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Injurious Falls and Syncope in Older Community-Dwelling Adults Meeting Inclusion Criteria for SPRINT

The Systolic Blood Pressure Intervention Trial (SPRINT) demonstrated that treating adults 75 years of age or older with hypertension to reach a systolic blood pressure target of less than 120 mm Hg compared with a systolic blood pressure target of less than 140 mm Hg reduced the numbers of cardiovascular events and death without a significant increase in the number of injurious falls or syncope.[1] However, prior to the adoption of an intensive strategy to lower systolic blood pressure in the oldest segment of the population, it is prudent to determine if individuals meeting inclusion criteria for SPRINT outside the clinical trial context are similar to trial participants, especially with regard to risk for adverse outcomes. We used The Irish Longitudinal Study on Ageing[2,3] (TILDA) to compare baseline rates of injurious falls and syncope in community-dwelling older adults with the rates in the standard care group of SPRINT.

Methods | The Irish Longitudinal Study on Ageing is a nationally representative prospective cohort study of community-dwelling adults 50 years of age or older in the Republic of Ireland.[2,3] Random sampling of geographical clusters was used to select households. Data collection involved an in-home interview, a self-completed questionnaire (N = 8175), and a comprehensive health assessment (N = 5751). Mean follow-up for TILDA was 3.4 years, compared with a median of 3.4 years in SPRINT. Our study used data from wave 1 of TILDA (completed July 31, 2011) to retrospectively identify participants meeting final inclusion criteria for SPRINT. Outcomes were then reported at wave 2 (February 1, 2012-March 31, 2013) and wave 3 (March 1, 2014-December 31, 2015) follow-up. Ethical approval for TILDA was obtained from the Faculty of Health Sciences Research Ethics Committee at Trinity College Dublin. All participants provided written informed consent.

We used the SPRINT eligibility criteria to identify TILDA participants who would be eligible for the trial.[1,4]; all SPRINT eligibility parameters apart from degree of proteinuria were available for TILDA participants. Falls and syncope were assessed either by self-report or proxy at each wave. Participants were asked if they had fallen since their last interview and, if so, if they injured themselves seriously enough to need medical treatment. These questions were repeated for syncope. All analyses were performed using R statistical software (R Foundation for Statistical Computing) and Stata, version 14.1 (StataCorp), incorporating inverse probability weighting to account for complex survey designs. $P < .05$ was considered significant.

Results | The **Table**[5] displays a comparison of characteristics between TILDA participants meeting inclusion criteria for the subgroup of SPRINT participants who were 75 years of age or older and those of participants in the standard care arm of SPRINT.[1] All 407 participants in TILDA were white, as opposed to participants in SPRINT (987 of 1319 [74.8%]). Orthostatic hypotension at baseline was more common in TILDA participants than SPRINT (50 of 407 [12.3%] vs 124 of 1319 [9.4%]).[2,3] History of cardiovascular disease (309 of 1319 [23.4%] vs 72 of 407 [17.7%]), as well as rates of aspirin (765 of 1319 [58.0%] vs 160 of 407 [39.3%]) and statin use (697 of 1319 [52.8%] vs 159 of 407 [39.1%]), were higher in SPRINT participants, suggesting a higher cardiovascular risk profile. While the 407 TILDA participants were undergoing standard care in the community for a similar duration of follow-up, 111 (27.3%) reported an injurious fall and 54 (13.3%) reported syncope. In SPRINT, 73 of 1319 participants (5.5%) reported injurious falls and 32 of 1319 (2.4%) reported syncope (**Figure**).

Discussion | In a community-based prospective cohort with contemporaneous follow-up of comparable duration (TILDA), participants 75 years of age or older who met inclusion criteria for SPRINT had rates of injurious falls and syncope approximately 5-fold higher than the standard care group in SPRINT. Given the high baseline rates of falls and syncope, any increase in these rates due to intensive treatment of hypertension could result in harm.

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Table. Characteristics of Community-Dwelling TILDA Participants Meeting SPRINT Inclusion Criteria vs SPRINT Participants

Characteristic	TILDA Participants Aged ≥75 y Meeting Inclusion Criteria for SPRINT (N = 407)	SPRINT Participants Aged ≥75 y (N = 1319)
Female sex, No. (%)	239 (58.7)	501 (38.0)
Age, mean (SD), y	80.1 (6.1)	79.9 (4.1)
Race/ethnicity, No. (%)		
White	100	987 (74.8)
Black or African American	0	226 (17.1)
Hispanic	0	85 (6.4)
Other	0	21 (1.6)
Seated blood pressure, mean (SD), mm Hg		
Systolic	148.1 (14.1)	141.6 (15.8)
Diastolic	82.0 (10.1)	70.9 (11.0)
Orthostatic hypotension, No. (%)[a]		
No	357 (87.7)	1195 (90.6)
Yes	50 (12.3)	124 (9.4)
Serum creatinine, median (IQR), mg/dL[b]	0.94 (0.81-1.12)	1.1(0.9-1.3)
Estimated GFR, mean (SD), mL/min/1.73 m^2[c]	65.1 (19.9)	63.3 (18.3)
History of cardiovascular disease, No. (%)		
No	335 (82.3)	1010 (76.6)
Yes	72 (17.7)	309 (23.4)
Statin use, No. (%)		
No	248 (60.9)	622 (47.2)
Yes	159 (39.1)	697 (52.8)
Aspirin use, No. (%)		
No	247 (60.7)	554 (42.0)
Yes	160 (39.3)	765 (58.0)
Total cholesterol, mean (SD), mg/dL[d]	185.3 (38.6)	181.8 (38.7)
Triglycerides, mean (SD), mg/dL[d]	137.2 (84.0)	99.0 (72.0-134.5)[e]
HDL cholesterol, mean (SD), mg/dL[d]	59.5 (17.4)	55.7 (14.9)
Body mass index, mean (SD)[f]	28.0 (5.0)	27.7 (4.6)
Gait speed, median (IQR), m/s[g,h]	1.17 (1.05-1.32)	0.92 (0.77-1.06)
>0.8 m/s, No. (%)	389 (95.5)	950 (72.0)
<0.8 m/s, No. (%)	18 (4.5)	369 (28.0)
Frailty, No. (%)[i]		
Not frail (TILDA) or fit (SPRINT)	147 (36.1)	190 (14.4)
Prefrail (TILDA) or less fit (SPRINT)	221 (54.3)	745 (56.5)
Frail	39 (9.6)	375 (28.4)

Abbreviations: GFR, glomerular filtration rate; HDL, high-density lipoprotein; IQR, interquartile range; SPRINT, Systolic Blood Pressure Intervention Trial; TILDA, The Irish Longitudinal Study on Ageing.

SI conversion factors: To convert creatinine to micromoles per liter, multiply by 88.4; to convert total and HDL cholesterol to millimoles per liter, multiply by 0.0259; and to convert triglycerides to millimoles per liter, multiply by 0.0113.

[a] Criterion for orthostatic hypotension was a decrease in systolic blood pressure of 20 mm Hg or more or a decrease in diastolic blood pressure of 10 mm Hg or more after standing.

[b] A total of 55 participants were missing data.

[c] Estimated using Modification of Diet in Renal Disease.

[d] A total of 30 participants were missing data.

[e] Reported as median (IQR).

[f] Calculated as weight in kilograms divided by height in meters squared.

[g] A total of 160 participants were missing data.

[h] In TILDA, gait speed was measured using GAITRite portable electronic walkway system (CIR Systems Inc). Participants were instructed to walk at their usual pace along a 4.88-m walkway. They started walking 2.5 m before the walkway to allow for acceleration and finished walking 2 m after the walkway to allow for deceleration. The mean gait speed from 2 walks was recorded in units of centimeters per second. In SPRINT, gait speed was measured via a timed 4-m walk performed at the participant's usual pace from a standing start.[1]

[i] Frailty in TILDA determined by Freid criteria[5]; frailty in SPRINT determined by SPRINT-specific frailty index.

Author Contributions: Dr Sexton had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Sexton, Canney, Moore, Little, O'Seaghdha, Kenny.
Acquisition, analysis, or interpretation of data: Sexton, Canney, O'Connell, O'Seaghdha, Kenny.
Drafting of the manuscript: Sexton, Canney.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Sexton, Canney, O'Connell, Little.
Obtained funding: Kenny.
Administrative, technical, or material support: Sexton, Moore.
Study supervision: Sexton, Little, O'Seaghdha, Kenny.

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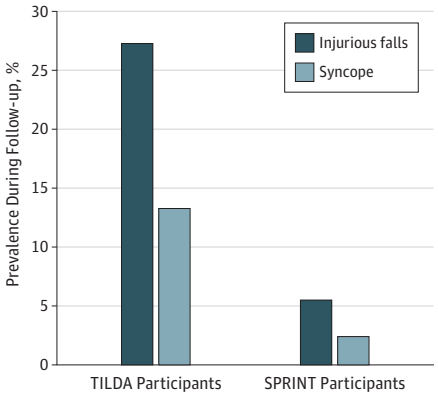
Figure. Comparison of the Prevalence Rates of Injurious Falls and Syncope Between the Systolic Blood Pressure Intervention Trial (SPRINT) and The Irish Longitudinal Study on Ageing (TILDA) Participants 75 Years or Older



Outcome prevalence is reported while also accounting for the attrition rate over the course of the study. Between wave 1 and wave 2 of TILDA, 46 of 407 participants (11.3%) were no longer participating in the study owing to death (n = 21), loss to follow-up (n = 2), refusal to answer questions as part of the study (n = 22), or withdrawal from the study (n = 1). Between wave 2 and wave 3, 109 of 407 participants (26.8%) were no longer participating in the study. Ascertainment of the reasons for this attrition at wave 3 is currently still ongoing at the time of writing.

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A Survey of Unregulated Direct-to-Consumer Treatment Centers Providing Stem Cells for Patients With Heart Failure

Stem cell therapy for the treatment of heart failure (HF) is under investigation but not approved by the US Food and Drug Administration (FDA).[1] Nevertheless, through direct-to-consumer promotion, "stem cell centers" claim to offer this treatment to patients. We sought to assess the type of treatments, cost, and statements made about efficacy.

Methods | Stem cell centers marketing treatment for HF were identified using a published database.[2] We used a standardized script in a telephone survey to ensure consistency in data collection. Several centers had multiple satellite locations; for these, only 1 was contacted. Inquiries included stem cell source, infusion method, treatment number, preprocedural evaluation, follow-up, and price. Representative statements by stem cell center personnel were chronicled. The board certifications of physicians named on center websites were compared against online registries.[3,4]

Standard descriptive statistics were used (IBM SPSS Statistics for Windows; version 24.0). For centers that provided a range (n = 5), the mean of the minimum and maximum price was calculated. The study was deemed exempt by the Saint Louis University institutional review board.

Results | Of 61 centers listed as offering HF therapy in 2016,[2] 15 were satellite sites. Seven centers no longer had active websites or had been closed by the FDA; 2 could not be contacted; 2 refused to provide data; 3 did not offer HF treatment despite online claims; 1 did not offer treatment for severe HF; and 1 required advance payment ($250) for telephone consultation.

Half of the remaining 30 centers responding to the survey were located in 3 states (8 in California, 4 in Florida, and 3 in New York). The self-reported number of procedures performed varied widely; 5 claimed more than 100. Medical records were required at only 9 centers, and a cardiologist's note was requested at 6. None of the sites discussed methodologies used to isolate or identify stem cells; most claimed to use autologous stem cells alone (24 adipose-derived, 1 from bone marrow), 2 treated with allogeneic stem cells (umbilical or placental), and 3 offered multiple sources. Stem cells were delivered intravenously in 29 centers; 1 performed direct coronary infusion. Stem cells were infused on the same day as harvest in all centers offering autologous infusions; 6 offered cell banking. Ancillary treatments (vitamin infusions and hyperbaric oxygen) were offered in 5. Follow-up was required at 2 centers.

The mean (SD) price for a single treatment was $7694 ($2737) for autologous and $6038 ($3145) for allogeneic cells. A discount ($500) was offered at 2 centers if the procedure was paid for in cash; additional procedures were offered for a discounted price (7 centers; mean discount, $3893 [$888]).

From 39 centers with websites advertising HF treatment, 79 physicians were identified: board certified in cardiology (n = 1), board certified in another field (n = 55), and unverified board certification status (n = 13). Ten had no formal medical training but were described as "naturopathic medical doctors." Characteristic statements recorded during the telephone survey are shown in the **Box**.

Discussion | A recent analysis identified 570 businesses in the United States engaged in direct-to-consumer marketing of stem cell interventions including centers purported to provide stem cells for cardiac repair[2] to patients with HF despite lack of FDA approval. We found that such treatment is delivered without rigorous preprocedural evaluations or postprocedural follow-up. Most physicians were not board certified in cardiology. The reasons why these businesses can continue to operate are not clear; in a recent publication, the former FDA commissioner did not address the FDA's role,[5] though some monitoring of these businesses does occur.[6]

Limitations. The survey was restricted to US sites only; nevertheless, the issue is global.[7] Information derived in this study cannot be independently verified; however, the data provided are largely unavailable on websites and are not publicly reported.

Given the prognosis of advanced heart failure and relatively limited options, clinicians need to be aware that patients may seek out this option and thereby may expose