

Parachute use to prevent death and major trauma when jumping from aircraft: a randomised placebo-controlled trial

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Abstract

Objectives: To determine whether using a parachute prevents death or major traumatic injury when jumping from aircraft.

Design: Parallel group, randomised, controlled, multicentre trial.

Setting: Private or commercial aircraft between September 2017 and August 2018.

Participants: 92 aircraft passengers ≥18 years of age were screened for participation. 23 agreed to be enrolled and were randomised.

Interventions: Jumping from an aircraft (airplane or helicopter) with a parachute versus an empty backpack (open-label).

Main Outcome Measures: Composite of death or major traumatic injury (defined by an Injury Severity Score of >15) upon impact with the ground measured immediately after landing.

Results: Parachute use did not significantly reduce death or major injury (0.0% for parachute, vs. 0.0% for placebo, p = 1.00). This finding was consistent across multiple subgroups. Compared with individuals screened but not enrolled, participants included in the study were on aircraft at significantly lower altitude (0.63 metres ± 0.13 for participants, 9145.9 metres ± 2164.3 for non-participants, p <0.001) and lower velocity (0 ± 0 kph for participants, 799.7 ± 124.3 kph for non-participants, p<0.001).

Conclusions: Parachute use did not reduce death or major traumatic injury when jumping from aircraft in the first randomized evaluation of this intervention.

However, the trial was only able to enroll participants on stationary aircraft on the ground, suggesting cautious interpretation to high-altitude jumps. When strongly

held beliefs regarding the effectiveness of an intervention exist in the community, randomised trials may selectively enroll individuals with a lower perceived likelihood of benefit, thus diminishing applicability of results to clinical practice.

Trial registration: Attempts were made to register this study with the Sri Lanka Clinical Trials Registry (application number APPL/2018/040). After several rounds of discussion, the Registry was unable to register the trial due to well-founded the research y.
aningful". We appreciated the. concerns that "the research question lacks scientific validity" and "the trial data cannot be meaningful". We appreciated their thorough review.

Introduction

Parachutes are routinely employed to prevent death or major traumatic injury among individuals jumping from aircraft. However, evidence supporting the efficacy of parachutes is weak¹ and guideline recommendations for their use are principally based on biological plausibility and expert opinion.² Despite this widely held yet unsubstantiated belief of efficacy, many studies of parachutes have suggested injuries related to their use in both military³ and recreational⁴ settings, and parachutist accidents are formally recognized in the World Health Organization's 10th revision of the *International Statistical Classification of Diseases and Related Health Problems* (ICD)⁵. This raises important concerns for those of us steeped in the lore of evidence-based medicine, as numerous medical interventions believed to be useful have ultimately failed to demonstrate efficacy when subjected to properly executed, randomised clinical trials.⁶⁷

Prior attempts to evaluate parachutes in a randomised setting have hitherto not been undertaken due to both ethical and practical concerns. Perceived lack of equipoise could inhibit the ability to recruit subjects to participate in such a trial. However, whether preexisting beliefs about the efficacy of parachutes would, in fact, impair the enrollment of subjects in a clinical trial has not been formally evaluated. In order to address these important gaps in evidence, we first screened individuals seated on aircraft to assess the willingness of potential trial enrollees to be included in a randomised clinical trial evaluating use of parachutes versus placebo when jumping from aircraft. We then enrolled eligible and willing participants to perform

the first randomized clinical trial of the efficacy of parachutes in reducing death or major injury.

Methods

Study Population

Between September 2017 and August 2018, subjects were screened for inclusion in the <u>PA</u>rticipation in <u>RA</u>ndomised Trials <u>C</u>ompromised by Widely <u>Held</u> Beliefs Abo<u>U</u>t Lack of <u>Treatment Equipoise</u> (PARACHUTE) trial. In order to be considered for inclusion, participants had to be at least 18 years of age, be seated on an aircraft, and deemed to be rational decision makers by the enrolling investigator. In August 2018, individuals willing to participate in the trial and meeting inclusion criteria were enrolled in the study and randomised to the intervention or placebo.

Study Protocol and Interventions

After much deliberation about the nature and intent of the trial, the Institutional Review Board (IRB) of the Beth Israel Deaconess Medical Center ultimately approved the study (protocol number 2018P000441).

During the screening phase, prospective participants were approached and screened by study investigators while on private or commercial aircraft between the time of initial seating and the time of exiting the aircraft. Potential study participants completed an initial survey in which they were asked whether they would be willing to be randomised to jump from the aircraft at its current altitude and velocity.

Participants agreeing to be randomised were then enrolled in the randomisation phase of the study, and written informed consent was obtained. Subjects were randomised to wear either a parachute (National 360, National Parachute Industries, Inc., Palenville, NY; or Javelin Odyssey, Sun Path Products, Inc., Raeford, NC; Appendix Figure 1) or an empty backpack. Block randomisation was used, stratified by site and gender with a block size of two. There was no blinding of the treatment assignment. Subjects were then instructed to jump from the aircraft.

Research staff recorded the altitude and velocity of the aircraft at the time of the jump, and conducted a follow-up interview with each participant to ascertain vital status and to record any injuries sustained from the free fall within 5 minutes of impact with the ground, and again at 30 days. Data were collected electronically or with paper forms and uploaded to an online de-identified, password-protected database.

Data Collection

We collected data on basic demographic characteristics including age, gender, race/ethnicity, height, and weight using paper forms or a mobile application. We also collected information on subjects' past medical history including a history of broken bones, acrophobia (i.e. fear of heights), prior parachute use, family history of parachute use, and frequent flier status. Flight characteristics included carrier, velocity, altitude, make and model of the aircraft, the subject's seating section, and whether the flight was international or domestic. Velocity and altitude were captured using aircraft-provided flight information on individual

television screens when available, as well as through public pilot announcements. When neither was directly available, visual estimations were made by the study investigators.

Outcomes

The primary outcome was the composite of death and major traumatic injury, defined by an Injury Severity Score (ISS) >15, within 5 minutes of impact.

The ISS is a commonly used anatomical scoring system to grade the severity of traumatic injuries. Separate scores are assigned to each of 6 anatomical regions, and the 3 most highly injured regions contribute to a final score ranging from 0 to 75 with higher scores indicating more severe injury. Secondary outcomes included death and major traumatic injury assessed at approximately 30 days using the ISS, as well as 30-day quality of life assessed by the Short Form Health Survey (SF-12), a multipurpose questionnaire which measures a subject's overall health-related quality of life based on mental and physical functioning. 10

Statistical Analysis

The primary efficacy analysis tested the hypothesis that use of a parachute is superior to the control in preventing death and major traumatic injury at the significance level of 0.05 (two-sided). Based on historical data, we projected that 99% of the control arm would experience the primary outcome at ground impact with a relative risk reduction of 95% in the intervention arm. A sample size of 14 (7 in each arm) would yield 99% power to detect this difference at a two-sided alpha of

0.05. In anticipation of potential drop-out after enrollment due to "wimping out", a sample size of 20 subjects was targeted. Analysis was performed on an intention-to-treat basis. We performed secondary subgroup analyses stratified by aircraft type (airplane vs. helicopter) and prior parachute use through formal tests of statistical interaction.

We tabulated baseline characteristics of the two trial arms to examine for potential imbalance in variables. Continuous variables were summarized as mean \pm standard deviation, and compared using two-sample t tests. Categorical data were summarized by frequency and percentage and analyzed using the Chi-square or Fisher's exact test, as appropriate. To better understand what drove willingness to participate in the trial, we also compared characteristics of individuals who were screened but chose not to enroll with those who enrolled.

All analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC).

Results

Study Population

A total of 92 subjects were screened and surveyed regarding their interest in participating in the PARACHUTE trial. Among those screened, 69 (75%) were unwilling to be randomised or found to be otherwise ineligible by investigators. A total of 23 individuals were deemed eligible for randomisation (Figure 1).

Baseline characteristics of enrolled subjects were generally similar between the intervention and control arms (Table 1). The median age of randomised

subjects was 38.4 years and 56.5% were male. Three (13.0%) of the randomised subjects had prior parachute use and 9 (39.1%) had a history of acrophobia. Participants enrolled in the study were similar to subjects screened but not enrolled with regards to most demographic and clinical characteristics (Table 2). However, participants who ultimately enrolled were less likely to be seated on a jetliner (and instead were located on a biplane or helicopter) (0.0% vs. 100%, p<0.001), were at a lower mean altitude (0.63 metres \pm 0.13 vs. 9145.9 metres \pm 2164.3, p<0.001), and were traveling at a slower velocity (0 kph \pm 0 vs. 799.7 kph \pm 124.3, p<0.001) (Table 2).

Among the 12 participants randomised to the intervention arm, the parachute did not deploy in all 12 (100%) due to the short duration and altitude of falls. Among the 11 participants randomised to receive an empty backpack, none crossed over to the intervention arm. A photograph of a representative jump is shown in Figure 2; for interested readers, images of each jump in the trial are shown in Appendix Figure 2.

Outcomes

Results for the primary and secondary outcomes are shown in Table 3. There was no significant difference in the rate of death or major traumatic injury between the treatment and control arms within 5 minutes of ground impact (0.0%) for parachute versus 0.0% for placebo, p = 1.00 or at 30 days (0.0%) for parachute versus 0.0% for placebo, p = 1.00. Health status as measured by the SF-12 was similar between groups (43.9 ± 1.8) for parachute versus 44.0 ± 2.4 for placebo, p = 1.00

0.90). In subgroup analyses, there were no significant differences in the effect of parachute use on outcomes when stratified by type of aircraft or prior parachute use (interaction p = 1.00 for both comparisons).

Discussion

We have performed the first randomized clinical trial evaluating the efficacy of parachutes for preventing death or major traumatic injury among individuals jumping from aircraft. Our groundbreaking study found no statistically significant difference in the primary outcome between the treatment and control arms, contradicting widely held beliefs that parachute use reduces catastrophic bodily damage in this setting. Our findings should give momentary pause to experts who advocate for routine use of parachutes for jumps from aircraft in recreational or military settings.

The rigorous design of the PARACHUTE trial – randomized, placebo-controlled, multicenter, using diverse aircraft – greatly enhances the validity and generalisability of our findings. Although decades of anecdotal experience have suggested that parachute use during jumps from aircraft may be life-saving, these observations are vulnerable to selection bias and confounding. Indeed in their seminal work published in the *BMJ* in 2003, Smith and Pell cautioned that documented benefits of parachutes may result from a "healthy cohort effect" as individuals using parachutes are less likely to suffer psychiatric comorbidities than those who do not¹. Their systematic search for randomized clinical trials evaluating the efficacy of parachutes during gravitational challenge yielded no published

studies. In part, our study was designed as a response to their call to (broken) arms in order to address this critical knowledge gap.

By some recent estimates, 25 to 42% of elderly patients in the US receive unproven or ineffective therapies, contributing to rising healthcare costs¹¹. Strongly held beliefs about the efficacy of commonly used but untested interventions often drive daily clinical decision-making. Yet these beliefs, typically grounded in biological plausibility and expert opinion, have been overturned time and again by subsequent rigorous randomised evaluations¹². We believe the PARACHUTE trial represents one more such historic moment. Should our results be reproduced in future studies, cessation of routine parachute use during jumps from aircraft could save the global economy billions of dollars spent each year to prevent injuries related to gravitational challenge.

A minor caveat to our findings is that the rate of the primary outcome was substantially lower in this study than was anticipated at the time of its conception and design, which may have somewhat underpowered our ability to detect clinically meaningful differences. Although randomised participants had similar demographic and clinical characteristics compared with those who were screened but did not enroll, they may have been at lower risk of death or major trauma because they jumped from an average altitude of 0.63 ± 0.13 metres on aircraft moving at an average of 0 ± 0 kilometres per hour. Clinicians will need to consider this information when extrapolating to their own settings of parachute use.

Opponents of evidence-based medicine have frequently employed the strategy of *reductio ad absurdum* – arguing that no one would perform a randomised

trial of parachutes. We have demonstrated this argument to be specious, having conclusively shown that it is possible to randomise subjects to jumping from aircraft with versus without parachutes, albeit under limited and specific scenarios. In our study, we had to screen many more subjects in order to identify eligible and willing participants. Yet this is not dissimilar to the experiences of other contemporary trials that frequently enroll only a small fraction of the thousands of patients screened. Prior research has suggested that participants in randomised clinical trials are at lower risk than patients treated in routine practice. ^{13 14} This is particularly relevant to trials examining interventions that the medical community believes to be effective: this perceived lack of equipoise often pushes well-meaning but ill-informed physicians or study investigators to withhold from participation study patients who they erroneously may believe have the most to gain from treatment.

Critics of the PARACHUTE trial are likely to make the argument that even the most efficacious of treatments can be shown to have no effect in a randomised trial if individuals who would derive the greatest benefit selectively decline participation. They will claim that although few medical treatments are likely to be as effective as parachutes, 15 the exclusion of selected patients could result in null trial results, whether or not the therapy being evaluated was truly effective. They might further argue that although randomised controlled trials are the gold standard for evaluating treatments, their results are not always guaranteed to be relevant for clinicians. While we believe our study has undoubtedly contributed to a deeper

understanding of the role of parachutes, it will be up to the reader to determine the relevance of these findings in real-world settings.

Our study has only a few, rather trivial limitations. We address them in a perfunctory manner in this paragraph to appease reviewers. First, it may be imprudent to extrapolate our findings directly to current military or recreational use of parachutes in aircraft traveling at higher altitudes or velocity. Although we are considering conducting additional randomised clinical trials in these higher-risk settings, we have been advised against this based on somewhat outdated theoretical work supporting parachutes. 16 Second, our study was not blinded to treatment assignment. While we did not anticipate a strong placebo effect for our primary endpoint, it is possible that other subjective endpoints including sensations of fear as well as its associated somatic manifestations (e.g. possible transient loss of fecal or urinary continence) would have necessitated use of a sham parachute as a control. Third, the subjects screened but not enrolled in the study were limited to passengers seated next to study investigators during commercial flights who were kind enough to participate in a rather unusual survey administered by complete strangers. They are clearly not representative of all aircraft passengers. Finally, although all endpoints in the study were prespecified, we were unable to register the PARACHUTE trial due to a careful and thorough review by the Sri Lanka Clinical Trials Registry; future investigators interested in this type of work will need to pursue registration from less rigorous authorities.

With these limitations in mind, what are the ultimate lessons of this work? In truth, the PARACHUTE trial demonstrates that studies evaluating devices already

entrenched in clinical practice face a difficult task. They need to ensure that patients with the greatest expected benefit from treatment are included during enrollment. To safeguard this, we see several solutions. First, overcoming such a hurdle requires extreme commitment on the part of the investigators, clinicians and patients; thankfully, recent examples of such efforts do exist. Second, stronger efforts could be made to ensure that definitive trials are conducted *before* new treatments become inculcated into routine practice, when greater equipoise is likely to exist. Third, the comparison of baseline characteristics and outcomes of study participants and non-participants should be utilized more frequently and reported consistently to facilitate interpretation of results and assessment of study generalisability. Here may be instances where clinical beliefs justifiably prevent a true randomised evaluation of treatment to be conducted.

Conclusion

Parachute use compared with placebo did not reduce death or major traumatic injury when used in subjects jumping from aircraft in this first randomised evaluation of the intervention. This largely resulted from our ability to only recruit participants jumping from stationary aircraft on the ground. When strongly-held beliefs regarding the effectiveness of an intervention exist in the community, randomised trials evaluating their effectiveness may selectively enroll individuals with a lower likelihood of benefit, thereby diminishing the applicability of trial results to practice. Therefore, although we can confidently recommend that individuals jumping from stationary aircraft on the ground do not require

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Contributor and Guarantor Information

RWY (guarantor) had the original idea but was reluctant to say it out loud for years. In a moment of weakness, he shared it with MWY and BKN, both of whom immediately recognized this as the best idea RWY will ever have. RWY and LRV wrote the first draft, CS, DBK, JBS, EAS and JLH provided critical review, and RMD provided subject matter expertise. DBK took this work to another satirical level. Everyone suffered substantial abdominal discomfort from laughter while RWY worried that BKN would not keep his mouth shut until the Christmas issue was published. Finally, Sri Lankans can smell BS from two oceans away.

Competing Interests Declaration

All authors have completed the ICMJE uniform disclosure form and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Public and Patient Involvement Statement

The public was not involved in the development, design, or assessment of the intervention.

Transparency Statement

The guarantor affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned have been explained.

Role of the Funding Source

There was no funding source for this study.

Data Sharing

The investigators are willing to make the relevant anonymized trial data available upon a reasonable request for re-analysis.

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Table 1. Baseline characteristics of subjects randomised to parachute vs. no parachute

	Parachute	No parachute
Demographics	N=11	N=12
Age (years)	38.1±8.7	38.6±11.0
Gender		
Female	4 (36.4%)	6 (50%)
Male	7 (63.6%)	6 (50%)
Race/Ethnicity		
American Indian or Alaska Native	0 (0%)	0 (0%)
Asian	4 (36.4%)	4 (33.3%)
Black or African American	0 (0.0%)	0 (0.0%)
Native Hawaiian or Other Pacific Islander	0 (0.0%)	0 (0.0%)
More than one race	0 (0.0%)	0 (0.0%)
White	7 (63.6%)	8 (66.7%)
Unknown or not reported	0 (0%)	0 (0%)
Height (cm)	171.8 ± 9.12	171.7 ± 8.4
Weight (kg)	75.9 ± 24.4	74.6 ± 13.0
Past Medical History		
Prior broken bones	4 (36.4%)	5 (41.7%)
Acrophobia (fear or heights)	3 (27.3%)	6 (50%)
Prior parachute use	3 (27.3%)	0 (0.0%)
Family history of parachute use	2 (18.2%)	0 (0.0%)
Frequent flier (average >4 flights per month)	0 (0.0%)	4 (33.3%)

Flight/Aircraft Characteristics

 ${\it International vs. domestic flight}$

Domestic	11 (100.0%)	12 (100.0%)
International	0 (0.0%)	0 (0.0%)
Aircraft model		
Jetliner	0 (0.0%)	0 (0.0%)
Biplane	5 (45.5%)	6 (50%)
Helicopter	6 (54.5%)	6 (50%)
Velocity (kph)	0 ± 0	0 ± 0
Altitude (metres)	0.64 ± 0.13	0.63 ± 0.13

Table 2. Baseline characteristics of enrolled subjects versus those screened but not enrolled

	Enrolled	Not enrolled	
	N=23	N=69	p-value
Demographics			
Age (years)	38.4±9.7	43.0±14.9	0.09
Gender			0.81
Female	10 (43.5%)	32 (46.4%)	
Male	13 (56.5%)	37 (53.6%)	
Race/Ethnicity			0.40
American Indian or Alaska Native	0 (0.0%)	2 (2.9%)	
Asian	8 (34.8%)	13 (18.8%)	
Black or African American	0 (0.0%)	2 (2.9%)	
Native Hawaiian or Other Pacific Islander	0 (0.0%)	0 (0.0%)	
More than one race	0 (0.0%)	4 (5.8%)	
White	15 (65.2%)	48 (69.6%)	
Unknown or not reported	0 (0.0%)	0 (0.0%)	
Height (cm)	171.7 ± 8.5	171.2 ± 11.0	0.82
Weight (kg)	75.2 ± 18.9	73.5 ± 15.5	0.67
Past Medical History			
Prior broken bones	9 (39.1%)	26 (37.7%)	0.90
Fear of heights	9 (39.1%)	23 (33.3%)	0.61
Prior parachute use	3 (13.0%)	9 (13.0%)	1.00
Family history of parachute use	2 (8.7%)	10 (14.5%)	0.72
Frequent flier (average >4 flights per	4 (17 40/)	14 (20 20/)	1.00
month)	4 (17.4%)	14 (20.3%)	1.00
Flight/Aircraft Characteristics			
International vs. domestic flight			0.02
Domestic	23 (100%)	31 (79.5%)	

International	0 (0.0%)	8 (20.5%)	
Aircraft model			<.001
Jetliner	0 (0.0%)	69 (100%)	
Biplane	11 (47.8%)	0 (0.0%)	
Helicopter	12 (52.2%)	0 (0%)	
Velocity (kph)	0.0 ± 0.0	799.7±124.3	<.001
Altitude (metres)	0.63 ± 0.13	9145.9±2164.3	<.001

Table 3. Event rates for primary and secondary endpoints

Endpoint	Parachute	No Parachute	p-value
Upon Impact			
Death or major traumatic injury	0 (0.0%)	0 (0.0%)	1.00
Death	0 (0.0%)	0 (0.0%)	1.00
Injury Severity Score	0 ± 0	0 ± 0	1.00
30 Days Post-Impact			
Death or major traumatic injury	0 (0.0%)	0 (0.0%)	1.00
Injury Severity Score	0 ± 0	0 ± 0	1.00
SF-12	43.9 ± 1.8	44.0 ± 2.4	0.90
Physical health subscore	19.6 ± 0.7	19.7 ± 0.5	0.88
Mental health subscore	24.3 ± 1.3	24.3 ± 2.1	0.92

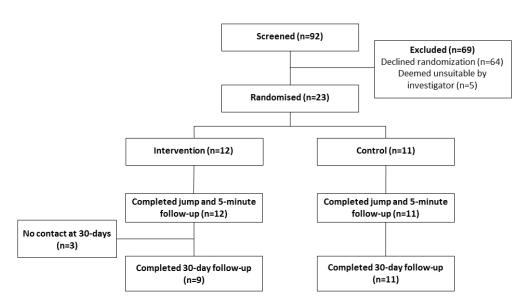


Figure 1. Study flow diagram

81x44mm (300 x 300 DPI)



Figure 2. Representative study subject jumping from aircraft with placebo backpack. Remarkably, this individual did not incur death or major injury upon impact with the ground despite not having a parachute.

256x341mm (300 x 300 DPI)

APPENDIX

The PARACHUTE Trial Organization

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Appendix Figure 1. Parachute and placebo backpack used at each study site Panel A. Parachute (left) and backpack (right) used for biplane jumps



Panel B. Parachute (right) and backpack (left) used for helicopter jumps



Appendix Figure 2. Still frame image of each jump from aircraft in the PARACHUTE Trial *Panel A.* Photographs of participants jumping from a biplane.



Panel B. Photographs of participants jumping from a helicopter.























