LE ..........................

Other Ocular Co-morbidities:  RE ..........................  LE ..........................

1. Yes 2. No

If Yes, Please mention:  RE ..........................  LE ..........................

CONTROL VARIABLES:

Doctor ID for the Appointment

........................................

Signature of the Examining Doctor:

........................................
Trial Visit-2

DATE: 

Unique Identity of the Appointment: ........................................

One-on-one or SMA : ........................................

On Trial Time (Yes/No): ........................................

Number of the Patients in the Appointment: ..........................

Arrival Time in the Glaucoma Clinic: ..................................

Start Time of Registration: ........................................

Time of Entry to the Glaucoma Department: ...........................

Start Time of Vision Check/Refraction: ..............................

End Time of Vision Check/Refraction: ..............................

Start Time for Taking History and Checking Eye Pressure: ..........

End Time for Taking History and Checking Eye Pressure: ..........

Start Time for the Preliminary Examination: ........................
End Time for the Preliminary Examination: ...........................................

Start Time for HFA: .........................................................

End Time for HFA: .........................................................

Start Time for Dilatation: ..................................................

End Time for Dilatation: ..................................................

Start Time of OCT: .........................................................

End Time of OCT: .........................................................

Start Time for Final Examination: .......................................

End Time for Final Examination: ........................................

Duration of the Entire Appointment: ....................................

(From Start of Registration to the End of Final Examination)

**Start and End Times for Follow-Up Steps**

Start Time for Meeting with Study Coordinator

For Counselling and/or Scheduling a Follow-up Appointment: ........................................

End Time for Meeting with Study Coordinator

For Counselling and/or Scheduling a Follow-up Appointment: ........................................

Next Appointment On: .................................................
Efficacy Measures

Patient Perceptions: Administer a brief survey following each appointment, which includes the questions below. Knowledge assessment questions will be used during the pilot period to conduct a sample size calculation, as described in the protocol, and will also be asked throughout the study:

1. Knowledge assessment: Glaucoma is:
   a. Contagious disease
   b. Hereditary
   c. Both
   d. None of the above

2. Knowledge assessment: What causes glaucoma?
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3. Knowledge assessment: Glaucoma causes:
   a. Loss of visual field/side vision
   b. Loss of central vision
   c. Eye pain
   d. Headache

4. Knowledge assessment: Treatment for glaucoma:
   a. Eye drops
   b. Laser therapy
   c. Surgery
   d. All of the above.
5. Knowledge assessment: Glaucoma leads to:
   a. High intra-ocular pressure
   b. Loss of visual field
   c. Optic nerve damage
   d. All of the above

6. How satisfied were you with today’s appointment:
   a. Very satisfied
   b. Satisfied
   c. Neutral
   d. Dissatisfied
   e. Very dissatisfied

7. To what extent were your doubts addressed during today’s appointment?
   a. Fully
   b. Almost fully
   c. Somewhat
   d. Not very well
   e. Not at all

8. Relative to your expectations, how much did you learn about glaucoma during today’s appointment?
   a. Much more than expected
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   c. As much as expected
   d. Less than expected
   e. Much less than expected
9. How well did you understand the doctor’s instructions?
   a. Fully
   b. Almost fully
   c. Somewhat
   d. Not very well
   e. Not at all

10. How likely are you to return for your next appointment?
   a. Very likely
   b. Likely
   c. Somewhat likely
   d. Not likely
   e. Very unlikely

**OBJECTIVE MEASURES:**

Best corrected visual acuity: RE ....................  LE ....................

Intra Ocular Pressure: RE ....................  LE ....................

Number of Medications: RE ....................  LE ....................

Details of Medication:

   RE ....................  LE....................

   1. Beta blocker
   2. Alpha agonist
   3. Pilocarpine
   4. CAI
   5. PG Analogues
Has the patient complied with the prescribed protocol since the last visit?

(Yes or No): ........................

Optic Nerve Head Examination: RE ......................... LE ......................

Other Ocular Co-morbidities: RE ......................... LE ......................

1. Yes 2. No

If Yes, Please mention: RE ......................... LE ......................

CONTROL VARIABLES:

Doctor ID for the Appointment

........................................

Signature of the Examining Doctor:

........................................
Trial Visit-3

DATE: 

Unique Identity of the Appointment: .........................................

One-on-one or SMA: ..............................................

On Trial Time (Yes/No): ...........................................

Number of the Patients in the Appointment: ...................................

Arrival Time in the Glaucoma Clinic: ........................................

Start Time of Registration: .............................................

Time of Entry to the Glaucoma Department: ................................

Start Time of Vision Check/Refraction: ........................................

End Time of Vision Check/Refraction: ........................................

Start Time for Taking History and Checking Eye Pressure: ......................

End Time for Taking History and Checking Eye Pressure: ........................

Start Time for the Preliminary Examination: .................................
End Time for the Preliminary Examination: ........................................

Start Time for HFA: ..................................................

End Time for HFA: ..................................................

Start Time for Dilatation: ............................................

End Time for Dilatation: .............................................

Start Time of OCT: ..................................................

End Time of OCT: ...................................................

Start Time for Final Examination: ...................................

End Time for Final Examination: ...................................

Duration of the Entire Appointment: ...............................

(From Start of Registration to the End of Final Examination)

**Start and End Times for Follow-Up Steps**

Start Time for Meeting with Study Coordinator

For Counselling and/or Scheduling a Follow-up Appointment: ........................................

End Time for Meeting with Study Coordinator

For Counselling and/or scheduling a follow-up Appointment: ...........................................

Next Appointment On: .............................................
Efficacy Measures

Patient Perceptions: Administer a brief survey following each appointment, which includes the questions below. Knowledge assessment questions will be used during the pilot period to conduct a sample size calculation, as described in the protocol, and will also be asked throughout the study:

1. Knowledge assessment: Glaucoma is:
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2. Knowledge assessment: What causes glaucoma?
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   d. Headache

4. Knowledge assessment: Treatment for glaucoma:
   a. Eye drops
   b. Laser therapy
   c. Surgery
   d. All of the above.
5. Knowledge assessment: Glaucoma leads to:
   a. High intra-ocular pressure
   b. Loss of visual field
   c. Optic nerve damage
   d. All of the above

6. How satisfied were you with today’s appointment:
   a. Very satisfied
   b. Satisfied
   c. Neutral
   d. Dissatisfied
   e. Very dissatisfied

7. To what extent were your doubts addressed during today’s appointment?
   a. Fully
   b. Almost fully
   c. Somewhat
   d. Not very well
   e. Not at all

8. Relative to your expectations, how much did you learn about glaucoma during today’s appointment?
   a. Much more than expected
   b. More than expected
   c. As much as expected
   d. Less than expected
   e. Much less than expected
9. How well did you understand the doctor’s instructions?
   a. Fully
   b. Almost fully
   c. Somewhat
   d. Not very well
   e. Not at all

10. How likely are you to return for your next appointment?
   a. Very likely
   b. Likely
   c. Somewhat likely
   d. Not likely
   e. Very unlikely

**OBJECTIVE MEASURES:**

Best corrected visual acuity: RE ..................... LE ......................

Intra Ocular Pressure: RE ..................... LE ......................

Number of Medications: RE ..................... LE ......................

Details of Medication:

   RE ..................... LE ......................
   1. Beta blocker
   2. Alpha agonist
   3. Pilocarpine
   4. CAI
   5. PG Analogues
Has the patient complied with the prescribed protocol since the last visit?

(Yes or No): ................................

Optic Nerve Head Examination: RE .............................. LE ............................

Other Ocular Co-morbidities:  RE .............................. LE ............................

1. Yes 2. No

If Yes, Please mention: RE .............................. LE ............................

CONTROL VARIABLES:

Doctor ID for the Appointment

...........................................

Signature of the Examining Doctor:

...........................................
Trial Visit-4

DATE: 

One-on-one or SMA: ........................................

Unique Identity of the Appointment: ..............................

On Trial Time (Yes/No): ........................................

Number of the Patients in the Appointment: ........................

Arrival Time in the Glaucoma Clinic: ............................

Start Time of Registration: .................................

Time of Entry to the Glaucoma Department: ........................

Start Time of Vision Check/Refraction: ..........................

End Time of Vision Check/Refraction: ..........................

Start Time for Taking History and Checking Eye Pressure: ..........................

End Time for Taking History and Checking Eye Pressure: ..........................

Start Time for the Preliminary Examination: ..........................
End Time for the Preliminary Examination: ...........................................

Start Time for HFA: ...................................................

End Time for HFA: ...................................................

Start Time for Dilatation: ............................................

End Time for Dilatation: ............................................

Start Time of OCT: ................................................

End Time of OCT: ................................................

Start Time for Final Examination: .................................

End Time for Final Examination: .................................

Duration of the Entire Appointment: ............................
(From Start of Registration to the End of Final Examination)

**Start and End Times for Follow-Up Steps**

Start Time for Meeting with Study Coordinator
For Counselling and/or Scheduling a Follow-up Appointment ..........................

End Time for Meeting with Study Coordinator
For Counselling and/or scheduling a follow-up Appointment .........................
Efficacy Measures

Patient Perceptions: Administer a brief survey following each appointment, which includes the questions below. Knowledge assessment questions will be used during the pilot period to conduct a sample size calculation, as described in the protocol, and will also be asked throughout the study. We also have additional questions to assess patient’s perceptions on glaucoma care.

1. Knowledge assessment: Glaucoma is:
   a. Contagious disease
   b. Hereditary
   c. Both
   d. None of the above

2. Knowledge assessment: What causes glaucoma?
   a. Diabetes
   b. Age related
   c. Trauma
   d. All of the above

3. Knowledge assessment: Glaucoma causes:
   a. Loss of visual field/side vision
   b. Loss of central vision
   c. Eye pain
   d. Headache

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   a. Eye drops
   b. Laser therapy
   c. Surgery
   d. All of the above.
5. Knowledge assessment: Glaucoma leads to:
   a. High intra-ocular pressure
   b. Loss of visual field
   c. Optic nerve damage
   d. All of the above

6. How satisfied were you with today’s appointment:
   a. Very satisfied
   b. Satisfied
   c. Neutral
   d. Dissatisfied
   e. Very dissatisfied

7. To what extent were your doubts addressed during today’s appointment?
   a. Fully
   b. Almost fully
   c. Somewhat
   d. Not very well
   e. Not at all

8. Relative to your expectations, how much did you learn about glaucoma during today’s appointment?
   a. Much more than expected
   b. More than expected
   c. As much as expected
   d. Less than expected
   e. Much less than expected
9. How well did you understand the doctor’s instructions?
   a. Fully
   b. Almost fully
   c. Somewhat
   d. Not very well
   e. Not at all

10. How likely are you to return for your next appointment?
   a. Very likely
   b. Likely
   c. Somewhat likely
   d. Not likely
   e. Very unlikely

**Additional questions for final patient survey:** After the patients fourth visit during the study, the patient will also be asked the following questions:

11. How frequently did you discuss your appointments with others (family members, friends, etc.)?
   a. Very frequently
   b. Frequently
   c. Occasionally
   d. Not frequently
   e. Never

**Patients in the treatment (SMA) condition will additionally be asked:**

12. How often did you call other patients that you met during your shared appointments?
   a. Very frequently
   b. Frequently
   c. Occasionally
   d. Not frequently
   e. Never
13. If they were made available in the future, how likely is it that you would choose to continue using shared medical appointments?

a. Very likely
b. Likely
c. Somewhat likely
d. Not likely
e. Very unlikely

14. How likely would you be to recommend shared medical appointments to a friend, colleague, or relative?

a. Very likely
b. Likely
c. Somewhat likely
d. Not likely
e. Very unlikely

OBJECTIVE MEASURES:

Best corrected visual acuity: RE ....................... LE .........................
Intra Ocular Pressure: RE ....................... LE .........................
Number of Medications: RE ....................... LE .........................

Details of Medication:

RE ................. LE.........................

1. Beta blocker
2. Alpha agonist
3. Pilocarpine
4. CAI
5. PG Analogues
Has the patient complied with the prescribed protocol since the last visit?
(Yes or No): ........................................

Optic Nerve Head Examination: RE ........................... LE .............................
Other Ocular Co-morbidities: RE ........................... LE .............................
1. Yes 2. No
If Yes, Please mention: RE ......................... LE .............................

CONTROL VARIABLES:

Doctor ID for the Appointment
......................................................

Signature of the Examining Doctor:
......................................................
 Unscheduled Visit-1

DATE: __________________________

Arrival Time in the Glaucoma Clinic ........................................

Departure Time from the Glaucoma Clinic .................................

Reason for Visit ..............................................................

OBJECTIVE MEASURES:

Best corrected visual acuity:  RE ...................... LE ......................

Intra Ocular Pressure:  RE ..................... LE ......................

Number of Medications:  RE ..................... LE ......................

Details of Medication:

RE ..................... LE ......................

1. Beta blocker
2. Alpha agonist
3. Pilocarpine
4. CAI
5. PG Analogues

Has the patient complied with the prescribed protocol since the last visit?

(Yes or No): ..............................

Optic Nerve Head Examination:  RE ...................... LE ......................

Other Ocular Co-morbidities:  RE ...................... LE ......................

1. Yes 2. No

If Yes, Please mention:  RE ...................... LE ......................

To be continued in the trial (Yes/No): ..............................

CONTROL VARIABLES:

Name and Affiliation of the Examining Doctor

..................................................
Unscheduled Visit-2

DATE: ____________

Arrival Time in the Glaucoma Clinic
Departure Time from the Glaucoma Clinic
Reason for Visit

OBJECTIVE MEASURES:
Best corrected visual acuity: RE ______________ LE ______________
Intra Ocular Pressure: RE ______________ LE ______________
Number of Medications: RE ______________ LE ______________
Details of Medication:
RE ______________ LE ______________

1. Beta blocker
2. Alpha agonist
3. Pilocarpine
4. CAI
5. PG Analogues

Has the patient complied with the prescribed protocol since the last visit?
(Yes or No): ______________

Optic Nerve Head Examination: RE ______________ LE ______________
Other Ocular Co-morbidities: RE ______________ LE ______________
1. Yes 2. No
If Yes, Please mention: RE ______________ LE ______________

To be continued in the trial (Yes/No): ______________

CONTROL VARIABLES:
Name and Affiliation of the Examining Doctor

__________________________________________
Unscheduled Visit-3

DATE: 

Arrival Time in the Glaucoma Clinic ……………………………

Departure Time from the Glaucoma Clinic ……………………………

Reason for Visit……………………………………

OBJECTIVE MEASURES:

Best corrected visual acuity: RE ………………… LE …………………

Intra Ocular Pressure: RE ………………… LE …………………

Number of Medications: RE ………………… LE …………………

Details of Medication:

   RE ………………… LE………………

    1. Beta blocker
    2. Alpha agonist
    3. Pilocarpine
    4. CAI
    5. PG Analogues

Has the patient complied with the prescribed protocol since the last visit?

(Yes or No): ………………………

Optic Nerve Head Examination: RE ………………… LE …………………

Other Ocular Co-morbidities: RE ………………… LE …………………

1. Yes 2. No

If Yes, Please mention: RE ………………… LE …………………

To be continued in the trial (Yes/No): ………………………

CONTROL VARIABLES:

Name and Affiliation of the Examining Doctor

……………………………………
Unscheduled Visit-4

DATE: 

Arrival Time in the Glaucoma Clinic ……………………………

Departure Time from the Glaucoma Clinic ……………………………

Reason for Visit………………………………………………

OBJECTIVE MEASURES:

Best corrected visual acuity:  RE …………………. LE ……………………..

Intra Ocular Pressure:  RE …………………. LE ……………………..

Number of Medications:  RE …………………. LE ……………………..

Details of Medication:

RE ………………… LE…………………

1. Beta blocker
2. Alpha agonist
3. Pilocarpine
4. CAI
5. PG Analogues

Has the patient complied with the prescribed protocol since the last visit?

(Yes or No): ……………………………

Optic Nerve Head Examination:  RE …………………. LE ……………………..

Other Ocular Co-morbidities:  RE …………………. LE ……………………..

1. Yes 2. No

If Yes, Please mention:  RE …………………. LE ……………………..

To be continued in the trial (Yes/No): ……………………………

CONTROL VARIABLES:

Name and Affiliation of the Examining Doctor

…………………………………………
Post-Trial Visit-1

DATE: 

Arrival Time in the Glaucoma Clinic ………………………………
Departure Time from the Glaucoma Clinic ………………………………

OBJECTIVE MEASURES:

Best corrected visual acuity:  RE  …………………..  LE  ……………………..
Intra Ocular Pressure:  RE  …………………..  LE  ……………………..
Number of Medications:  RE  …………………..  LE  ……………………..
Details of Medication:
RE  …………………..  LE  ……………………..

1. Beta blocker
2. Alpha agonist
3. Pilocarpine
4. CAI
5. PG Analogues

Has the patient complied with the prescribed protocol since the last visit?
(Yes or No): ………………………

Optic Nerve Head Examination:  RE  …………………..  LE  ……………………..
Other Ocular Co-morbidities:  RE  …………………..  LE  ……………………..
1. Yes 2. No
If Yes, Please mention:  RE  …………………..  LE  ……………………..

CONTROL VARIABLES:

Name and Affiliation of the Examining Doctor

……………………………………
Post-Trial Visit-2

DATE: ____________

Arrival Time in the Glaucoma Clinic

Departure Time from the Glaucoma Clinic

OBJECTIVE MEASURES:

Best corrected visual acuity: RE .................... LE ....................

Intra Ocular Pressure: RE .................... LE ....................

Number of Medications: RE .................... LE ....................

Details of Medication:

RE .................... LE ....................

1. Beta blocker
2. Alpha agonist
3. Pilocarpine
4. CAI
5. PG Analogues

Has the patient complied with the prescribed protocol since the last visit?

(Yes or No): .........................

Optic Nerve Head Examination: RE .................... LE ....................

Other Ocular Co-morbidities: RE .................... LE ....................

1. Yes 2. No

If Yes, Please mention: RE .................... LE ....................

CONTROL VARIABLES:

Name and Affiliation of the Examining Doctor

……………………………………
Post-Trial Visit-3

DATE: 

Arrival Time in the Glaucoma Clinic .................................

Departure Time from the Glaucoma Clinic ............................

OBJECTIVE MEASURES:

Best corrected visual acuity:  RE ......................... LE .........................

Intra Ocular Pressure:  RE ......................... LE .........................

Number of Medications:  RE ......................... LE .........................

Details of Medication:

RE ................. LE .........................

1. Beta blocker
2. Alpha agonist
3. Pilocarpine
4. CAI
5. PG Analogues

Has the patient complied with the prescribed protocol since the last visit?

(Yes or No): .................................

Optic Nerve Head Examination:  RE ......................... LE .........................

Other Ocular Co-morbidities:  RE ......................... LE .........................

1. Yes 2. No

If Yes, Please mention:  RE ......................... LE .........................

CONTROL VARIABLES:

Name and Affiliation of the Examining Doctor

.................................
Post-Trial Visit-4

DATE:                      

Arrival Time in the Glaucoma Clinic ..............................

Departure Time from the Glaucoma Clinic ............................

OBJECTIVE MEASURES:

Best corrected visual acuity:  RE .........................  LE .........................

Intra Ocular Pressure:  RE  .........................  LE .........................

Number of Medications:  RE  .........................  LE .........................

Details of Medication:

RE .........................  LE .........................

1. Beta blocker
2. Alpha agonist
3. Pilocarpine
4. CAI
5. PG Analogues

Has the patient complied with the prescribed protocol since the last visit?

(Yes or No):  .........................

Optic Nerve Head Examination:  RE .........................  LE .........................

Other Ocular Co-morbidities:  RE .........................  LE .........................

1. Yes 2. No

If Yes, Please mention:  RE .........................  LE .........................

CONTROL VARIABLES:

Name and Affiliation of the Examining Doctor

......................................................
GENERAL COMMENTS

Record any additional relevant information which can not be captured elsewhere in the casebook.

Was there any additional information?  NO  YES - If yes please specify below:

DATE: ........../ ............/ .....................
Details: ..............................................

Signature: ...........................................

DATE: ........../ ............/ .....................
Details: ..............................................

Signature: ...........................................

DATE: ........../ ............/ .....................
Details: ..............................................

Signature: ...............................................

...
Section 5 – Patient Information Sheet
PATIENT INFORMATION SHEET

Shared Medical Appointments Randomized Trial (SMART)

This study is conducted at Aravind Eye Hospital, Pondicherry by Dr. S. Kavitha, Glaucoma Consultant and Dr R. Venkatesh, Chief Medical Officer and Head of the Department of Glaucoma Services, in collaboration with Professor Kamilini Ramdas from London Business School and Ryan Buell from Harvard Business School.

You are being invited to take part in this screening study. Before you make a decision, it is important for you to understand why this screening is being done and what it will involve. Please do not hesitate to ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Glaucoma is the second most common cause of blindness and is an important cause of irreversible visual loss in India and the world. Glaucoma is a lifetime disease and taking appropriate medications and treatment, and following up regularly with a glaucoma specialist can slow its progression. The concept of Shared Medical Appointments (SMAs) has been introduced in leading hospitals in the US as a way to improve patient outcomes for lifetime diseases such as diabetes and cardiac disease. The aim of this study is to estimate the impact of using an SMA rather than a traditional one on one appointment during the final examination stage routine follow up appointments at the glaucoma clinic at the Aravind Eye Hospital, Pondicherry. The study will examine how SMAs impact patient outcomes, and also why the effect of SMAs may be different from that of traditional one on one appointments.

What is an Shared Medical Appointment(SMA)?

In an SMA, a patient meets the doctor for the final examination stage of a routine glaucoma follow up appointment in a group, with a target of four other glaucoma patients, rather than one on one. During the SMA, each patient in the group is
examined by the doctor one on one just as in a traditional appointment, while the other
patients in the group are watching and listening. After that there is time for question
and answer in the group.

Why have I been chosen?

We are asking you to take part in this study because you are a patient of Primary
Open Angle Glaucoma or Primary Angle Closure Glaucoma needing review follow-up
visits.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part
you will be given this information sheet to keep and be asked to sign a consent form.
If you decide to take part you are still free to withdraw at any time and without giving
reason. A decision to withdraw at any time or a decision not to take part, will not affect
the standard of care you receive.

What will happen to me if I take part?

If you take part in this screening, your demographic data like age, gender,
address, occupation, family history of glaucoma, previous treatment history and history
of previous ophthalmic check up will be obtained. Your medical history will be
recorded, which includes history of hypertension, cardiac, renal, gastrointestinal,
asthma and any other systemic illness along with their treatment history.

Both eyes will be examined for visual acuity, best corrected visual acuity
(BCVA), slit lamp bio microscopy of anterior segment, IOP with Goldmann
applanation tonometry, undilated fundus evaluation for optic disc assessment,
gonioscopy, dilated fundus examination and cases requiring Humphrey field analysis
(HFA) and Optical coherence tomography (OCT) will be done whenever it is ordered
by the glaucoma consultant. All these procedures are usually done during your normal
review visit.

Once you consent to take part in this trial, you will be included in a small group
of 4 other patients who have also consented to take part in this trial. Then your group
will be randomized to either one on one or shared medical appointment for your final examination. After the final examination you are requested to answer a questionnaire. This is to assess your understanding about glaucoma. Following this you will need to fix up an appointment for review with the study co-ordinator. If you consent to take part in the study you need to come for 3 additional visits, spaced approximately four months apart. That is, the study duration will be 1 year from your recruitment. The data described above, as well as data from your four most recent visits, as well as the four visits after the end of this study will be shared with the researchers to facilitate the analysis.

During each follow up visit you will undergo the same procedures as described above, and you will experience one on one or SMA final examination stages, depending upon the randomization during your enrolment. During your final visit you will be requested to complete an additional questionnaire to assess your perception of glaucoma care.

The final examination stage of each appointment will also be videotaped, which will be transcribed, and only the coded transcript of your appointments will be retained by researchers. To protect your confidentiality, your name and identity will not be made available to researchers, and after transcription, and a six-year waiting period to accommodate the research publication process, the videotapes will be destroyed.

**What are the benefits of taking part?**

We hope that all the investigation and examination will add to improvement in your care. Also, the information about SMAs, we get from this study may help us to treat future patients with this condition better.

**Will my taking part in this study be kept confidential?**

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you that leaves the hospital will have your name and address removed so that you cannot get recognized from it. The videotapes will also be transcribed from which your name and identity will be removed and only the transcribed text will be used by the researchers. Following transcription,
the videotapes will be destroyed. Until then it will be maintained by the study co-
ordinator and will not be made available to the researchers. Although researchers will
only receive de-identified data about you, other study participants who may be joining
you in a shared medical appointment will be able to identify you and receive
information about you during a specific session.

**What are all the risks involved in this study?**

The study does not pose any risk to the participants. At every step, measures are
taken to maintain the confidentiality. Except for the questionnaire, the tests you
undergo are part of your routine glaucoma care.

**Whom should I contact if I need more information or help?**

If you need any more information about the study you can contact Dr. S. Kavitha
at: Aravind Eye Hospital, Cuddalore Main Road, Thavalakuppam Pondicherry -
605007. Tel no. 0413 2619100. Additionally, if you have complaints you can report to
Institutional Ethics Committee, Aravind Eye Hospital, Thavalakuppam, Pondicherry
or you can mail to pdy.irb-office@pondy.aravind.org
Section 6 – Informed Consent Form
(English)
INFORMED CONSENT FORM

Subject identification number for this trial

________________________________________

Title of the Project:

Shared Medical Appointments Randomized Trial (SMART)

Name of the Principal Investigator:  Dr. S. Kavitha

Tel. No: 0413 2619100

I have received the information sheet on the above study and have read / or read to me, and understood the written information.

I have been given the chance to discuss the study and ask questions.

I consent to take part in the study and I am aware that my participation is voluntary.

I understand that I may withdraw at any time without this affecting my future care.

I understand that information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible persons (ethics Committee members / regulatory authorities). I give access to these individuals to have access to my records.

I understand that my final examination stage will be videotaped which will be transcribed and used by the investigators. I consent for the same.

I understand that my data will be shared with the researchers identified above from London Business School and Harvard Business School in a way that my identity will not be revealed. I consent for the same.

I understand I will receive a copy of the patient information sheet and the informed consent form.

______________________________
Printed name of the subject in capitals

___________________________________                               ____________
Signature / Thumb Impression of subject                                        Date
Signature of the Impartial witness

Name of the Impartial witness

Signature of the Investigator

Date

Name of the Investigator
Section 7 – Informed Consent Form
(Tamil)
சின்யாபாரின் கையற்ற படைம

பதினாறாவது பரிசுத்திகளத்துறை - சனவரியின்றி ஆப்பா

தாக்கு செய்யுடன் உண்டுகுள்ளது கையற்றகாலம் பரிசுத் திதியினர் கையற்ற தளம் பரிசுத் திதியினர் கையற்றகாலம் என்று. நோக் கையற்ற, கையற்ற பரிசுத் திதியினர் கையற்றகாலம் என்றும் அதைச் சொல்லும் கையற்ற பரிசுத் திதியினர் கையற்றகாலம் என்றும் அர்ப்பன தக்க பார்வையில் காணப்படுகின்றது.

தீவியானது தாக்கு செய்யோர் மாற்றாக அளவறுகின்றது. கையற்ற பரிசுத் திதியினர் அளவைச் செய்ய நோக்கில் தாக்கு செய்யோர் கையற்றகாலம் என்றும் அளவைச் செய்ய நோக்கில் தாக்கு செய்யோர் கையற்றகாலம் என்றும் அர்ப்பன நோக்கில் 

தாக்கு செய்யுடன் சின்யாபாரின் நோக்கில் காந்தியுடன் வாசகாலம் நோக்கில், காந்தியுடன் வாசகாலம் நோக்கில் வாசகாலம் நோக்கில் வாசகாலம் நோக்கில் வாசகாலம் நோக்கில் வாசகாலம் நோக்கில் வாசகாலம் நோக்கில் வாசகாலம் நோக்கில் வாசகாலம் நோக்கில் 

தாக்கு செய்யுடன் சின்யாபாரின் நோக்கில் காந்தியுடன் வாசகாலம் 

பக்தை முதலாம் பரிசுத்திகளத்துறைக் கையற்றம் காந்தம்

தாக்கு செய்யுடன் பரிசுத்திகளத்துறையினர் கையற்ற தளம் பரிசுத் 

தாக்கு செய்யுடன் பரிசுத்திகளத்துறையினர் கையற்ற தளம் 

தாக்கு செய்யுடன் பரிசுத்திகளத்துறையினர் கையற்ற தளம் 

தாக்கு செய்யுடன் பரிசுத்திகளத்துறையினர் கையற்ற தளம் 

தாக்கு செய்யுடன் பரிசுத்திகளத்துறையினர் கையற்ற தளம்
தமிழில்திட்டமல் இருள் விளக்கத்தில் விளக்கம் அனைத்துச் சீரடைக்கவும் விளக்கம். அனைத்தும் பிரிவுகள் பிள்ளை கொண்டு இருக்கும் கொண்டு விளக்கத்தில் விளக்கம் அனைத்தும் பிள்ளை கொண்டு விளக்கத்தில் விளக்கம்.

1. என்று அவர்கள் முன்னைக்கு அளிப்பதுக்கு விளக்கங்கள்?

குறு குறு தோன்ற வெள்ளை கொண்டு அருகே அப்படி கொண்டு கவலை அது நோக்கிய போற்றுதல் நோக்கிய போற்றுதல் வெள்ளை கொண்டு வெள்ளை கொண்டு விளக்கம் அனைத்தும் பிள்ளை கொண்டு விளக்கம்

2. என்று அவர்கள் பாதுகாப்பு விளக்கங்கள்?

இது அவர்கள் பாதுகாப்புகள் இரும்பிற்கு காட்சிகள் விளக்கம் நோக்கியது. இங்கு பாதுகாப்பு இரும்பிற்கு காட்சிகள் விளக்கம் நோக்கியது. இங்கு பாதுகாப்பு இப்படி விளக்கம் அனைத்தும் பிள்ளை கொண்டு விளக்கம்

3. என்று அவர்கள் பாதுகாப்பு விளக்கங்கள் வேறு வேறு விளக்கங்கள் வேறு வேறு விளக்கங்கள்?

இங்கு இங்கு அவர்கள் பாதுகாப்பு விளக்கங்கள் அடுக்குள் வேறு வேறு விளக்கங்கள் வேறு வேறு விளக்கங்கள் வேறு வேறு விளக்கங்கள்

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தற்போது புதிய அந்தக் குடியிருப்பதற்கு விளக்கப்பட்டது. அதன் பின்னர் இறுதியை மற்றும் இறுதியின் விளக்குமதியுடன் பார்வை இறக்கும் தொடர்புடையது. இதன் அப்படி வரவடை காலத்தில் தன்னுடைய ரீதியாக இருந்து, தன்னுடைய வலையமுறையாக செய்யும் பார்வை இறக்கும் விளக்கத்தின் விளக்கம் ஆகியவற்றுடன் ஒப்பிட்டு, அந்தக் குடியிருப்பதற்கு விளக்கப்பட்டது.

நேரடையாக முன்னேற்றவு இல்லை. முன்னேற்றத்தின் மூலமாக அல்லது பெருமளவு முன்னேற்றத்தில் இருந்து முன்னேற்றத்தின் விளக்கப்பட்டது. முன்னேறுவ முன்னேற்றத்தில் இருந்து பெருமளவு முன்னேற்றத்தின் விளக்கப்பட்டது. முன்னேறுவ முன்னேற்றத்தில் இருந்து பெருமளவு முன்னேற்றத்தின் விளக்கப்பட்டது. முன்னேறுவ முன்னேற்றத்தில் இருந்து பெருமளவு முன்னேற்றத்தின் விளக்கப்பட்டது.

அணுவில் பாதுகாப்பு போன்ற பாதுகாப்பின் மூலமாக அல்லது பெருமளவு பாதுகாப்பில் இருந்து பெருமளவு பாதுகாப்பின் விளக்கப்பட்டது. பெருமளவு பாதுகாப்பில் இருந்து பெருமளவு பாதுகாப்பின் விளக்கப்பட்டது.
நமது அம்மார்களின் நுழைவுக்காக அம்மார்கள் நல்லூரில் திறந்து கொண்டு நல்லூர் விளையாட்டுக்களின்றியும், நல்லூர் நடனத்தில் திறந்துவரும் நல்லூர் விளையாட்டுக்களின்றியும் பல்வேறு பிரிவைகளை விளக்க அளவாகக் குறிப்பிட்டு நல்லூர் விளையாட்டுக்களின் அம்மார்கள் நல்லூர் விளையாட்டுக்களின் பாதுகாப்பு செய்யப்படுகின்றது.

நல்லூர் விளையாட்டுக் கேம்பிரியா நல்லூர் விளையாட்டுக்களின் ஆர்வத்திற்கு நல்லூர் விளையாட்டுக்கள் நல்லூர் விளையாட்டுக்களை சாய்வுப் பகுதிகள் பார்வைகளின் பாதுகாப்பு செய்யப்பட்டுள்ளது.

நல்லூர் விளையாட்டுக் கேம்பிரியா நல்லூர் விளையாட்டுக்களின் ஆர்வத்திற்கு நல்லூர் விளையாட்டுக்களை சாய்வுப் பகுதிகள் பார்வைகளின் பாதுகாப்பு செய்யப்பட்டுள்ளது. inst.pdy.irb-office@pondy.aravind.org எல்லாம் அரசாங்க முறைப்படுத்தப்பட்டுள்ளது.
உபவு பொழுது

முன்னெச்சரிட்டி:

முன்னெச்சரிட்டியின் விளக்கம்:

பாரம்பரிய புரிவல புரிவல புரிவல புரிவல புரிவல புரிவல
முன்னெச்சரிட்டியின் விளக்கம்:

நேரான செயலில் வேலை மணக்கி வேலை மணக்கி வேலை மணக்கி வேலை

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சொன்னும் அமன் விளக்கம் சொன்னும் விளக்கம் சொன்னும் விளக்கம் சொன்னும் விளக்கம்

1. சொன்னும் அமன் விளக்கம் சொன்னும் விளக்கம் சொன்னும் விளக்கம் சொன்னும் விளக்கம் சொன்னும் விளக்கம்

சொன்னும் விளக்கம், முன்னெச்சரிட்டியின் விளக்கம் இருவருக்கும் இருவருக்கும் இருவருக்கும் இருவருக்கும்

சொன்னும் விளக்கம், முன்னெச்சரிட்டியின் விளக்கம் இருவருக்கும் இருவருக்கும் இருவருக்கும் இருவருக்கும்

சொன்னும் விளக்கம், முன்னெச்சரிட்டியின் விளக்கம் இருவருக்கும் இருவருக்கும் இருவருக்கும் இருவருக்கும்

சொன்னும் விளக்கம், முன்னெச்சரிட்டியின் விளக்கம் இருவருக்கும் இருவருக்கும் இருவருக்கும் இருவருக்கும்
திர்நாளில் கடம்பசு / திர்நாளில் கால்மூட்டி

திர்நாளில் எம்.ஆ

ஆம்பல் மாமில் கடம்பசு

ஆம்பல் மாமில் எம்.ஆ

சாத்கீர்கள் கடம்பசு

சாத்கீர்கள் எம்.ஆ