SynDA: Syncope Decision Aid for Emergency Care
PI: Marc A. Probst, MD
NCT02971163
Document Date: 05-01-2018

Mount Sinai	Protocol Title:	SynDA: Syncope Decision Aid for Emergency Care
	Principal Investigator Name/Contact Info:	Marc A. Probst, MD 212-824-8094 marc.probst@mssm.edu
	Primary Contact Name/Contact Info	Avis A Harper-Brooks 212-824-8080 avis.harperbrooks@mountsinai.org
	Date Revised:	5/1/2018
	Study Number:	Study ID: GCO#: 15-1016, IF#:1768978

MSSM Protocol Template HRP-503a

Instructions:

1. *Prepare a document with the following sections. Note that, depending on the nature of your research, certain sections below may not be applicable. Indicate N/A as appropriate, explaining where possible.*
2. *For any items described in the sponsor's protocol, grant application or other source documents submitted with the application, you may reference the title and page numbers of these documents rather than cutting and pasting into this document.* ***Do NOT refer to any derived documents, such as the Sample Consent document, or other internal documents required with the submission.***
3. *If you reference page numbers, attach those pages to this protocol.*
4. *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*

Brief Summary of Research (250-400 words):

Syncope, or transient loss of consciousness, is a common emergency department (ED) complaint responsible for over 1 million ED visits and $2.4 billion in hospital costs yearly(Sun, Emond et al. 2004, Sun, Emond et al. 2005). Presyncope is defined as the sudden onset of a sense of impending loss of consciousness, but without actual loss of consciousness. Potential causes of syncope/presyncope include benign conditions such as dehydration or vaso-vagal syncope. Rarely, syncope/presyncope is the result of serious cardiac conditions such as dysrhythmia or structural heart disease, but often no cause is found(Serrano, Hess et al. 2010). In older patients without a clear cause of syncope hospital admission is frequently initiated at very low risk thresholds(Manheimer, Pacio et al. 2014), though there is little evidence that these diagnostic admissions improve patient outcomes(Canzoniero, Afshar et al. 2015). These decisions are often made without significant patient input or discussion of reasonable alternatives. This clinical equipoise surrounding the disposition decision creates a situation in which a patient's values, preferences and particular circumstances should be taken into account. This mutualistic approach to clinical management is referred to as Shared Decision-Making. Shared Decision-Making (SDM) is a joint process of choice selection between providers and patients in clinical scenarios where multiple reasonable management options exist (Probst, Kanzaria et al. 2015). To improve syncope/presyncope emergency care, we can leverage recent advances in risk stratification to engage patients in SDM and deliver superior, patient-centered care.

Mount Sinai	Protocol Title:	SynDA: Syncope Decision Aid for Emergency Care
	Principal Investigator Name/Contact Info:	Marc A. Probst, MD 212-824-8094 marc.probst@mssm.edu
	Primary Contact Name/Contact Info	Avis A Harper-Brooks 212-824-8080 avis.harperbrooks@mountsinai.org
	Date Revised:	5/1/2018
	Study Number:	Study ID: GCO#: 15-1016, IF#:1768978

In this research project, we will conduct a randomized controlled feasibility trial of a patient Syncope Decision Aid (SynDA) use vs. usual care in patients 30 years or older who present to the Emergency Department with syncope or presyncope. SynDA is a paper-based, personalized decision aid which gives information to patients about their medical condition and options for care. It is written in lay language and aims to create an informed conversation between a patient and their ED provider. Only stable, asymptomatic patients with a normal evaluation, i.e. no serious diagnosis found in the ED, will be included. We plan to enroll 50 patients, 25 in each arm, over 24 months from the Mount Sinai Emergency Department and the Mount Sinai Beth Israel Emergency Department. Primary (feasibility) outcomes will include recruitment and follow-up rates. Secondary outcomes will include patient knowledge and satisfaction measured via survey immediately post-visit, as well as provider satisfaction. Data on clinical outcomes will also be collected including serious adverse events, admission rates, and downstream testing at 30 days.

This study will provide the groundwork for a larger, randomized controlled trial evaluating the effects of the decision aid for management of low-risk syncope/presyncope.

1) Objectives:

Research Question: *Is a randomized controlled trial (RCT) of our syncope decision aid (SynDA) feasible in stable, adult syncope and presyncope patients age 30 and over with a normal ED work-up?*

Hypothesis 1: *We will be able to recruit and enroll a sufficient number of patients as needed to calculate feasibility and follow-up rates of the use of SynDA. We hypothesize that we will be able to enroll at least 50 patients over a 24-month period.*

Hypothesis 2: *We predict that using this structured approach to SDM with the SynDA tool will be superior to usual care with regard to patient satisfaction and knowledge.*

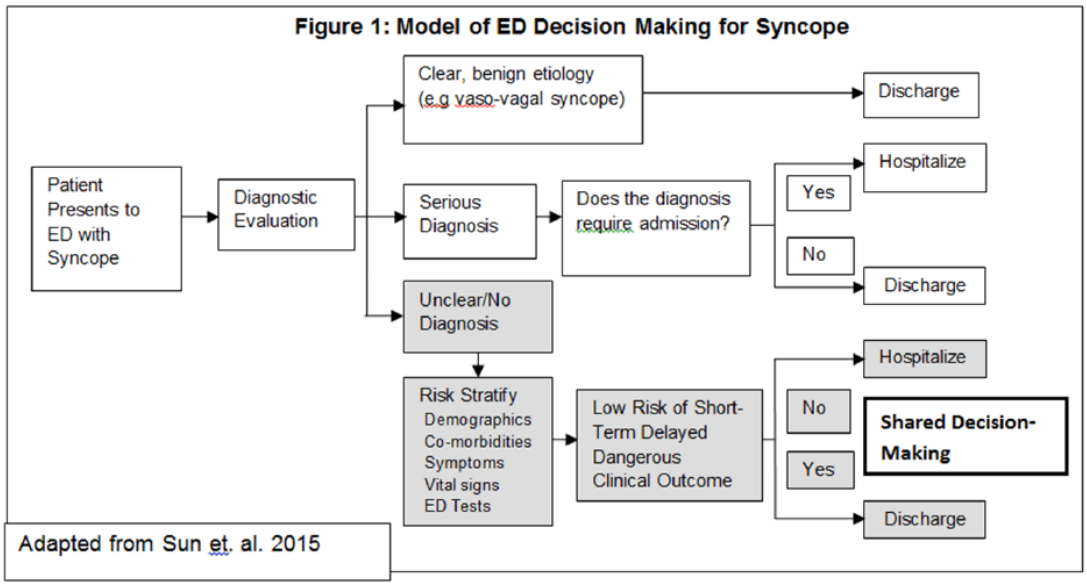
Objective: *To determine whether a randomized, controlled trial of SynDA use vs. usual care after a normal ED evaluation in adult syncope/presyncope patients (age >30) is feasible at the Mount Sinai Emergency Department.*

2) Background

Syncope is defined as a “transient loss of consciousness, associated with inability to maintain the postural tone and spontaneous recovery” (Sun, Costantino et al. 2014). Presyncope is defined as the sudden onset of a sense of impending loss of consciousness, but without actual loss of consciousness. They

are common and potentially serious complaints responsible for over 1 million Emergency Department (ED) visits per year in the United States (US) with roughly one third resulting in admission to the hospital (Probst, Kanzaria et al. 2015). National data from 2001 to 2010 demonstrate that the absolute number of

Figure 1: Model of ED Decision Making for Syncope



ED visits for syncope is on the rise (Probst, Kanzaria et al. 2015). These admissions account for over $2.4 billion in health facility costs per year[1]. While syncope/presyncope is most often benign and self-limited, its etiology can be difficult to discern. Potential causes include benign conditions such as dehydration or vaso-vagal syncope (i.e. triggered by emotional distress) as well as rare but potentially serious cardiac conditions such dysrhythmias or structural heart disease. The ED diagnostic evaluation typically consists of careful history-taking, physical exam, EKG, laboratory tests, and imaging if indicated. There are then three possible outcomes: 1) a clear, benign etiology is found (e.g. vasovagal syncope), 2) a dangerous diagnosis is revealed (e.g. third-degree heart block), or 3) no diagnosis is made [see above figure]. The initial evaluation of syncope only reveals a clear diagnosis 20-50% of the time (Blanc, L'Her et al. 2002). In this common third scenario where no diagnosis is made, a disposition decision must be made under conditions of uncertainty: was the syncope/presyncope a result of a serious but occult cardiac condition (e.g. dysrhythmia) or was it truly benign?

Current clinical practice guidelines and existing risk-stratification tools offer differing recommendations on admission criteria and in-patient admissions to exclude possible cardiac causes are often initiated at very low-risk thresholds

(Linzer, Yang et al. 1997, Linzer, Yang et al. 1997, Sun, Emond et al. 2004, Strickberger, Benson et al. 2006, Huff, Decker et al. 2007, Task Force for the, Management of et al. 2009). Clinicians are fearful of inappropriately discharging these patients lest they suffer a rare preventable adverse event. Admission rates ranged from 27% to 35% and showed an upward trend. The diagnostic yield of in-patient admission also remained steady; the most common International Classification of Diseases, 9th Revision (ICD-9) hospital discharge diagnosis remained "syncope and collapse" at 36% of all admitted patients.

Despite substantial efforts by researchers and professional societies, considerable inefficiencies remain in the acute care of syncope/presyncope patients. It is still unclear if syncope patients with a negative ED work-up benefit from subsequent in-patient admission (Crane 2002, Mendu, McAvay et al. 2009, Sun, Costantino et al. 2014, Canzoniero, Afshar et al. 2015). Diagnostic in-patient hospitalization can lead to iatrogenic harms, such as medication errors, delirium and nosocomial infections. A recent study of patients admitted for low-risk syncope found that in-patient admission may actually be harmful; 13% of patients experienced adverse events such as medication errors, delirium, and nosocomial infections.

Adults who present to the ED with syncope/presyncope often have no etiology uncovered during their visit and risk developing an adverse event through diagnostic in-patient admission. For this subgroup of patients, often both out-patient and in-patient management can be medically reasonable. Both pathways are associated with small and difficult to precisely quantify risk and benefits.

The clinical equipoise surrounding the disposition decision of patients who present to the ED with syncope/presyncope creates a situation in which the patient's values, preferences, and circumstances could be taken into account for their disposition decision (admit vs. discharge). Patient engagement can be broadly defined in the ED context as active patient involvement in their own healthcare to strengthen their influence on medical decisions and behaviors (Coulter 2011). This mutualistic approach to clinical management is referred to as Shared Decision-Making (SDM).

We believe that structured approach to SDM for syncope/presyncope patients using a paper-based, patient decision-aid containing personalized risk-stratification and information on medical options is safe and superior to usual care with regard to patient satisfaction and knowledge. Decision aids are evidenced-based tools designed to increase patient understanding of medical options and possible outcomes. They have been shown to increase patient knowledge and engagement in decision-making (O'Connor, Bennett et al. 2009). Our preliminary

work demonstrated that a majority of emergency physicians perceive that Shared Decision-Making is appropriate for the disposition of low-risk ED syncope patients (Kanzaria, Hoffman et al. 2015). Previous studies have shown that emergency physicians are, in general, amenable to the use of shared decision-making (Kanzaria, Brook et al. 2015).

Structured shared decision-making using a decision-aid has been successfully applied to the management of ED patients with low-risk chest pain (Hess, Knoedler et al. 2012). We propose a similar methodology but for syncope and presyncope patients. During the last year, we conducted semi-structured interviews with ED providers investigating the rationale behind their clinical management of low-risk ED syncope patients and their opinions on the use of SDM for this scenario.

Similarly, we conducted interviews with patients who had presented to the ED with syncope and had been discharged or sent to the observation unit. We asked them to what extent they wanted to be involved in the decision to be admitted and what information they felt was necessary to engage meaningfully in this process. Patients wanted to be more informed and involved, and preferred information be presented to them verbally from their physician or via short, simple text. Based on our findings, we developed SynDA, an ED-based decision aid to be used to facilitate SDM between patients and providers after a non-diagnostic ED visit for syncope (Appendix 1). This 11x14 inch, paper-based tool provides an easy-to-understand, 4-step process to engage patients in their disposition decision: 1) describe syncope and its potential causes, 2) explain the concept of downstream risk, 3) provide an individualized risk evaluation presented as a 100-man, color-coded pictogram, and 4) present options for further management. SynDA is now ready for pilot testing in this proposed trial.

We believe SynDA will be an appropriate tool to engage syncope/presyncope patients in SDM in the Mount Sinai Hospital Emergency Department/ Mount Sinai Beth Israel Emergency Department and it will increase patient satisfaction and knowledge. To test this hypothesis, we must perform an experimental trial. Using the final, refined version of SynDA, we will conduct a small scale, single-center RCT to assess the feasibility and necessary logistics of performing such a trial. Results of future trials of SynDA could positively impact the over 1 million patients who present to US EDs with syncope/presyncope every year.

3) Setting of the Human Research

Mount Sinai Hospital (MSH) is a 61-bed adult Emergency Department with a volume of over 100,000 patient visits/year or approximately 300 visits/day. MSH is a large academic tertiary care medical center located in East Harlem and serves a large black and Hispanic community.

4) Resources Available to Conduct the Human Research

Projected Recruitment: Based on internal data from 2014, there are 60 MSH ED visits for syncope per month of which 35 per month are by patients above age 40. Roughly half of these do not have a clear etiology of their syncope discovered in the ED. We project that of the 17 potentially eligible patients per month, three will be successfully enrolled for a projected 72 patient enrollees at the completion of our 24-month recruitment period. Assuming an attrition rate of 20%, the target sample size (50) will be reached within 24 months.

There are an estimated 30-40 ED visits for syncope per month at Mount Sinai Beth Israel Emergency Department. Similarly, about half of these do not have a clear etiology of their syncope discovered in the ED. We project that of the 8-9 potentially eligible patients per month, 1-2 will be successfully enrolled. This will augment our total enrollment to ensure that we reach our target sample size of 50 patients within 24 months.

Available Staff: The research staff for this study includes Dr. Marc Probst (Principal Investigator), Lauren Gordon (Project Manager). This research team has extensive experience conducting and completing both observational and interventional prospective research. SRAs staff the ED from 8 a.m. to 8 p.m. seven days per week at Mount Sinai Hospital Emergency Department. Clinical Research Coordinators are now working at Mount Sinai Beth Israel (MSBI) Emergency Department 5 days a week for 8 hours per day. The PI, clinical research coordinators, and SRAs will monitor the real-time electronic tracking system for all ED patients and will identify any patient over age 30 with a chief complaint of syncope/presyncope or loss of consciousness.

Resources: The research material obtained from the participants includes clinical data extracted from the electronic health record (EHR), contact information to obtain 30-day clinical follow-up, and the audio recording of the final discussion between the patient and the physician regarding admission vs. discharge. The contact information, survey data, and EHR data will be safely stored in an electronic database (REDCap) on the password-protected computers of the PI and clinical research coordinators.

The PI will meet with the clinical research coordinators (CRCs) on a weekly basis to ensure that enrollment is progressing as planned, that no protocol violations have occurred and to address any potential issues as they arise.

5) Study Design

a) Recruitment Methods

Participants will be recruited from the MSH/MSBI ED and will be identified by the PI or trained research associates (RA) from the Sinai Research Associate program. SRAs staff the MSH ED from 8 a.m. to 8 p.m. seven days per week and the MSBI ED 8 hours a day from Monday to Friday. All potential patients will be identified from the Emergency Department of Mount Sinai Hospital and Mount Sinai Beth Israel. Patients will NOT be recruited from the Mount Sinai Queens or Elmhurst Hospital EDs. The PI, CRCs, and SRAs will monitor the real-time electronic tracking system (EPIC) for all ED patients and will identify any patient over age 30 with a chief complaint of syncope/presyncope or loss of consciousness. A HIPAA Waiver is requested solely for the purpose of identifying eligible patients in the ED, i.e. pre-screening. If a SRA has identified a syncope/presyncope patient over age 30, he or she will alert a clinical research coordinator. The on-call CRC will screen the patient's ED visit chart for evidence of exclusion criteria and confirm if the patient had a syncopal episode according to the team's notes. Patients will be recruited solely from the ED and not from any other settings since the intervention (i.e. the SynDA tool) is designed and intended for use in the ED by ED clinicians to engage patients in ED medical decisions.

A total of $50 in cash payments will be offered to the patient as incentive. A $25 cash payment will be offered in person upon completion of the pre and post-encounter survey. An additional $25 cash payment will be mailed to the patient after 30-day follow-up information is obtained from them. The CRC will verify the patient's e-mail, mailing address and telephone number (with a real time call) at the time of enrollment to maximize the fidelity of follow-up.

b) Inclusion and Exclusion Criteria

Patient participants eligible for inclusion will be adults 30 years or older who present to the ED with a chief complaint of either loss of consciousness, syncope/presyncope, fall, or dizziness and who have a normal ED evaluation (i.e. no serious diagnosis was made in the ED).

They must have capacity to make medical decisions, be proficient in English and be deemed appropriate for either inpatient or outpatient management by the treating attending physician.

Other exclusion criteria include inability to read in English, major communication barrier, or lack of fixed address and telephone number.

The SynDA tool was developed based on input derived from interviews with English-speaking patients and English-speaking clinicians. The tool was then shown to English-speaking patients for iterative feedback and modification. Thus, even if translated into Spanish, the tool would not culturally be adapted for Hispanic/Latino patients. It may not adequately communicate information and concepts to Spanish-speakers. For this reason, we are currently excluding Spanish-speaking patients. However, if the results of this study are promising, our research team intends to culturally and linguistically adapt the SynDA tool for use with Spanish-speaking patients.

All ED treating clinicians (Attendings, residents, and PAs) will be eligible for inclusion for participation.

c) Number of Subjects

Based on internal data from 2014, there are 60 MSH ED visits for syncope per month, approximately 35 of which are for patients above age 40. Roughly half of these do not have a clear etiology of their syncope discovered in the ED. We project that of the 17 potentially eligible patients per month, three will be successfully enrolled for a projected 72 possible enrollees at the completion of our 24-month recruitment period. Assuming an attrition rate of 20%, the target sample size (50) will be reached within 24 months.

There are an estimated 30-40 ED visits for syncope per month at Mount Sinai Beth Israel Emergency Department. Similarly, about half of these do not have a clear etiology of their syncope discovered in the ED. We project that of the 8-9 potentially eligible patients per month, 1-2 will be successfully enrolled.

All MSH attending physicians, ED residents, and physician assistants (PAs) – approximately 140 ED treating clinicians – will be pre-consented and trained on the use of SynDA to facilitate SDM during a 1-hour training course prior to the start of the trial.

The MSBI attending physicians, ED residents not already trained and consented will be trained and consented in the same fashion as those at MSH. There are currently ED residents from MSH who are working clinically at MSBI.

d) Study Timelines

Duration of the participant actively engaging in SDM the study in the ED will last up to two hours from the time of consent. This includes randomization, pre-encounter survey, engaging in shared decision-making with the provider (audio recorded with prior consent, and post-encounter survey. Participants will be followed for 30 days post index visit and a medical record review will be conducted. The Clinical Research Coordinator (CRC) will review the Emergency Health Records of enrolled patients and hospital billing statements to determine the disposition of patient after the index ED encounter (discharge to home, admission to observation, admission to hospital) and any subsequent encounters that have occurred including repeat ED visits, hospitalizations, new diagnoses or procedures, and further diagnostic testing (e.g. cardiac stress testing, coronary CT angiography, echocardiography, neuroimaging, pulmonary CT angiography, etc.).

Approximately 30 days (up to 45 days) after the index ED visit, the CRC will contact the patient by phone or e-mail. If this is not successful after three attempts, the research coordinator will contact the patient using the secondary method of contact specified by the patient at the time of consent to arrange a telephone interview. During the follow-up telephone interview, the clinical research coordinator will inquire about major adverse cardiac events, hospital admissions, ED visits, physician office visits, and further testing since discharge within the 30 days of discharge from the ED. Attempts to contact patients will last up to 15 days after the 30-day post ED visit day or after ten attempts to contact the patient, whichever comes first. The follow-up interview will last approximately 15 minutes.

Data analysis will take approximately six months to complete starting from the enrollment of the last patient. Descriptive summaries for all demographic and clinical variables will be performed. Pre and post-encounter survey results will be tabulated and compared between the two arms of the trial. Outcomes with continuous distributions will be evaluated using independent samples t-tests while binary outcomes (e.g. admitted or not) will be assessed using logistic regression. We will follow an intention to treat protocol. Analyses will be conducted with the help of Dr. Winkel using SAS software (version 9.3; SAS Institute, Cary, NC).

We expect to reach our enrollment goal in 24 months and we plan on completing final analysis and submitting a manuscript for publication within one year after completing recruitment.

e) Study Endpoints

The primary outcome for the study is feasibility. Feasibility will be determined by calculating the proportion of eligible syncope/presyncope patients who are enrolled in the study. A de-identified record (e.g. a screening log) of the number of patients who were eligible but were excluded from the study for any reason will be maintained on a secure shared drive accessible by members of the research team.

Other parameters we will measure relevant to feasibility will be follow up rate (proportion of enrolled patients who are successfully contacted at 30 days) and proportion of patients deemed inappropriate for SDM by the ED team. Secondary outcomes will include the OPTION scale and the Informed Decision Making scale used to evaluate the quality of the decision making based on the audio recordings. The scale enables a viewer to quantify the extent to which clinicians involve patients in the decision making process. We will also measure differences in patient satisfaction, knowledge, and provider satisfaction with the tool.

We will compare the two study groups with respect to admission rate (hospital/observation unit vs discharge home), post-randomization diagnostic testing (e.g. exercise stress testing, echocardiography, computed tomography scans), repeat visits to the ED, and clinical outcomes at 30 days.

Clinical outcomes will include death from any cause, myocardial infarction, dysrhythmia, new diagnosis of clinically significant structural heart disease, pulmonary embolism, significant hemorrhage/anemia, aortic dissection, acute pulmonary edema, stroke, transient ischemic attack, or syncope-related surgery/medical procedure within 30-days.

f) Procedures Involved in the Human Research

Overall Study Design: A randomized, controlled, unblinded, feasibility trial of SynDA use versus usual care for clinically stable, adult ED syncope/presyncope patients. The ideal sample size will be 50 patients with an age-stratified 1:1 allocation to each arm. Participants will be followed for 30 days post index visit.

Detailed Study Procedure:

The PI, CRCs, and SRAs will monitor the real-time electronic tracking system (EPIC) for all ED patients and will identify any patient over age 30 with a chief complaint of syncope/presyncope, loss of consciousness, fall, or dizziness. These additional chief complaints are included because some patients with syncope/presyncope are initially triaged by the triage nurse as “dizziness” or “fall”. If a SRA has identified a potential patient, he or she will alert a clinical research coordinator. The on-call CRC will screen the patient’s ED visit chart for signs of any obvious exclusion criteria. Exclusion criteria the CRC can preliminarily identify through screening a potential patient’s chart include advanced dementia, psychosis, altered mental status, present intoxication, hemodynamic instability (e.g. low blood pressure, elevated pulse), elevated troponin level, or any documented serious diagnosis that was identified in the ED. Examples of serious diagnoses include but are not limited to clinically significant cardiac dysrhythmia, structural heart disease, gastrointestinal hemorrhage, myocardial infarction, pulmonary embolism, arterial dissection, serious infection, ectopic pregnancy, subarachnoid hemorrhage, or stroke. After ruling out all of the above, the CRC will calculate the Canadian Syncope Risk Score (CSR) of the potential patient using results from labs and EKGs, and also from speaking with the ED team. The CRC explicitly will confirm the interpretation of the lab results and the EKG with the physician or PA caring for the patient, as well as confirming the clinical variables. To calculate the CSR, he or she will use clinical data from our Electronic Health Record (EHR) to extract blood pressure, troponin results, and objective EKG parameters (variables 3, 6-9). The clinician judgment criteria of the risk score (variables 1, 2, 4 and 5) will be verified by the CRC using direct consultation with the attending physician, resident, or physician assistant. If the CSR is equal to or greater than 15.3%, the patient will be excluded from participating in the study.

If no exclusion criteria are present in the patient’s chart at the time of screening and the CSR is calculated to be less than 15.3% (i.e. total risk score below 5), the CRC will then inform the ED clinical team that the patient is eligible to participate in the study. If the ED team deems that the patient is potentially appropriate for SDM and is agreeable to engage in SDM with the patient, the PI or CRC will consent the patient into the study if he or she expresses interest in participating. All ED providers (residents, attending physician, and physician assistants) will have been pre-consented. The PI or clinical research coordinator will confirm with the treating ED team that the patient experienced a true

syncopal/presyncopal episode, no serious diagnosis has been made, and ask whether the patient is potentially appropriate for SDM. For patient participants, the CRC or PI will consent at beside after ED provider approval.

After consent, the PI or CRC will record the patient's contact information and complete a pre-encounter survey (Appendix 2). This pre-encounter survey contains 12 short questions and will assess demographics, preferences, numeracy, health literacy, education level, and income.

After completing the initial necessary documentation, the CRC will randomize the patient to the SynDA arm vs. usual care stratified by age (less than or greater than 60 years) to ensure a balance of geriatric patients in both groups. The age-stratified randomization process will involve sealed, opaque envelopes stored in a secure area of in the ED (i.e. the Clinical Research Office). Patients will only be randomized after their ED diagnostic evaluation is fully complete (not revealing a serious diagnosis) and the treating attending physician has deemed the patient is appropriate for shared decision making i.e. has medical decision-making capacity.

For those patients in the intervention arm (SynDA), the CRC will print the appropriate version of the SynDA based on the patient's individualized risk score and the corresponding estimated probability of a serious medical event within 30 days. If the calculated 30-day risk exceeds the comfort level of the attending physician, he or she will have the option to override the study protocol calling for SDM and unilaterally determine the disposition (e.g. admit to hospital).

If SDM is still deemed to be appropriate, the attending will perform SDM with the patient using the SynDA tool. The CRC will give a copy of the print out to the clinician to use at the bedside with the patient. All attending physicians, ED residents, and physician assistants (PAs) will be pre-consented and trained on the use of SynDA to facilitate SDM during a 1-hour training course prior to the start of the trial. The CRC will also review the contents of the decision aid in real time with the clinician before the disposition discussion.

For participants in the usual care arm, the ED clinical team will proceed with clinical management as per standard care for ED syncope/presyncope patients, without any study intervention. This may or may not include some form of shared decision making with the patient, depending on the

usual practice of the clinicians involved. However, the ED team will not use the SynDA tool in order to make their decision and the patient will not be shown the tool.

All participants will be offered the option of having the final disposition discussion audio recorded. If they consent to audio recording, the CRC will record these discussions using portable electronic device (e.g. a tablet computer) with the patient and provider's explicit consent. The audio recordings will be done in the patient's designated care area within the ED, where s/he has been receiving their care. This is where all disposition discussions occur during usual care. As well, if a family member or caregiver is present in the ED and would like to participate in the discussion with the patient and the physician, the will be given the option to consent (caregiver consent attached) to being audio-recorded. The recording device and all recordings will be securely managed. The purpose of the audio recording is to objectively assess how involved the patient was in the decision-making process. The audio recordings will be kept for 30 days after completion of the transcription and review by the PI and then will be deleted.

If the patient or the provider does not consent to the recording, patients will still be permitted to remain in the trial and participate in SDM with SynDA or usual care discussions with the treating team and complete the rest of the study. In the event that either participant does not consent to being audio recorded, the CRC will silently observe the interaction.

Recordings will be used to calculate the OPTION scale or the Informed Decision Making scale rating by independent observers at a later time. These validated scales are used to evaluate the degree of patient engagement.

All enrolled participants will complete a post-encounter survey (Appendix 3). This will occur after the disposition decision has been made, i.e. the decision to discharge home, admit to the observation unit, or admit to hospital. This survey will be administered to the patient by the CRC to assess the patient's perceptions about the amount, clarity and helpfulness of the information shared, their knowledge about syncope, their decisional conflict, and their satisfaction with the ED visit. ED providers (the resident, attending or PA) will also be asked to complete a survey (Appendix 4) assessing their perception of the decision-making process and the acceptability of the SynDA tool if in the SynDA arm. For encounters without the intervention, a shorter clinician survey will be

administered (Appendix 5). The post-visit surveys were adapted from a previous randomized trial of decision aid vs. usual care for low risk chest pain patients and have demonstrated construct validity (Hess, Knoedler et al. 2012).

All participants in the study will be contacted by phone or email at 30 days. A chart review of four Mount Sinai System EHRs (MSH, Mount Sinai Beth Israel, Mount Sinai Queens, Elmhurst Medical center) will be queried to determine downstream diagnostic testing and clinical events.

Approximately 30 days after the index ED visit, the CRC will contact patient participants by phone or e-mail. If this is not successful after three attempts, the research coordinator will contact the patient using the secondary method of contact specified by the patient at the time of consent to arrange a telephone interview. During the follow-up telephone interview, the clinical research coordinator will inquire about major adverse cardiac events, hospital admissions, ED visits, physician office visits, and further testing since discharge within the 30 days of discharge from the ED. Opening script and questions in the telephone follow-up at 30 days are described in Appendix 6. Attempts to contact patients will last up to 15 days after the 30-day post ED visit day or after ten attempts to contact the patient, whichever comes first. The follow-up interview will last approximately 15 minutes. Patient participants will be given a $25 cash payment after the completion of the surveys and an additional $25 cash payment if they provide follow-up information at 30 days. The New York State social security death index may be consulted for patients who were not reachable at 40 days.

g) Specimen Banking

N/A

h) Data Management and Confidentiality

Data will be collected by the CRCs using telephone/email follow-up and review of the EHR at four Mount Sinai Medical Centers (MSH, Mount Sinai Beth Israel, Mount Sinai Queens, and Elmhurst Medical Center). Electronic data collection forms using REDCap will be used to record data including patient demographics and clinical variables, pre- and post-encounter surveys and 30-day clinical outcomes. In the case of unclear clinical outcomes, a panel of two emergency physicians, blinded to the treatment arm will adjudicate. Identifiable data will be kept on a password protected database on a secure server. All data that are shared (i.e. with the

statistician, Dr. Winkel) will be de-identified; participants will be assigned a unique study ID number.

Analysis:

Basic descriptive summaries for baseline demographic and clinical variables will be conducted. Secondary outcomes with continuous distributions will be evaluated using independent samples t-tests while binary outcomes (e.g. admitted or not) will be assessed using Logistic Regression. While we anticipate no mean differences in the Canadian Syncope Risk Scores between the SynDA and the usual care groups at baseline, it is quite possible that these scores may influence the SDM outcomes. In an effort to increase the precision of the differences between the two groups, each patient's syncope score will be used a covariate in addition to the main effect of treatment group. All analyses will be run with two-sided tests and a significance level of 0.05. We will follow an intention to treat protocol. Analyses will be conducted with the help of Dr. Gary Winkel using SAS software (version 9.3; SAS Institute, Cary, NC).

Sample size considerations: Since the primary outcome of this trial relates to feasibility, the study is not powered to detect differences in clinical outcomes. Previous RCTs of ED decision aids (versus usual care) for chest pain have shown a 21% increase in patient satisfaction (61% vs 40%). This result is encouraging but we do not know what the effect size for the mean (or percentage) differences are for the SynDA and usual care arms(Sun, Costantino et al. 2014). An estimate of this would inform the sample size needed to achieve power >= 0.80 at alpha equal to 0.05 in a future study of ED syncope/presyncope patients. However, we believe that a sample of 50 patients divided into two arms equally will be sufficiently large to allow us to obtain a reliable estimate of the effect size which can be used to guide sample size considerations in a larger study of SynDA effectiveness.

i) Provisions to Monitor the Data to Ensure the Safety of Subjects

The intervention is a paper-based decision aid (SynDA) designed to improve patient-provider communication around syncope/presyncope risk and clinical management options. Therefore, the proposed research involves only activities that present minimal risk of harm to subjects. Clinical care will not be altered by this trial since clinicians will always provide the care they feel is appropriate for each syncope/presyncope patient. Possible risks include risks to privacy of individuals or

confidentiality of data, which includes demographic data, though accidental disclosure of participants' responses could not reasonably place the participants at risk of liability or damage to their financial standing, employability, or reputation. Nevertheless, appropriate protections against loss of confidentiality will be taken by study investigators and staff using standard data handling procedures. The likely effectiveness of these protections to avoid accidental disclosure of participant information is very high.

Part I: List the name(s) of the individual(s) at MSSM who will be responsible for data and safety monitoring of this study. For each individual, indicate their role, name, title, and department

MSSM Principal Monitor: **Dr. Lynne Richardson**
Indicate whether this person is the PI, a Team Member, or is Independent:
Supervisor and Team Member
Last Name: Richardson
First Name: Lynne
Academic Title: Full Professor, Vice Chair of Research
Department: Emergency Medicine
Mailing Address: 1 Gustave Levy Place Box 1620
Phone: (212) 824-8066
Fax: (212) 426-1946
E-mail: lynne.richardson@mountsinai.org

MSSM Additional Monitor: **Dr. Marc Probst**
Indicate whether this person is the PI, a Team Member, or is Independent: PI
Last Name: Probst
First Name: Marc
Academic Title: Assistant Professor
Department: Emergency Medicine
Mailing Address: [redacted]
New York, NY USA
10029
*Phone: (*212)-824-8094
*Fax: (*212)-426-1946
E-mail: marc.probst@mssm.edu

Part II:

Due to the minimal risk to participants, a formal Data and Safety Monitoring Board (DSMB) will be not convened for the feasibility trial. Dr. Probst (PI) will actively monitor the clinical data for any safety concerns on a weekly basis. The PI will be responsible for reporting adverse events to the IRB with all necessary information.

Although no serious adverse events are anticipated, all adverse events, regardless of relationship to the research, will be reported to the IRB within 24 hours, as per IRB policies, and will be listed in the annual IRB application for continuation or termination of the research.

All expected non-serious adverse events that occur at a greater frequency or severity than anticipated and all unexpected non-serious adverse events will be reported to the IRB within 15 working days and summarized annually to the IRB in the continuation or termination applications. Non-serious adverse events include unscheduled health care visit to the ED, urgent care, or out-patient clinic for benign reasons not related to syncope, not cardiopulmonary or neurological in possible etiology (e.g. mild rash, urinary symptoms, medication refill.)

Reports of adverse events will also be reviewed by the PI and the primary mentor (Dr. Richardson) at their biweekly meetings.

j) Withdrawal of Subjects

If at any time, a subject expresses verbal or nonverbal unwillingness to participate, the subject will be withdrawn from the study.

If new clinical information arises that causes the treating ED team to deem the patient too high risk for potential discharge home, then the patient will be withdrawn from the study for safety reasons. For example, if while the patient is on the cardiac monitor in the ED and demonstrates a serious cardiac arrhythmia, then the attending physician will tell the patient that they should be admitted to the hospital for medical treatment and thus cannot participate in shared decision-making with the option to go home.

The CRC and ED provider will explain the change in clinical course and the reason for the withdrawal from the trial to the patient. All medical questions will be answered by the ED provider

The CRC will record the specific clinical reason why the patient was withdrawn from the trial. These reasons will be collected alongside other exclusion criteria being met by patients. Already collected data will be analyzed to measure any differences between enrolled and excluded

patients to assess for selection bias. No further data collection will occur after a patient has been withdrawn from the trial.

6) Risks to Subjects

The intervention is a paper-based decision aid (SynDA) designed to improve patient-doctor communication around syncope risk and management options. Therefore, the proposed research involves only activities that present minimal risk of harm to subjects. There may be non-serious psychological risks to the physicians who may appear to be uninformed about syncope or recent research in this area in front of the patient who may ask questions, however, there is a low likelihood of this occurring. There may be mild psychological risks to the patients who may be caused anxiety from learning about potential causes of syncope/presyncope and their 30-day risk of serious medical events. This anxiety will be mitigated by the provider who will emphasize that these risks are population-level estimates. Despite the possible anxiety caused, it is ethical to share information with patients about the probability of adverse events. Additional risks include risks to privacy of individuals or confidentiality of data, which includes demographic data, though accidental disclosure of participants' responses could not reasonably place the participants at risk of liability or damage to their financial standing, employability, or reputation. There are no physical, legal, or financial risks to subjects. Nevertheless, appropriate protections against loss of confidentiality will be taken by study investigators and staff using standard data handling procedures. The likely effectiveness of these protections to avoid accidental disclosure of participant information is very high.

7) Provisions for Research Related Injury

We do not expect any research related injuries since the intervention is a piece of paper (SynDA) with information for the patient and provider to discuss. This tool is designed to facilitate conversation between the patient and the ED provider.

8) Potential Benefits to Subjects

Patients and clinicians may benefit psychologically from knowing that they have helped advance medical science. Clinicians (residents, attending

physicians, PAs) will not be reimbursed. Other future patients presenting to the ED with syncope could potentially benefit from the results of this research.

9) Provisions to Protect the Privacy Interests of Subjects

There is potential risk to privacy of individuals or confidentiality of data, which does include demographic data, though accidental disclosure of participants' responses could not reasonably place the participants at risk of liability or damage to their financial standing, employability, or reputation. Nevertheless, appropriate protections against loss of confidentiality will be taken using standard data handling procedures (unique study ID, password-protected computers, de-identifying data prior to analysis) as has been done with other clinical trials at the MSH ED. The likely effectiveness of these protections to avoid accidental disclosure of participant information is very high.

10) Economic Impact on Subjects

None, since the study coincides with the patients' ED visit. All tests that are performed will be as part of the patient's ED work-up determined by the attending and clinical team.

11) Payment to Subjects

Participants will receive a [redacted] after successful completion of the post-encounter survey. Another [redacted] will be mailed to the participant's provided address upon completion of the telephone interview 30 days after enrollment.

12) Consent Process

To consent obtain written consent, the PI or CRC will approach eligible patients in the bed area of the ED once all diagnostic testing is complete and the ED attending physician has deemed the patient clinically appropriate for the study. If the patient expresses interest in participating in the study, the PI or CRC will provide additional information about the study as stated in the consent form and only after that is complete will the patient sign the form. It will be made clear to the patient that refusing to enroll in the study will in NO WAY alter their clinical care. Patients will have the opportunity to ask questions about the study before signing the consent form.

All ED residents, attending physicians and PAs will be consented prior to the start of the trial. For new hires in the department which occur after the commencement of the trial, the PI will consent the providers as soon as feasible.

Since children, cognitively impaired adults, and non-English speaking subjects meet exclusion criteria for this study, they will not be consented nor will be participants of this study. We will also exclude vulnerable populations from this study, as stated in section 14 of the protocol.

13) Process to Document Consent in Writing

Plans for the recruitment of subjects and the process for obtaining informed consent for participation are described in the section above. Written informed consent will be obtained from each participant as approved by the Mount Sinai Hospital IRB. All ED attending physicians, residents and PAs will be pre-consented (by written informed consent) during the 1-hour training session on shared decision-making and SynDA use. All completed written consent forms will be collected by the CRCs and kept in a secure location at Mount Sinai.

14) Vulnerable Populations

Include	*Exclude*	*Vulnerable Population Type*
	X	*Adults unable to consent*
	X	*Individuals who are not yet adults (e.g. infants, children, teenagers)*
	X	*Wards of the State (e.g. foster children)*
	X	*Pregnant women*
	X	*Prisoners*

15) Multi-Site Human Research (Coordinating Center)

N/A

16) Community-Based Participatory Research

N/A

17) Sharing of Results with Subjects

N/A

18) External IRB Review History

N/A

19) Control of Drugs, Biologics, or Devices

N/A

References

Blanc, J. J., C. L'Her, A. Touiza, B. Garo, E. L'Her and J. Mansourati (2002). "Prospective evaluation and outcome of patients admitted for syncope over a 1 year period." Eur Heart J **23**(10): 815-820.

Canzoniero, J. V., E. Afshar, H. Hedian, C. Koch and D. J. Morgan (2015). "Unnecessary hospitalization and related harm for patients with low-risk syncope." JAMA Intern Med **175**(6): 1065-1067.

Coulter, A. (2011). Engaging Patients in Healthcare. Maidenhead, McGraw Hill/Open University Press;.

Crane, S. D. (2002). "Risk stratification of patients with syncope in an accident and emergency department." Emerg Med J **19**(1): 23-27.

Hess, E. P., M. A. Knoedler, N. D. Shah, J. A. Kline, M. Breslin, M. E. Branda, L. J. Pencille, B. R. Asplin, D. M. Nestler, A. T. Sadosty, I. G. Stiell, H. H. Ting and V. M. Montori (2012). "The chest pain choice decision aid: a randomized trial." Circ Cardiovasc Qual Outcomes **5**(3): 251-259.

Huff, J. S., W. W. Decker, J. V. Quinn, A. D. Perron, A. M. Napoli, S. Peeters, A. S. Jagoda and P. American College of Emergency (2007). "Clinical policy: critical issues in the evaluation and management of adult patients presenting to the emergency department with syncope." Ann Emerg Med **49**(4): 431-444.

Kanzaria, H. K., R. H. Brook, M. A. Probst, D. Harris, S. H. Berry and J. R. Hoffman (2015). "Emergency physician perceptions of shared decision-making." Acad Emerg Med **22**(4): 399-405.

Kanzaria, H. K., J. R. Hoffman, M. A. Probst, J. P. Caloyeras, S. H. Berry and R. H. Brook (2015). "Emergency physician perceptions of medically unnecessary advanced diagnostic imaging." Acad Emerg Med **22**(4): 390-398.

Linzer, M., E. H. Yang, N. A. Estes, 3rd, P. Wang, V. R. Vorperian and W. N. Kapoor (1997). "Diagnosing syncope. Part 1: Value of history, physical examination, and electrocardiography. Clinical Efficacy Assessment Project of the American College of Physicians." Ann Intern Med **126**(12): 989-996.

Linzer, M., E. H. Yang, N. A. Estes, 3rd, P. Wang, V. R. Vorperian and W. N. Kapoor (1997). "Diagnosing syncope. Part 2: Unexplained syncope. Clinical Efficacy Assessment Project of the American College of Physicians." Ann Intern Med **127**(1): 76-86.

Manheimer, E. D., G. Pacio and K. J. Ferrick (2014). "Limited yield of hospitalization for the evaluation of syncope in patients presenting to an urban tertiary medical center." Am J Emerg Med **32**(9): 1113-1116.

Mendu, M. L., G. McAvay, R. Lampert, J. Stoehr and M. E. Tinetti (2009). "Yield of diagnostic tests in evaluating syncopal episodes in older patients." Arch Intern Med **169**(14): 1299-1305.

O'Connor, A. M., C. L. Bennett, D. Stacey, M. Barry, N. F. Col, K. B. Eden, V. A. Entwistle, V. Fiset, M. Holmes-Rovner, S. Khangura, H. Llewellyn-Thomas and D. Rovner (2009). "Decision aids for people facing health treatment or screening decisions." Cochrane Database Syst Rev(3): CD001431.

Probst, M. A., H. K. Kanzaria, M. Gbedemah, L. D. Richardson and B. C. Sun (2015). "National trends in resource utilization associated with ED visits for syncope." Am J Emerg Med **33**(8): 998-1001.

Serrano, L. A., E. P. Hess, M. F. Bellolio, M. H. Murad, V. M. Montori, P. J. Erwin and W. W. Decker (2010). "Accuracy and quality of clinical decision rules for syncope in the emergency department: a systematic review and meta-analysis." Ann Emerg Med **56**(4): 362-373 e361.

Strickberger, S. A., D. W. Benson, I. Biaggioni, D. J. Callans, M. I. Cohen, K. A. Ellenbogen, A. E. Epstein, P. Friedman, J. Goldberger, P. A. Heidenreich, G. J. Klein, B. P. Knight, C. A. Morillo, R. J. Myerburg, C. A. Sila, C. N. C. D. i. t. Y. American Heart Association Councils on Clinical Cardiology, Stroke, C. Quality of, G. Outcomes Research Interdisciplinary Working, F. American College of Cardiology, S. Heart Rhythm and S. American Autonomic (2006). "AHA/ACCF Scientific Statement on the evaluation of syncope: from the American Heart Association Councils on Clinical Cardiology, Cardiovascular Nursing, Cardiovascular Disease in the Young, and Stroke, and the Quality of Care and Outcomes Research Interdisciplinary Working Group; and the American College of Cardiology Foundation: in collaboration with the Heart Rhythm Society: endorsed by the American Autonomic Society." Circulation **113**(2): 316-327.

Sun, B. C., G. Costantino, F. Barbic, I. Bossi, G. Casazza, F. Dipaola, D. McDermott, J. Quinn, M. Reed, R. S. Sheldon, M. Solbiati, V. Thiruganasambandamoorthy, A. D. Krahn, D. Beach, N. Bodemer, M. Brignole, I. Casagranda, P. Duca, G. Falavigna, R. Ippoliti, N. Montano, B. Olshansky, S. R. Raj, M. H. Ruwald, W. K. Shen, I. Stiell, A. Ungar, J. G. van Dijk, N. van Dijk, W. Wieling and R. Furlan (2014). "Priorities for emergency department syncope research." Ann Emerg Med **64**(6): 649-655 e642.

Sun, B. C., J. A. Emond and C. A. Camargo, Jr. (2004). "Characteristics and admission patterns of patients presenting with syncope to U.S. emergency departments, 1992-2000." Acad Emerg Med **11**(10): 1029-1034.

Sun, B. C., J. A. Emond and C. A. Camargo, Jr. (2005). "Direct medical costs of syncope-related hospitalizations in the United States." Am J Cardiol **95**(5): 668-671.

Task Force for the, D., S. Management of, C. European Society of, A. European Heart Rhythm, A. Heart Failure, S. Heart Rhythm, A. Moya, R. Sutton, F. Ammirati, J. J. Blanc, M. Brignole, J. B. Dahm, J. C. Deharo, J. Gajek, K. Gjesdal, A. Krahn, M. Massin, M. Pepi, T. Pezawas, R. Ruiz Granell, F. Sarasin, A. Ungar, J. G. van Dijk, E. P. Walma and W. Wieling (2009). "Guidelines for the diagnosis and management of syncope (version 2009)." Eur Heart J **30**(21): 2631-2671.