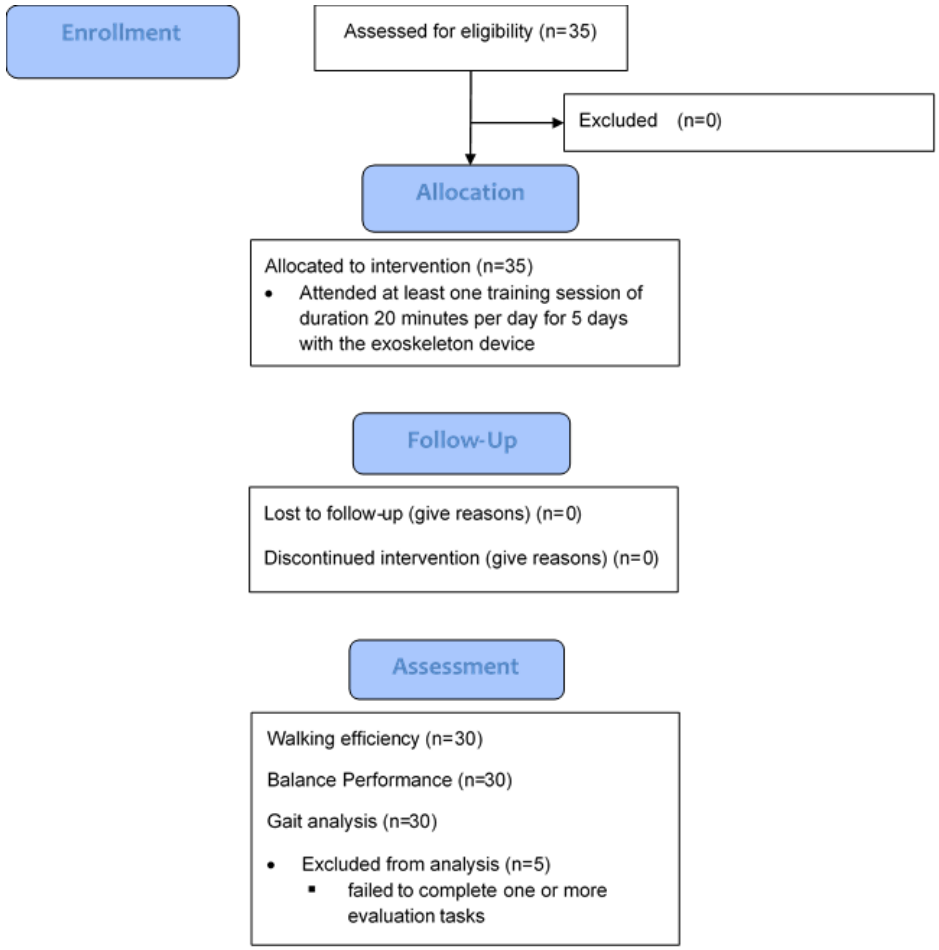
CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	The Kickstart Walk Assist system for improving balance and walking function in stroke survivors: a feasibility study	Title, Page 1
	1b	**Methods**: Thirty stroke survivors were enrolled in the study and experienced walking with the Kickstart exoskeleton device that provided spring-loaded assistance during gait. After 5 days of wearing the exoskeleton, participants were evaluated in the two states of wearing and not wearing the exoskeleton. Outcome measures included: a) gait measures, b) balance measures and c) exoskeleton-use feedback questionnaire. **Results**: In comparison to not wearing the device, wearing the Kickstart Walk Assist system, weight bearing asymmetry was reduced. The time spent on the 10-meter walk test was reduced, but there was no difference in the timed-up-and-go test (TUGT). Gait analysis data showed reduction in step time and double support time. Stroke survivors were positive about the Kickstart Walk Assist system's ability to improve their balance, speed and gait. In addition, their confidence level and willingness to use the device was also positive. **Conclusions:** These findings show the feasibility of using the Kickstart Walk Assist system for improving walking performance in stroke survivors. Our future goal is to perform a longer duration study with more comprehensive pre- and post-testing in a larger sample of stroke survivors. Thirty stroke survivors were enrolled in the study and experienced walking with the Kickstart exoskeleton device that provided spring-loaded assistance during gait. After 5 days of wearing the exoskeleton, participants were evaluated in the two states of wearing and not wearing the exoskeleton. Outcome measures included: a) gait measures, b) balance measures and c) exoskeleton-use feedback questionnaire.	Abstract, Page 2
Introduction			
Background and objectives	2a	The Kickstart Walk Assist system is such a rehabilitation device that consists of a belt, an external support structure and an Exotendon. The effect of the Exotendon is similar to an artificial tendon, which stores energy during the stance phase and releases it during the swing phase of the gait cycle. The Exotendon mechanism is inspired by the anatomical features of the hind limbs of the horse: in the hind limbs of the horse, several long tendons span multiple joints, and during the stance phase, the tendons stretch and store energy, and then the stored energy is used to initiate gait swing and consequently, reduce muscle exertion. Compared to other robotic lower extremity exoskeleton systems, the Kickstart system is lighter in weight, easier to wear and take off, and with lower economic cost. In a series of case studies (2 stroke survivors and one spinal cord injury patient), it was shown that the Kickstart Walk Assist system could increase wearers' walking speed and endurance.	Background, Page 5

		Study participants were tested for several measures with/without the device after experiencing walking with the exoskeleton over a duration of five days. Significant reductions were determined in the 10MWT, weight bearing asymmetry, step time, and DST. These findings show that the exoskeletal device has short-term feasibility and therefore, using the device for longer periods would be feasible for stroke survivors.	Conclusions, Page 16
	2b	The purpose of this study was to determine the feasibility of using the Kickstart Walk Assist system in a sample of stroke survivors who were in the subacute and chronic stages of the disease and attending an inpatient rehabilitation center. Study participants were tested for several measures with/without the device after experiencing walking with the exoskeleton over a period of 5 days. Outcome measures included: a) gait measures, b) balance measures and c) exoskeleton-use feedback questionnaire. Results from this study will help us to explore if the technology can offer a new option for encouraging the recovery of walking ability of stroke patients, optimizing the rehabilitation treatment strategy, and providing some reference for subsequent related research.	Background, Page 5
Methods			
Trial design	3a	This is a non-randomized single-arm observational study to evaluate the feasibility of using Kickstart Walk Assist system for improving balance and walking function in stroke patients.	Title, Page 1
	3b	There are no major changes to methods after pilot trial commencement.	
Participants	4a	Study participants met the following inclusion criteria: 1) diagnostic criteria for stroke by the Fourth Chinese National Cerebrovascular Disease Conference, modified from the standard WHO definition of stroke; 2) confirmation by cranial CT/MRI; 3) diagnosis of primary subcortical ischemic stroke with a disease duration greater than 1 month; 4) Ability to walk alone > 20 meters with or without a walking aid. The exclusion criteria were the following: 1) a history of severe arrhythmia; 2) peripheral nerve injury; 3) uncontrolled hypertension; 4) severe orthopedic conditions; 4) chronic pain; and 5) severe cognitive impairment.	Methods, Page 6
	4b	Shanghai Yangzhi Rehabilitation Hospital (Shanghai Sunshine Rehabilitation Center), Tongji University School of Medicine.	Methods, Page 6
	4c	In this study, a sample of 30 stroke survivors, were recruited from the Shanghai Yangzhi Rehabilitation Hospital (Shanghai Sunshine Rehabilitation Center), Tongji University School of Medicine. Each participant was required to sign an informed consent form approved by the hospital's review board. Volunteers participating in the experiment were those admitted to the inpatient rehabilitation center between September and December of 2018.	Methods, Page 6
Interventions	5	Each study participant was assigned a trained physical therapist who fitted the patient with the passive	Methods,

		exoskeleton device and who assessed their walking and balancing ability with or without the device. Prior to the experiment, each study participant attended at least one training session of duration 20 minutes per day for 5 days with the exoskeleton device while they carried out their routine rehabilitation activities. After the 5-day familiarization period, each participant was assessed in the following tasks with and without an exoskeleton: (1) the 10-meter walking test or 10-MWT; (2) the Timed Up and Go or TUG test; (3) The Weight Bearing/Squat Test; (4) Gait analysis during over ground walking, and (5) Feedback questionnaire.	Page 6
Outcomes	6a	*Walking efficiency* was evaluated using the 10-MWT and the TUG Test. **The 10-MWT test**: in this test, the set distance between the starting and the end point is 10 meters. One meter is added at either end of the set distance to allow the participant to accelerate and decelerate. The experimenter started timing with a stopwatch when the subject initiated walking from the starting line and stopped timing as the subject reached the finish line. Three trials were performed each with and without the exoskeleton device and the results were averaged and compared. **The TUG Test**: The participant started in a seated position and upon hearing a "start" command, stood up from the chair, walked 3 meters forward at their own comfortable walking pace, turned around over the thick line or mark, walked back to the chair and sat down. No physical help was given during the test. The experimenter recorded the time (in seconds) it took the participant to complete the test. Three trials were performed each with and without the exoskeleton device and the results were averaged and compared. *Balance performance* was evaluated using the Weight Bearing/Squat test of the NeuroCom Balance Master (Neurocom International, Clackamas, OR). Relative weight bearing on each limb of each patient were measured without and with the exoskeleton device. Before testing, the patient was fitted with a harness for safety and stood on the force plate to align his/her center of gravity with the center of the screen (Figure 1A and B). In this test, the percentage of body weight borne on each limb is calculated at different knee flexion angles. Each participant was asked to flex his/her knee joints by 0°, 30°, 60°, and 90° and the percentage of weight bearing at each flexion angle was used to calculate differences in weight bearing between the limbs (unimpaired – impaired). This was averaged across the four flexion angles. The higher the value, more asymmetrical is the weight bearing between the legs. *Gait recording and analysis of the overground walking trials:* Each participant performed a 6-meter overground walking trial each with and without the exoskeleton. Each participant's gait was tracked with an 8-camera 3D Motion capture System (Vicon Motion Systems Ltd. UK) at a sampling frequency of 100Hz using 21 retro-reflective markers. These markers were placed at specific anatomical landmarks. A lower body marker set was used (the plug-in-gait lower body model) that included the anterior and posterior superior iliac spines, sacrum, lateral and medial markers at the knee and ankle, tibia, thigh, heel and toe. Several kinematic parameters were analyzed the Vicon Nexus software (version 1.8.5; Vicon Motion Systems Ltd. UK). These were the following: cadence, walking speed, double support time, limp index, step length, step time, and step width.	Methods, Page 7 Methods, Page 8 Methods, Page 8

		Feedback Questionnaire: Study participants filled up a 1-5 Likert-scale based questionnaire that had 8 items. These were the subjective perceptions of: gait improvement, speed improvement, stability improvement, ease of wearing the device, level of comfort, confidence level, willingness to use and peer recommendation.	Methods, Page 9
	6b	There is no change to pilot trial assessments or measurements after the pilot trial commenced.	
	6c	*Walking efficiency* measured by the 10-meter walk test and *Balance Performance* measured by Weight Bearing/Squat Test were the main outcome measures of this pilot trial. Investigators had established a priori threshold for specific feasibility and acceptability criteria. There were the following: (i) the proportion of stroke patients in the pilot study who had an improved walking function would be 60% or greater; (ii) the proportion of stroke patients in the pilot study who had an improved balance performance would be 60% or greater. The secondary outcome measure, for example, the average subjective perception by participating stroke patients of the Kickstart exoskeleton device would be greater than 3.0 on a 1-5 Likert-scale based questionnaire, 1 being least positive and 5 being the most positive perception.	
Sample size	7a	Given this was a feasibility study, a formal sample size calculation was not performed. Investigators started with 13 patients (11 male, 2 female) during the first phase of this study, and had observed significant differences in 10-meter walking speed and balance measures in these patients, which gave the investigators confidence to increase the sample size to 30 stroke patients for the full study.	
	7b	Investigators were to perform an interim analysis of up to 15 stroke patients, at which point they could recommend stopping the trial if there was no significant improvement in main outcome measures on the basis of critical significance level ($p<0.05$).	
Randomisation:		This study is not randomized.	
Sequence generation	8a	Not applicable.	
	8b	Not applicable.	
Allocation concealment mechanism	9	Not applicable.	
Implementation	10	Not applicable.	
Blinding	11a	Not applicable.	

	11b	Not applicable.	
Statistical methods	12	Statistical analysis was done using SPSS 22.0 software. This experiment was a single-sample experimental research design with each subject performing balance and gait tasks with and without the exoskeletal device after 5-days of being familiarized with the device. Paired t-tests were done to compare the dependent variables for the same sample group with and without the exoskeleton device. A value of $p<0.05$ was considered statistically significant.	Methods, Page 10
Results			
Participant flow (a diagram is strongly recommended)	13a		

	13b	This is a single-arm non-randomized study. If a patient is unwilling or unable to complete one or more evaluation tasks, therefore can not be included in the final assessment, the investigators would screen and allocate a new patient to the study group.	
Recruitment	14a	Patient enrolment started in August 2018 and was completed in December 2018.	
	14b	The pilot trial ended when the total sample size reached 30 patients, which would be sufficient to meet the specific feasibility and acceptability criteria.	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1

Subject #	Stroke Diagnosis	Age (years)	Sex	Side Impaired	Disease Onset (Months)	Assistive Device	Exotendon Scale (0-N)
1	Hemorrhagic	53	Male	Right	4	None	0
2	Ischemic	60	Female	Left	10	None	0
3	Hemorrhagic	65	Female	Left	6	Walker	0
4	Ischemic	53	Male	Right	3	None	0
5	Ischemic	57	Male	Left	5	None	0
6	Hemorrhagic	38	Male	Left	27	Crutch	0
7	Ischemic	50	Male	Right	5	None	0
8	Ischemic	62	Male	Right	1	None	0
9	Hemorrhagic	38	Male	Left	5	Walker	0
10	Ischemic	51	Male	Right	11	None	0
11	Hemorrhagic	27	Female	Right	2	Walker	5
12	Ischemic	51	Male	Right	3	Walker	5-7
13	Hemorrhagic	52	Male	Right	3	None	4-6
14	Hemorrhagic	32	Male	Right	19	None	5-6
15	Ischemic	61	Male	Left	10	Crutch	6
16	Ischemic	48	Male	Left	0.67	None	7
17	Ischemic	55	Male	Left	0.73	None	6
18	Ischemic	55	Male	Right	1	None	7
19	Ischemic	46	Male	Right	5	None	5
20	Ischemic	63	Male	Left	4	Walker	7

		21	Ischemic	60	Male	Right	13	Walker	6	
		22	Hemorrhagic	76	Female	Left	7	Crutch	5	
		23	Ischemic	79	Male	Right	6	Walker	7	
		24	Hemorrhagic	58	Male	Left	15	Crutch	6	
		25	Ischemic	26	Male	Left	4	None	7	
		26	Ischemic	42	Male	Left	5	None	5	
		27	Ischemic	68	Male	Left	4	Crutch	6	
		28	Ischemic	52	Male	Right	10	Walker	5	
		29	Ischemic	52	Male	Right	5	None	5	
		30	Hemorrhagic	47	Male	Right	3	Walker	5	
		N=30	**Hemorrhagic=10 Ischemic=20**	**52.57±2.28**	**Male=27 Female=3**	**Right=16 Left=14**	**6.58±1.06**	**Device=14 None=16**	**Range 4-7**	
Numbers analysed	16	Out of 35 patients who had received the invention, 30 completed all three evaluation tasks, walking efficiency, balance performance and gait analysis. Out of the 30 analysed patients, 2 were unable to return the feedback questionnaire timely, and the remaining 28 were included in the report.								
Outcomes and estimation	17	The purpose of this study was to determine the feasibility of using the Kickstart Walk Assist system in a sample of stroke survivors who were in the subacute and chronic stages of the disease and attending an inpatient rehabilitation center. Study participants were tested for several measures with/without the device after experiencing walking with the exoskeleton over a period of 5 days. Outcome measures included: a) gait measures, b) balance measures and c) exoskeleton-use feedback questionnaire. ***Walking efficiency*** Figures 2C and 2E show the results of the 10-meter walk test and the *Timed Up and Go* Test respectively. For the 10-meter walk test (2C and 2D), walking for 5 days with the exoskeleton device resulted in a significantly shorter time spent (p=0.036, $t_{1,29}$=2.201) on average to cover 10meters while wearing the device (27.52±22.14) seconds than without (30.81±26.09) seconds. For the *Timed Up and Go* test, there was no significant difference between the two conditions (Figure 2E; p=0.991, $t_{1,29}$=0.011). ***Balance function*** Figures 2A and 2B show the results of the *Weight Bearing/Squat* test. Walking for 5 days with the exoskeleton device resulted in a significant reduction in the asymmetrical weight bearing between the legs. This asymmetry was significantly lower (p=0.011, $t_{1,29}$=2.733) while wearing the device (19.13±12.01 percent) than without (24.83±15.5 percent). ***Gait biomechanics of overground walking trials*** The results of gait analysis demonstrated the acute effects of walking with an exoskeleton device for 5 days in									Results, Page 10 Results, Page 11 Results, Page 11

		our sample of stroke survivors. For step length (Table 2), walking for 5 days with the exoskeleton device did not result in a significant change for step initiated from the impaired (p=0.857, $t_{1,29}$=0.181) side. However, step time changed (Figure 3A), resulting in a significantly reduced duration (p=0.019, $t_{1,29}$=2.472) when wearing the device (1.001±0.448) than not (1.104±0.566). Double support time (Figure 3B), also showed a significantly reduced duration (p=0.0205, $t_{1,29}$=2.452) when wearing the device (0.805±0.768) than not (0.900±0.796). Finally, step width (Figure 3C) was significantly increased (p=0.001, $t_{1,29}$=3.665) when wearing the device (0.226±0.036) than not (0.203±0.032). Other gait variables (Table 2) were not significantly impacted by exoskeleton assistance. These included walking speed (p=0.267, $t_{1,29}$=1.131), cadence (p=0.343, $t_{1,29}$=0.964; Figure 2F) and limp index (p=0.453, $t_{1,29}$=0.761). **Exoskeleton-use feedback questionnaire.** Results were not recorded from two study participants. Results from the remaining 28 subjects showed that on a scale of 1 (least positive perception) to 5 (most positive perception), stroke survivors on average, perceived their exoskeleton experience as more positive (>3) for stability improvement (3.86±0.76), speed improvement (3.64±0.87) and gait improvement (3.57±0.74). In addition, their confidence level (3.59±0.80) and willingness to use (3.14±1.04) was also more positive which was reflected in viewing peer recommendation (3.54±1.10) more positively. The study participants were less positive (<3) about the ease of wearing the device (2.71±0.94), and their level of comfort (2.68±0.90).	Results, Page 11
Ancillary analyses	18	No other analyses were performed in this pilot trial.	
Harms	19	An unanticipated finding in this study was that stroke survivors experienced a significant widening of the step width after wearing the Kickstart walking system. This is possibly related to the relatively large training shoe that is part of the passive device. While stroke survivors are known to walk with a wider gait in comparison to healthy controls, the reason here is possibly device-related because stroke survivors are also known to walk slowly which is opposite to the exoskeleton-assistance effect in our study.	Results, Page 14
	19a	There was no other important unintended consequences in this study.	
Discussion			
Limitations	20	This study had certain limitations. Subjects could use the device for a maximum of only 5 days. Although a pre-post study would have been ideal, the study aimed to test the feasibility of walking with an exoskeleton device in a sample of stroke survivors after familiarizing them with the device over the 5-day period. However, even after this short exposure, significant differences were noted that are anticipated to be consolidated when our longer duration study is completed in a larger sample of stroke survivors. Several other measures like cadence, limp index and step length did not show differences when tested with or without the exoskeleton device. This is not necessarily a negative outcome. We have to remember that this was not a pre and post study, rather a feasibility study and so we were also exploring if the device hampered gait outcomes in a sample of stroke survivors. We found that this was not the case. This gives us confidence to proceed to a longer duration study	Discussion, Page 15

		with more comprehensive pre- and post-testing in a larger sample of stroke survivors.	
Generalisability	21	The pilot trial methods used in this study can be applied to future definitive trial and other studies in the assessment of walking function and balance.	
Interpretation	22	In this feasibility study, our aim was to test the Kickstart Walk Assist system which is a passive lower limb exoskeleton device, in a sample of stroke survivors. The study specifically targeted balance, gait and walking efficiency of the study participants. In addition, the participants were also surveyed for determining their perceptions of functional improvement and comfort issues encountered when using the device. Study participants were tested for several measures with/without the device after experiencing walking with the exoskeleton over a duration of five days. Significant reductions were determined in the 10MWT, weight bearing asymmetry, step time, and DST. These findings show that the exoskeletal device has short-term feasibility and therefore, using the device for longer periods would be feasible for stroke survivors.	Conclusions, Page 16
	22a	In future definitive trial, a control group will be added and participating patients will be trained with Kickstart exoskeleton device over longer period than 5 days in this study. In addition, Sufficient patient communications will be provided to boost recruitment/retention.	
Other information			
Registration	23	Trial registration: Chinese Clinical Trial Registry, ChiCTR2000032665. Registered 5 May 2020 - Retrospectively registered, http://www.chictr.org.cn/showproj.aspx?proj=53288	Page 3
Protocol	24	The pilot trial protocol can be made available upon request.	
Funding	25	Shanghai Real Star Rehabilitation Equipment Co., Ltd. supplied the Kickstart exoskeleton devices and provided financial support to fund the clinical study at Sunshine Rehabilitation Center. Support was provided by the Centers of Biomedical Research Excellence grant (1P20GM109090-01) from NIGMS/NIH, by a NASA EPSCoR grant (80NSSC18M0076), and an American Heart Association award (18AIREA33960251) for MM and from a Graduate Research and Creative Activity Award (GRACA) for TS. The content is solely the responsibility of the authors and does not necessarily represent the official views of NASA, NIH or AHA.	Page 17
	26	This study was approved by the Medical Ethics Committee of Shanghai Yangzhi Rehabilitation Hospital (Shanghai Sunshine Rehabilitation Center) and was registered with Chinese Clinical Trial Registry, ChiCTR2000032665.	Page 16

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.