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IRB Proposal
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ED Discharge Strategy to Minimize Recurrent Falls Amount Elders

A. Study Purpose and Rationale

Falls among elderly (patients at least 65y of age) is a public health concern. They account for 7.5% of all EMT calls and 20% of all ED presentations in by elderly individuals America. More than 40% of the elderly population falls at least once in any given year. This at-risk elderly population will be increasing in size as the baby-boomers continue to age. Falls can decrease quality of life and level of functioning among elderly. As such, they can hasten the transition of elderly individuals out of independent living. The high prevalence of falls should motivate researchers to establish efficient and effective uses of existing health care resources to treat and prevent falls. This study is designed to assess the benefit of an intervention to minimize recurrent falls among the elderly who are discharged from the ED after a fall. The intervention is to incorporate the following into discharge paperwork: information on strategies to lower risk of falls based on individual risk factor assessments.

B. Study Design and Statistical Analysis

This is a single-blinded, randomized-controlled clinical trial to investigate a potential intervention to reduce falls among the elderly over a 1yr follow-up period. The subjects are randomly assigned to either intervention or control group at time of discharge. The

administrative assistant will provide a sealed envelope the subjects can open one week after ED discharge. It will include a second copy of discharge instructions for all subjects and individualized information on fall prevention for subjects in the intervention group. There is no cross-over between the groups.

The randomization process is intended to control for potential differences in the study groups at baseline. In addition to common demographic information, a standardized measure of fragility will be recorder at baseline. This composite score can be considered an estimated correlate of fall risk. If randomization does not accomplish this task, the analysis will control for potential confounders. An intention-to-treat approach will be used to analyze the data irrespective of implementation of fall prevention strategies within each study group. This approach may bias the results in terms of effect of intervention on an individual person, but ti may be more reflective of a potential effect of intervention at population level as patience compliance is rarely 100% in practice.

The primary outcome of two proportions for comparison can be obtained through a chi-square test. A total of 500 subjects will be recruited for each study group. That sample size is powered at 80% to detect a 33% reduction in proportion of subjects who fall during first year after ED presentation. It sets alpha 5% and allows for 10% drop out. The estimates needed to calculate that sample size are based on previous studies and include an expected 60% of control subjects to fall during follow-up.

C. Study Procedure: NA

D. Study Drugs: NA

E. Medical Device: NA

F. Study Questionnaires

Physiotherapists on research team will use a questionnaire to assess subjects individual fall risk factors, which include physical fitness (balance, strength, vision), home environment safety, and current medications. Subjects will be asked to complete a questionnaire at end of study to inform research team of their implementation of fall prevention strategies and if they visited outside hospital for fall(s) or activated non-local EMT services. The questionnaires are still being designed and will be submitted for IRB approval at a later date.

G. Study Subjects

- Inclusion criteria
    - Age $\geq$65y
        - Intervention is targeted at outcome specific to this vulnerable population
    - Present to Columbia-New York Presbyterian for fall and are not admitted
    - Primary medical doctor approves participation
- Exclusion criteria
    - Cannot ambulate independently
        - Devices subjects can use on their own (ie walkers, canes) are

permitted but reliance on another person, wheelchairs or motorized equipment is not permitted

H. Recruitment of Subjects

Potential subjects will be identified by an automated program that registers "fall" as chief complaint for ED visit. That pool will be filtered further by Columbia-NYP house staff who determine if patients are admitted to the hospital. All patients not admitted to the hospital will be informed about the study. If they are interesting in participating a screening interview will occur before subjects are asked to consent to study. If consent is obtained, subject will enroll immediately and the primary medical doctor will be contacted. Given the nature of the study's research question, enrollment cannot be delayed until after primary medical doctor approves of subject's participation. Instead, there is a one-week period before ED discharge and when patients are instructed to read second materials provided at discharge as part of study for the research team to obtain that approval. If attempts to do so are unsuccessful, the research team informs subject that they are ineligible.

I. Confidentiality of Study Data

Data from study will be maintained on an encrypted file in a secure office accessible only to the investigators. Patient identifies will be used instead of names.

J. Potential Conflict of Interest

I have no known conflict of interest.

K. Location of the Study

This study is to be conducted in Columbia-New York Presbyterian Hospital. Subjects will be undergo risk assessment by physiotherapists on the research team in ED (or other clinical area depending on space limitations). The Chairman of Emergency Medicine has given his approval for this study.

L. Potential Risks

Potential risk and discomforts to the subject are minimal. It is possible that the risk assessment might alert patient to issues they deems unpleasant, such as the layout of their apartment being considered an unsafe home environment. It is also possible that patients may not tolerate medication changes to lower fall risk, but that reversible complication will be monitored by subjects' primary medical doctor.

M. Potential Benefits

All subjects may benefit from the experience of having a fall risk assessment by a physiotherapist to the extent that they are made aware of their individualized risk factors. As such, it is possible that the control group is dissimilar to current standard of care in ED, which does not involve a fall risk assessment. Subjects in the intervention arm may benefit from the information on strategies to lower fall risk provided at discharge. It is possible that the intervention is not superior to current standards of ED discharge for patients with falls, and the subjects could have no individual benefit. Still, they are providing valuable information to a society reconfiguring its health care system.

N. Alternative Therapies

No comparable alternative to proposed intervention is available to subjects, to the knowledge of research team.

O. Compensation to Subjects

Subjects will be compensated $52, one for each week of study at end of 1-yr follow-up period.

P. Costs to Subjects

Subjects will incur any additional costs as a result of participating in the study. It is possible, however, that there will be costs associated with implementing strategies to lower fall risk, such as purchasing balance boards to improve physical fitness. Whenever possible, subjects will be given prescriptions for such items to subsidize costs through health insurance.

Q. Minors as Research Subjects: NA

R. Radiation or Radioactive Substances: NA

S. References

- Mikolaizak et al. "Intervention to prevent further falls in older people who call an ambulance as a result of a fall: a protocol for the iPREFER randomized controlled

trial.” BMC Health Services Research 2013, 13:360

- Logan PA, Coupland CA, Gladman JR, Sahota O, Stoner-Hobbs V, Robertson K, Tomlinson V, Ward M, Sach T, Avery AJ: Community falls prevention for people who call an emergency ambulance after a fall: randomized controlled trial. BMJ 2010, 340:c2102.