PREVENTION OF SCUBA DIVING MISHAPS USING A PREDIVE CHECKLIST: A CLUSTER RANDOMIZED TRIAL

SHABBAR ISMAILBHAI RANAPURWALA

A dissertation submitted to the faculty at the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the Department of Epidemiology in the Gillings School of Global Public Health.

Chapel Hill
2014

Approved by:

Steven B Wing

Charles Poole

Stephen W Marshall

Petar J Denoble

Kristen L Kucera

ABSTRACT

Shabbar Ismailbhai Ranapurwala: Prevention of Scuba Diving Mishaps Using a Pre-dive Checklist: A Cluster Randomized Trial
(Under the guidance of Steven B. Wing)

Scuba diving mishaps, caused by equipment problems or human errors, increase the risk of morbidity and mortality while diving. Pre-dive checklists may mitigate mishaps. This study evaluated the effect of using a pre-dive checklist on the incidence of diving mishaps in recreational divers.

A multi-location cluster randomized trial with parallel groups and allocation concealment was conducted between June 1 and August 17, 2012. The participants had to be at least 18 years of age, permitted to dive by the dive operator, and planning to dive on the day of participation. They were recruited at the pier and dive boats at four locations. The intervention group received pre-dive checklist and post-dive log. The control group received a post-dive log only. The outcomes, self-reported major and minor mishaps, were prompted by a post-dive questionnaire. Mishap rates/ 100 dives were compared using Poisson regression with generalized estimating equations. Intent-to-treat, per-protocol, and marginal structural model analyses were conducted. Two nested studies were also conducted – first, among the control group participants, to evaluate the relationship of routine use of written self-checklist on the incidence of mishaps. And second, among the intervention group participants, to assess the factors affecting the adherence to the intervention pre-dive checklist.

Total 1043 divers (intervention=617; control=426) made 2041 dives, on 70 location-days (intervention=40; control=30) at four locations. Compared to the control group, the incidence of major mishaps decreased in the intervention group by 36%, minor mishaps by 26%, and all mishaps by 32%. On average, there was one fewer mishap in every 26 intervention dives. Routine use of a self-checklist was associated with 69% fewer major mishaps and 50% fewer all mishaps in the control group. 30% participants were non-adherent to the intervention checklist. Factors associated with greater adherence were routine use of self-checklist and older age. Factors that were associated with lower adherence were non-white race and diving in North Carolina.

In this trial, pre-dive checklist use prevented the incidence of mishaps which could prevent injuries and fatalities. Use of pre-dive checklists should not entail any risk and their use should be promoted.

Trial Registration: ClinicalTrials.gov ID NCT01960738

I dedicate this dissertation to my parents.

ACKOWLEDGEMENTS

Many thanks to my wonderful advisor, mentor and friend Dr. Steven B. Wing, PhD, for being ever so kind, inspirational, fatherly, patient, soothing, nurturing, supporting, and a person to look up to. Many thanks to my committee member and mentor Dr. Petar J Denoble, MD, DSc for being very kind, patient, believing in me, and guiding me at each step. Many thanks to the rest of my committee members – Dr. Charlie Poole, Dr. Stephen W Marshall, PhD, and Dr. Kristen L. Kucera, PhD, for being ever so supportive and interested in helping me. Many thanks to Divers Alert Network (DAN), Jeanette Moore – DAN Research Administrator, and the DAN summer 2012 interns: Patrick Dolezal, Samuel Hurley, Devon Donohue, and Marie Claire Joseph. Many thanks to Dr. Nicholas Bird, Regional Director, Duke Urgent Care, and Katy Locke, Dive Operator, Discovery Diving Company, Beaufort, NC.

Many thanks to the dive shops that allowed us to go on their boats and recruit divers, and their staff that co-operated with us: Discovery Diving Company, Beaufort, NC; Aquatic Safaris Dive Emporium, Wilmington, NC; Sand Dollar Sports, Cozumel, Mexico; Aldora Divers, Cozumel Mexico; Sunset House, Grand Cayman, Cayman Islands; Aqua Safari, Cozumel, Mexico. Many thanks to all the study participants.

Everlasting thanks to my parents – Ismailbhai S. Ranapurwala and Sakinaben I. Ranapurwala for their immense hard work, sacrifices, constant guidance, and everlasting love in raising me and helping me become who I am. Everlasting thanks to my better half – Rebecca A. Bruening for her companionship, warmth, patience, receptiveness, and nurturing love. Everlasting thanks my elder brothers – Mohammed I. Ranapurwala and Kausar I. Ranapurwala for the struggles they endured, and continue to endure, to help me realize my dreams, and for being the two pillars I can fall back on. Everlasting thanks to the rest of my family – my bhabhis, my nephew and my niece for the sheer joy and happiness they bring to me. And everlasting thanks to some great friends, worth mentioning – Abhinav Golas, Ravish Mehra, Elizabeth Rogawski, Ashley Naimi, Jerrod Nelms, and many others, who directly or indirectly, knowing or unknowingly, contributed immensely to my success at UNC Chapel Hill.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

95% CI – 95% confidence interval

AGE – Arterial gas embolism

AOR – Adherence odds ratio

BCD – Buoyancy control device

BMI – Body mass index

CDP – Conservative diving practices

CRT – Cluster randomized trial

DAG – Directed acyclic graph

DAN – Divers Alert Network

DCS – Decompression sickness

FAD – Flying after diving

GEE – Generalized estimating equations

ICC – Intra-class correlation

IRB – Institutional review board

ITT – Intent-to-treat

MSM – Marginal structural models

NNT – Number needed to treat

PADI – Professional Association of Diving Instructors

PBT – Pulmonary barotrauma

PFO – Patent foramen ovale

PFSI – Pre-flight surface-interval

PI – Principal investigator

PP – Per-protocol

RR – Rate ratio

UNC – The University of North Carolina, Chapel Hill, NC, USA

WHO – World Health Organization

I. BACKGROUND AND SIGNIFICANCE

A. Brief history of scuba diving and the advent of a recreational sport

The unknown has forever intrigued humans. And to satisfy this attraction there are many places in the world which are still untouched by humans. The wilderness of the world underwater has long been the focus of our fascination, much like the vastness of space, or the majestic forests and mountains.

The first known records of modern bell diving are from the 1640s, however these were not supplied with fresh air, and divers only had the air contained in the bell at their disposal. The first bell with continuous surface supplied fresh air was devised in 1790. A force pump on the surface accomplished this task. When it was understood that air pressure increases as one goes deeper, pressurized surface air supply was provided that allowed divers to go deeper. However, these supplies were manual, and pressure had to be monitored continuously. This bell was the forerunner of the future all modern bell chambers. These chambers were known as caissons. Caisse is a French word meaning box. Caisson is a watertight container, which is supplied by pressurized air and keeps the water out, thus providing a dry working environment.

The first scientist that recorded the symptoms of decompression sickness (DCS) in a viper and hinted that they may be due to bubble formation was Sir Robert Boyle in 1670, he also postulated the laws of gaseous exchange, which later became the basis for the explanation of bubble formation in decompression sickness (Acott, 1999a). Triger, in 1841, invented the caisson, and was the first to describe the symptoms of DCS in two coal miners. Thereafter, Pol and Watelle in 1854 observed that these symptoms may be alleviated by sending the divers back to the caisson. These were the symptoms of decompression sickness, usually skin lesions, joint pains that are constant and not affected by movement or pressure, and in some cases neurological symptoms, that could also prove to be fatal. In 1878, Paul Bert published his book, barometric pressure. He was the first to note that the symptoms result from gas bubbles, usually nitrogen, formed by rapid decompression. It was thus understood that the amount of the dissolved gases in the blood and plasma increases with proportional increase in ambient pressure (Acott, 1999a; Kindwall, 2004). When the pressure is released the gas comes out of the solution, just like it does in case of a bottle of sparkling water. The nitrogen bubbles released in the tissue lead to pain, and marbling of the skin, in extreme case there are neurological symptoms like weakness and paralysis. The set of symptoms caused by the release of inert gas (nitrogen) bubbles in the body is called as Decompression Sickness (DCS) (Vann, 2004).

Up until the end of the 18th century, divers usually dove while being contained in a Caisson with a constant surface supply of compressed air. Although rebreather diving equipment was first developed in the 17th century by Boreilli. It wasn't until 1819, when Siebe devised a diving rig for non-rebreather divers, with hard copper helmet attached to a leather jacket. This allowed divers to walk freely on the floor of the water column. This assembly, too, was needed to be supplied with air from the surface. Since maintaining a constant surface supply of air was difficult, newer ideas had to be conceived. One such idea was to carry tanks filled with air. This allowed divers to go deeper, but was time limited, and could only be used for specific predetermined objectives. However, there was another problem to overcome. While diving with a hard hat, gas would be supplied to the hat through the tanks, but there was a larger dead space of air between the diver and the air source which would increase the diver's breathing efforts especially with increasing ambient pressure. It wasn't until 1943 that the 'self-contained underwater breathing apparatus' (SCUBA) was introduced by Emile Gagnan and Jacques Cousteau. This method introduced a demand valve connected with gas tanks through hoses. This decreased the divers efforts to breathe, and also increased the efficiency so divers could be underwater for longer period of time. This was complemented by using a face mask and wet suit, instead of the heavy hard hat, and leather diving jacket. The whole assembly now became considerably lighter which meant that a less athletic person could scuba dive as well (Kindwall, 2004). Scuba diving caught on after world-war-II. The rapid advancement of diving technology, and commercialization promoted the sport and recreational diving. Commercialization allowed more advancements like dive computers, better thermal protection, advanced training for recreational divers. On the other hand increasing recreational participation called for safer practices, and fostered research in recreational diving injury.

B. The Diver Eligibility and diving fitness

The diving industry is mainly self-regulated. Training agencies determine the eligibility for diving on a broader level. They set the age limits for training and determine the minimum swim requirements. Professional Association of Diving Instructors (PADI) sets the minimum age limit for diving at 10 years for supervised divers, and 15 years for unsupervised divers. There is no upper age limit. Health and physical fitness related exclusion criteria are few. Training agencies and dive operators require a medical physical of divers if they report one of the major medical conditions suggested by the World Recreational Scuba Training Council or regional dive industry bodies, these conditions may increase the risk of an injury while diving.

Dive operators and dive shops may have their own additional criteria before they allow a diver to dive with them. Dive operators are known to refuse divers who have major clinical conditions even if they were provided clearance for diving by their physicians. On the other hand, many dive shops allow seasoned patrons to dive despite obvious health risks that would otherwise preclude one from diving. In the end, dive operators make a subjective assessment of risks for each diver.

C. Recreational diving equipment

The diving equipment consists of mask, fins, snorkel, breathing apparatus (scuba), buoyancy compensator device (BCD), diving suit, weights, and accessories including dive computers and gauges. The mask creates a pocket of air between the eye and the water, thus allowing the diver to see clearly underwater. The fins enhance propulsion while swimming. The snorkel is a curved tube that is open on both ends and has an exhaust valve near the mouth end. It allows the diver to breathe on the water surface with face immersed. Swimming on the water surface along with all the diving gear could be cumbersome; using fins and snorkel ease this difficulty.

The scuba consists of a gas tank that contains pressurized gas. It is connected to a first stage regulator that reduces the high pressure of the gas from the tank, and allows the gas to be sent into hose. The hose is connected to a second stage regulator which reduces the pressure of the gas to the ambient pressure and the pressure of the diver’s lungs. The second stage regulator consists of a demand valve that is connected to a mouthpiece. When the diver needs to breathe s/he breathes through the mouthpiece creating a negative pressure in the mouth, that allows the demand valve to open and air is released for the diver to breathe. The diver exhales through the mouthpiece and the exhaled air is exhausted out through a non-return valve. The tank is kept in a backpack, mounted on the BCD, to hold it in place.

The BCD is essentially a flotation device. It is connected to the diver's gas tank so that the diver can add or remove air into the BCD. Doing so helps the divers regulate buoyancy, thus facilitating their descent and ascent in the water column, and allowing them greater control over what they want to do. In emergency it can be used as a flotation device, too, the diver or their buddy can fill up the air in the BCD and launch the diver on to the surface in order to be rescued.

Dive suits are usually of three types – skin suits, wet suits, and dry suits. The skin suits are essentially very thin suits that do not provide thermal protection. It may only provide protection from sunburn in warm waters. Usually it may only consist of diving undergarments that are used to provide thermal protection to limited body area. These are generally used in warm summer equatorial waters. Wet suits are full body suits (except face) made up of neoprene that trap the water near the skin and protect the body by heat exchange due to constantly brushing up against flowing water. As the diver goes deeper the water temperature drops, and the wet suits also compress under increasing pressure reducing their thermal protection capacity. This can also change buoyancy. Wet suits are used usually in tropical waters which usually get colder as we go deeper even during the summer. Dry suits do not allow any water contact with the body and come with seals, to stop any water from entering the suit. While the dry suits provide superior thermal protection, they may limit diver's movements. Using dry suits may require specialized training. Dry suits are best for diving cold waters.

Apart from these, divers carry a weight belt and sometimes additional weights to help them be negatively buoyant in the water, so that the diver can go deeper. Weights allow the divers to submerge themselves easily and also control ascent as more weight would mean slower ascent.

Dive gauge provides depth measurement to the diver while diving, and along with a waterproof stop watch divers could monitor their decompression obligations and ascent. A pressure gauge allows a diver to monitor the amount of gas left during a dive. Dive gauge, gas gauge, and a watch allow divers to monitor their dive continuously, fulfill their decompression obligations, and return to surface unharmed.

This multitasking has been reduced by dive computers that use mathematical algorithms to calculate the time the diver can spend underwater, and their decompression obligations. However, the algorithms used by the dive computers seek to maximize the divers bottom time and hence may be less conservative approach, and may expose the divers to greater risk of DCS.

The tank backpack, the BCD, the weights, mask, fins, all have releases that need to be working properly in order to hold the equipment in place, and let go of it when needed, underwater or on surface. It is important that all of these work properly to provide a safe and incident free diving experience for a diver (Egstrom, 2004).

D. Diving injuries and fatalities

Recreational scuba diving is a widely popular sport. US census 2000 estimated that there are about 2.5 million scuba divers in the United States (US Census Bureau, 2000). Scuba diving training agencies permit participation for children who are at least 12 years of age; there is no upper age limit. Health and physical fitness related exclusion criteria vary worldwide. In some countries, for example in Australia, diving fitness medical exams are required before participation. However, in the United States there is no such requirement. Consequently, these vary from place to place in the US depending on the local diving conditions and the dive operators or dive shops. In 2011, Divers Alert Network (DAN) carried out a health survey within its member population which may provide an overview of the overall diving population. DAN is the largest not-for-profit membership organization for divers (about 200,000 members), which provides medical assistance, education, and training to divers and conducts diving medical research. The DAN members health survey included a diving questionnaire and modules from CDC's Behavioral Risk Factor Surveillance System (CDC, 2010). These data compare the health status of DAN's diving population to that in the general US population. The DAN diver population is older, healthier, wealthier and more educated than the general US population (table 1).

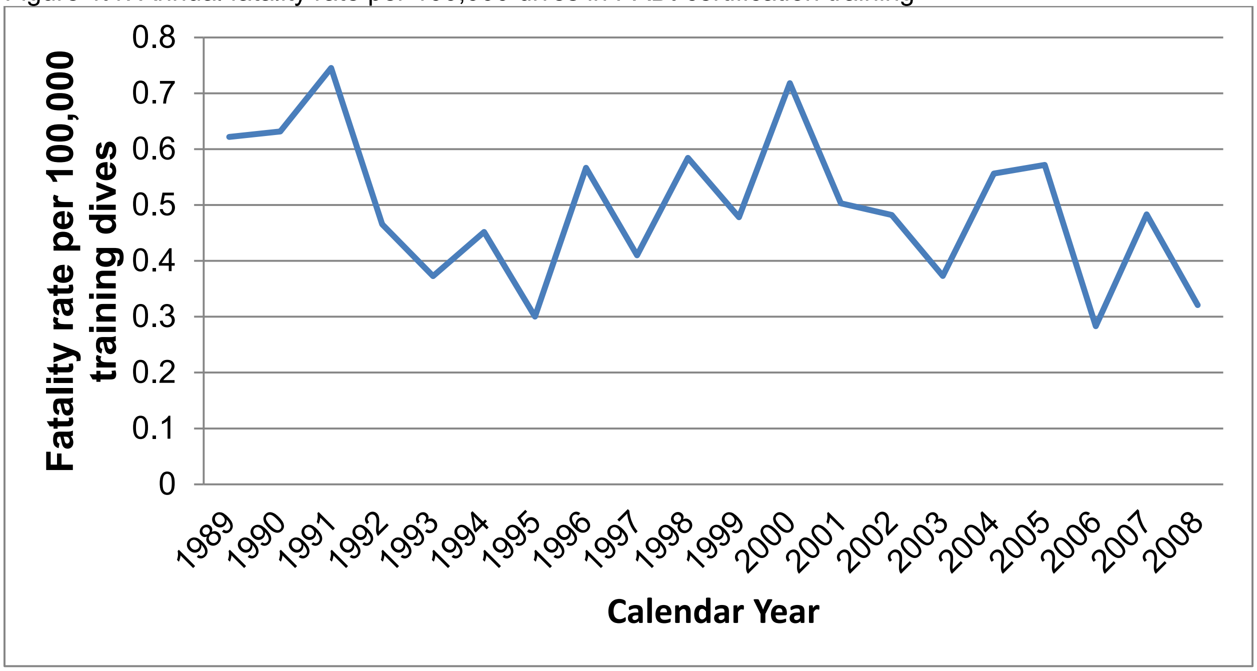
Table 1.1: Comparison of a defined Divers Alert Network diver population (18 years or older) with the general US population (18 years or older)

Variables	Percent (%) population	
	DAN	US
Age > 44 years	58.9	51.8
College education	72.0	33.5
Mean family income >$50,000	86.7	49.0
General health good or better	96.7	85.4
History of myocardial infarction	01.6	03.9
Coronary heart disease	03.1	03.8
Hypertension	26.0	28.6
Increased cholesterol	36.9	37.5
Diabetes	04.4	08.3
Overweight (BMI 25-29.9)	41.9	36.2
Obesity (BMI >=30)	20.7	26.9
Smoking	11.6	17.9
Insufficient physical activity	45.0	49.0
Disability	09.6	18.8

Scuba diving is a sport that involves challenges to mind and body, and has known risks of injuries and fatalities. Divers Alert Network (DAN) estimated a fatality rate of 16.4/100,000 person-years in their member population (Denoble et al., 2008). This number is very close to diving fatalities rates reported in a recreational diving population from Western Australia (1.3/10,000 person-years) (Buzzacott, Rosenberg, & Pikora, 2009a). Data in both these studies are all-cause diving mortality.

With advancement in diving equipment, training and safety procedures, fatality rates seem to have gradually decreased over past 20 years; this can be seen from Professional Association of Diving Instructor's (PADI) annual training data (Richardson, 2010). A plot for fatality rates among scuba diving students per 100,000 training dives over 20 years was created using this data (Figure 1.1). However, it is not clear if this decrease in the training fatality rates represent an actual decrease in the fatality rates in open water recreational diving. Fatality rates among DAN members remained unchanged from the year 2000–2006 (Denoble et al., 2008). Although the DAN reported rates were per capita measure instead of a per dive measure, which is what PADI data is. Hence, comparison of these reports may not be completely suitable. It is also hypothesized that DAN members may be more active than other recreational divers (Denoble, Ranapurwala, Vaithiyanathan, Clarke, & Vann, 2012).

Figure 1.1: Annual fatality rate per 100,000 dives in PADI certification training



DAN reports between 80-90 diving related deaths among US and Canadian divers every year (Denoble et al., 2008). Overall injury rates for all kinds of diving injuries are not known. Most studies focus their attention on decompression sickness (DCS) and arterial gas embolism (AGE), as they are treated at hyperbaric chambers and their information may be readily available. Conversely other injuries are treated at traditional medical care settings and not separately reported. One DAN study estimated DCS rate of 20.5/10,000 person-years (Denoble et al., 2012) in its member population over an eight-year period. DCS is just one kind of the many injuries of concern to scuba divers. It follows that scuba diving fatalities and injuries are rare events and hence hard to study. Data from a self-reported survey of divers suggest that the injury rate of all diving related injuries in 2010-2011 was about 3/100 dives (Ranapurwala, Bird, Vaithiyanathan, & Denoble, 2014). This was about 20 times greater than the rate of self-reported DCS symptoms from 2010-2011 which is about 1.52/1000 dives, and about 500 times more than the treated DCS cases from 2010-2011 which is 5.7/100,000 dives (Ranapurwala et al., 2014). Diving injuries amount to a significant financial burden due to treatment costs, residual disability, loss of productivity, and/or death (Buzzacott, 2012). Growing participation in the sport may further amplify the burden of injuries and fatalities. In addition, fatality rates increase with increase in age (Denoble et al., 2008) and since the diving population is rapidly ageing (Denoble et al., 2012) (also evident in table 1), presumed financial and healthcare burden (Buzzacott et al., 2009a; Buzzacott, 2012; Denoble et al., 2008; Denoble et al., 2012; Richardson, 2010) will be even greater. This makes a strong case for action.

E. Diving mishaps

Most common causes of diving-related mortality are drowning, arterial gas embolism with or without pulmonary barotrauma, cardiac events, aspiration of vomitus, trauma, marine animal injury, decompression sickness (DCS), and coincidental or unknown cause (Buzzacott, 2012). Most of the fatalities are labeled as drowning; however it is believed that drowning is preceded by other debilitating injuries that ultimately result in drowning (Denoble, Caruso, Dear, Pieper, & Vann, 2008). Denoble et al investigated 947 diving fatalities, identified sequence of mishaps and adverse events and grouped them in four major groups, viz. trigger of the event, disabling agent, disabling injury, and cause of death. They identified most common disabling injuries that lead to the fatality. Asphyxia, AGE, and cardiac-related causes comprised up to 88% of deaths, while unexplained loss of consciousness, DCS, and inappropriate gas (CO poisoning) constituted the remaining 12%. The authors identified sequence of adverse events and grouped them in four major groups, viz. trigger of the event, disabling agent, disabling injury, and cause of death (COD). It was suggested that the consequent fatalities could have been prevented by preventing triggering events (Denoble et al., 2008).

A similar study was conducted on all work-related deaths in Australia from 1982-1984 (Willamson & Feyer, 1990). They identified precursor events and contributing factors of all the fatalities. It is noteworthy that the triggers and disabling agents or contributing and precursor events could all be categorized into human errors, equipment failures, or environmental factors. Both papers conclude that appropriate prevention strategies aimed at these factors (triggers/ errors or precursor events/ accidents) could reduce the injuries and fatalities (Denoble et al., 2008; Willamson & Feyer, 1990).

While retrospective accident analysis may not always help establish the root-cause, it suggests that most accidents are triggered by mishaps (Denoble et al., 2008; Willamson & Feyer, 1990). Diving mishaps can be defined as unplanned and unwanted events that increase the risk of an injury. They can be classified as human errors (Acott, 1995a; Acott, 1999b; Edmonds & Walker, 1989), equipment failures (Acott, 1996; Edmonds & Walker, 1991), or adverse environmental factors(Edmonds & Walker, 1990).

Many interventions have been implemented to reduce the burden of diving-related injuries and fatalities from the diving community. Healthcare advancement and hyperbaric medicine focus on diver treatment, reducing disability, rehabilitation, and preventing death. However, it seems be prudent to act before the injuries occur. As discussed below there have been many improvements in technology over time. Consequently, divers diving in the 21st century are well equipped, educated, and safer than their predecessors who dove up until the early 1990's. While there is greater acceptance of technology, only a little consideration is afforded to prevent human errors, or equipment malfunction.

A Haddon examines the roles of human attributes, agent or vehicle attributes, and the physical environmental attributes in the pre-injury, during injury, and the post-injury phases. In the diving context, the human attributes are the attributes of the diver, the agent or vehicle is the diving equipment, and the environment is usually places like oceans, lakes, caves, etc. Cells A & B in the Haddon Matrix below (figure 1.2) are the pre-injury phases where human error and equipment problem may lead to mishaps and unsafe conditions. Identifying human error and equipment problems in this phase and preventing potentially ensuing mishaps and unsafe conditions is the key to prevent injuries, disabilities, and fatalities.

Figure 1.2: Haddon matrix of scuba diving

	Human **Diver**	**Agent/ Vehicle** **Diving equipment/ SCUBA**	**Physical Environment** **Oceans/ Caves/ Lakes**
Pre-injury	A	B	C
Injury	D	E	F
Post-injury	G	H	I

Most common mishaps are out-of-air scenarios, rapid ascent, equipment problems and entrapment (Buzzacott, Denoble, Dunford, & Vann, 2009; Denoble et al., 2008). Buzzacott et al analyzed a subset from 'project dive exploration' – a DAN cohort study that collected more than 150,000 dive profiles over 10 years. The authors studied four specific mishaps: Low to out of air, rapid ascent, computer-recorded rapid ascent, and buoyancy control. The incidence of these four diving mishaps in recreational divers was 2.17/100 dives (Buzzacott et al., 2009). A more extensive list of mishaps was used by DAN's summer 2012 cluster randomized trial (CRT), and can be found in the outcomes questionnaire (appendix 3). This list was created using the 'diving incident report form' from an ongoing study by DAN Asia Pacific (Australia) (Acott, 1994). However, this is not an exhaustive list, it acted as a prompt for divers to help them remember the mishaps; there is also an 'other' option to include anything else that might not have been on the list. Acott suggested that 30% of the reported diving mishaps (Acott, 2003) led to diving injuries. However, not all of the mishaps are reported, and hence it is difficult to know the actual percentage of mishaps that cause injuries. DAN CRT used mishaps as study outcomes based on three principles. Firstly, preventing mishaps will lead to better diving experiences. Secondly, to really prevent injuries we need to act before injuries have occurred, which means to essentially prevent mishaps and reduce unsafe diving conditions. And lastly, using diving mishaps as an outcome measure would allow us to study the effectiveness of our intervention much better because mishaps are more common than injuries. This would reduce the sample size requirement and the cost of the study.

F. Scuba diving interventions

Diving studies have noted that a large number of injuries occur as a result of preventable mishaps (Denoble et al., 2008; Edmonds & Walker, 1989; Edmonds & Walker, 1991). Traditionally, all injury prevention efforts in scuba diving have been targeted towards diving specific injuries like DCS, AGE, and other barotraumas. The post-world-war-II time of the 20^{th} century was characterized by many technological interventions that made scuba diving safer. Two of the notable ones are the use of oxygen-enriched-air and use of dive computers. Oxygen-enriched-air has less nitrogen, which reduces the saturation of tissues with inert gas at greater depths, thereby, reducing the incidence of DCS. On the other hand the tissues are saturated with higher oxygen, which, if managed properly, will be metabolized by the tissue. However, too much saturation with oxygen may lead to oxygen toxicity, which leads to convulsions and may prove to be fatal underwater (Hamilton, 2004). Dive computers are meant to reduce the diver's effort to calculate decompression obligations based on depth and time of the dive, adding a sense of safety and convenience to recreational diving. However, different dive computers follow different decompression algorithms and show different decompression obligations aimed to increase the bottom to maximum decompression limits, which may increase the risk of DCS. Moreover, it is hard to know when and if a dive computer is malfunctioning (Wilmshurst, 1998).

A few behavioral interventions have also had marked effect in reducing diving injuries. Free ascent – meaning rapidly ascending to the surface without a regulator in mouth while continuously exhaling, is taught to divers as a way of practicing an emergency ascent in case of being out of air. However, this technique is found to lead to PBT, especially in training dives (Lafère, Germonpré, & Balestra, 2009). Consequently, the Belgian Underwater Federation banned this technique, but it is still practiced in many parts of the world including the United States. Conservative decompression practices (CDP) have been utilized to reduce the incidence of DCS in divers with a previous history of DCS. Klingmann reported that CDP reduced the incidence of DCS in 23 divers over 0-11 years of follow-up from 20/10,000 dives to 3/10,000 dives. CDP is especially recommended for divers who have a right-to-left shunt (mainly a patent foramen ovale) where the incidence of DCS went down from 47.6/10,000 dives to 3.0/10,000 dives after the recommendation of CDP (Klingmann, Rathmann, Hausmann, Bruckner, & Kern, 2012).

Other interventions seek to identify, inform, and mitigate factors that increase the diver's susceptibility to DCS, e.g., flying after diving (FAD), and having a patent foramen ovale (PFO). FAD has long been considered a problem as it may precipitate DCS if enough pre-flight surface-interval (PFSI) is not allowed before flying (Vann, Gerth, Denoble, Pieper, & Thalmann, 2004). Various FAD trials done since 1993 have reported reduced incidence of DCS with increasing PFSIs (Vann et al., 2004; Vann et al., 2007). Billinger et al reported that a 5 year follow-up of 26 divers post PFO closure reduced their incidence of major decompression illness (DCS + AGE) from 5.6/10,000 dives at baseline to 0.5/10,000 dives at the end of the follow-up (Billinger et al., 2011). However, not all PFOs may have right to left shunting, hence, not all of them may need treatment. Also, CDP may be a better alternative than PFO closure in case of right-to-left shunting.

Concurrent to these advances in diving, the treatment of DCS advanced, too. Surface oxygen immediately after a dive is now commonplace as a first aid for suspected DCS. In the 1960s, the US navy developed hyperbaric oxygen treatment tables 5 and 6, still used today, to provide treatment to divers with DCS and AGE. The treatments are characterized by quick recompression followed by prolonged decompression while breathing oxygen with brief air breaks in between (Moon, 2004).

All these interventions and trials have fostered a culture of safety, awareness and have reduced the incidence of diving specific injuries like DCS, AGE, and consequent fatalities. However, there is a dearth of interventions to prevent non-diving-specific diving-related injuries. All the aforementioned interventions focus on the technical or medical aspects of injuries, which, although important, are not enough. Behavioral interventions allow divers to play a more active role in ensuring their safety. The only intervention that comes closest in doing so is CDP. A pre-dive checklist, when used immediately prior to the dive, can control most of diving injuries (specific and non-specific) that are caused by preventable diving mishaps.

G. Checklists

1. Checklist as an intervention

Remembering steps is important for accurate completion of any task. Avoiding, omitting, neglecting or not understanding the importance of these steps leads to human errors. Human error increases with increasing levels of stress (Acott, 1995a; Jablonski, 1965; Sexton, Thomas, & Helmreich, 2000). A further surge in the errors occurs due to difficult-to-operate or malfunctioning equipment (Acott, 1995a; Acott, 1996; Acott, 1999b; Acott, 2003; Jablonski, 1965). Errors are also supplemented by aberrations in natural conditions and the environment humans operate in. A Checklist can be a mnemonic (Scriven, 2000) or a reminder to do a certain set of actions. A proper checklist though must be a written physical tool that replaces mere mnemonics, the need to recall its components, and the need to remember to recall and use it. It is a simple and effective tool for reducing error (human and equipment), improve performance and meet safety requirements (Hales & Pronovost, 2006). Checklists do so by reducing the tendency to avoid, omit or neglect important steps in any task.

The importance of accurately completing tasks is greater in disciplines that involve higher stakes. Use of checklists originated in aviation in 1935 (Jablonski, 1965). In 1935 Boeing's Model 299 bomber aircraft considered as some of the best bombers even before it was tested and inducted in service by the army. However, during the first flight by the army, the pilots forgot one important task and the plane crashed. Two pilots died in the crash and it was a human error. In the search for solutions what came about was a pilot's checklist. Checklist, planning and training eventually made the army to induct more than 12,000 planes in to service, which are now known as the famous B-17s.Today pilots are required to complete checklists for their equipment, flying procedures, and even their individual health and mental status (Boorman, 2001; Civil Air Patrol, June 2004; Frick, 1989; G.Morrow, Leirer, Andrassy, Hier, & Menard, 1998; Golemboski, 2011; Hales & Pronovost, 2006; Helmreich, 2000; Sharps, Wilson-Leff, & Price, 1995; United States Air Force, 1969). Checklists are enforced upon pilots and crew members in armed forces as well as commercial airliners. Not only do these checklists enforce safety standards but they allow data collection and reporting to ensure a continued scrutiny and amendment of procedures (Scriven, 2000).

Another high risk setting is surgery. Based on the 2008 guideline of safe surgery by the World Health Organization (WHO) (World Health Organization, 2009), a surgical checklist was developed by Hayes et al (Haynes et al., 2009) in 2009 that aimed to reduce post-surgical deaths and morbidity. This checklist was administered in three stages: Before anesthesia, immediately before incision and before patient is to be moved out of the operation theater. The checklist intended to improve team communication and streamline the process of care. Its efficacy was tested in a trial in eight cities (from eight different countries) in more than 7500 patients. The trial compared patient outcomes pre- and post-intervention. It was observed that post-intervention the rate of post-surgical deaths and complications was reduced significantly as compared to pre-intervention. The checklist was subsequently adopted by WHO (World Health Organization, 2008) and its universal adoption in the National Health Services of UK by 2010 (Abdel-Galil, 2010) was announced. Positive outcomes increased with increased compliance (Van Klei et al., 2012) and better strategies for efficient implementations (Healy, 2012). The use of checklist improved communication, attitudes and satisfaction of patients and staff alike (Böhmer et al., 2012; Takala et al., 2011). Ko et al (Ko, Turner, & Finnigan, 2011) suggested that effectiveness of checklists may vary based on previous training, design of the checklist and the outcome measured; hence they advised caution in generalizing the findings. It has been noted that explanation of the use of checklists and communication about its effects are necessary to inspire a buy-in among the users, without which effectiveness of checklists is diminished (Conley, Singer, Edmondson, Berry, & Gawande, 2011; Fourcade, Blache, Grenier, Bourgain, & Minvielle, 2012; Hales & Pronovost, 2006).

Edwards et al developed a checklist to promote development of intervention projects that focus on quality of patient care and patient safety, thus ensuring improved delivery of medical care (Edwards et al., 2007). Recreational and health activity programs have also used checklists whilst improving outcomes, viz. Bikes, Blades and Boards program at Hamilton Health Sciences in Canada educates children about brain, various injury mechanisms to brain, prevention of those injuries, use of helmets in the prevention, the proper way to wear a helmet, and to assess the condition of a helmet. Following the education, every child's performance of wearing helmets is judged by using a Helmet checklist, which addresses the mishaps related to the condition of the helmet, proper fit, and the way a helmet is worn (Blake, Velikonja, Pepper, Jilderda, & Georgiou, 2008). Participants were 2nd grade students. They were given the checklist to take home and show to their parents so that they could continue to monitor and guide their children about proper helmet use. The experimental group received the education and the checklist while the control group did not. Helmet use for both the groups was rated by a blinded evaluator using the helmet checklist. It was observed that children who participated in the program and used the checklist (experimental group) scored better in helmet use than children who did not. One year later these children were re-evaluated and the children in the experimental group retained the helmet using skills.

Others have proposed to design checklists for self-observation to promote safe driving behavior among drivers and prevent motor vehicle injuries (Nielsen, 2010). One researcher placed a magnetic sign behind his car that said "Please use turn signals". He observed that prompting drivers this way improved their use of turn signals by 33.5%.

2. Pre-dive checklists

Use of check-lists in recreational scuba diving has is widely considered to be a good idea by the diving community, but rarely promoted or put in action. Standard pre-dive procedures include a thorough check of equipment, planning and organization of dive. A pre-dive checklist is expected to reinforce these procedures, which may reduce diving mishaps related to human and equipment errors. Divers are trained to conduct pre-dive checks and checklists may be found in all the training agency manuals but divers do not copy them and/ or use them. It is suggested that incidences of diving mishaps and injuries may be reduced by reinforcing the use of pre-dive checklists (Acott, 1995a; Acott, 1995b; Acott, 1996; Acott, 1999b; Buzzacott, Rosenberg, Heyworth, & Pikora, 2011; Denoble et al., 2008; Edmonds & Walker, 1989; Edmonds & Walker, 1990; Edmonds & Walker, 1991).

The US Navy uses a thorough pre-dive checklist which is strictly regulated (US Navy, 2008a; US Navy, 2008b). The Professional Association of Diving Instructors (PADI) uses an acronym 'BWARF' for a pre-dive check (Professional Association of Diving Instructors, 2008) for recreational divers. The acronym emphasizes issues with the **B**uoyancy compensator device, **W**eights, **A**ir, **R**eleases and a **F**inal ok. The National Association of Underwater Instructors diving manual includes various checklists including an on-site planning checklist with an acronym – SEA BAG (National Association of Underwater Instructors, 2000). The safety topics emphasized by this acronym are **S**ite survey, **E**mergency, **A**ctivity, **B**uoyancy, **A**ir, and **G**ear and Go. American Academy of Underwater Sciences also advises its divers to conduct a pre-dive check and has provided a format in their manual (American Academy of Underwater Sciences, 2009). Although present in the diving manual these checklists are not provided to the divers in printed form such that they may be used in the field. Besides, it is not known if either of these checklists is used routinely in the field. Moreover, none of these checklists have been evaluated for effectiveness. A more detailed literature review about the components of different pre-dive checklists from other agencies will follow as a part of the dissertation, including but not limited to a table comparing different checklists.

3. DAN pre-dive checklist

There is no gold standard pre-dive checklist. The checklists provided by the leading training agencies contain mnemonics. While remembering mnemonics may be easy, but in remembering the mnemonics divers undermine the multiple action items that characterize each mnemonic item. Hence, DAN developed a pre-dive checklist that was used in a cluster randomized trial (Appendix 1). The intent of the trial was to evaluate the effect of using a pre-dive checklist immediately before diving on the incidence of diving mishaps among recreational scuba divers. The pre-dive checklist was developed with input from diving medicine research experts, dive medicine physicians, diving instructors, and diving medical technicians. It was pretested on 16 divers in a field setting to ensure clarity of content, assess the effort involved in completing a checklist, and assess the acceptability of checklist by divers. Extreme depth-time dive profiles and running low on air are known to increase a diver's risk for having a mishap and/ or injury (Buzzacott et al., 2011). To address this, a dive plan was added to the checklist. Participants were asked to plan the depth of their dive and to estimate their gas needs for different stages of dive (gas management plan). Additionally, the pre-dive checklist had four dive tips, and a post-dive log to record actual dive parameters.

Using a cluster randomized trial design we investigated if the DAN pre-dive checklist could reduce the incidence of diving mishaps in recreational scuba divers? This evaluation of the checklist was innovative in many regards. Development of a more encompassing but concise pre-dive checklist for recreational diving was the foremost innovation of this study. So far diving studies have only focused on injuries and deaths. This is the first study to use diving mishaps as outcomes. Use of a gas management plan made the intervention more compelling as it emphasizes appropriate gas management, which may reduce mishaps like running out or low on gas. This was the first pre-dive checklist to include a gas management plan. The administration of the checklist immediately before dive at the dive site/ boat was an important component of this study. A randomized controlled trial design using a safety checklist as an intervention has been used previously in injury studies (Blake et al., 2008), but not to address diving related issues. This design allows causal interpretation in evaluating the effectiveness of checklists. Randomization on days to prevent cross-contamination among participants is another important innovation. Details about these are provided in the approach section.

II. STUDY AIMS

Standard pre-dive procedures include a thorough check of equipment, planning and organization of the dive. Different training agencies may advocate different training methods however pre-dive check procedures remain more or less consistent. Divers are trained to conduct step by step pre-dive checks but their compliance is questionable. In summer 2012, Divers Alert Network (DAN) conducted a cluster randomized trial (CRT) to study the effect of using a pre-dive checklist of safe diving practices, immediately before the dive, on the incidence of diving mishaps in recreational scuba divers. The principal investigator (PI) of this study was Shabbar I. Ranapurwala, BHMS, MPH - a research assistant at DAN. A pre-dive checklist is expected to reinforce compliance with pre-dive check procedures and is hypothesized to reduce diving mishaps related to human errors and equipment failures. To test this hypothesis, we will:

1. Investigate the effect of administration of a pre-dive checklist at the time of diving, on the incidence of diving mishaps in recreational scuba divers.

Rationale: It is hypothesized that the administration of a pre-dive check list at the time of diving may improve compliance with standard pre-dive check procedures, decrease human error and equipment problems, and may consequently reduce the incidence of diving mishaps. To the best of our knowledge, this study will be the first to evaluate the efficacy of checklist use in scuba diving.

Method: Data for this aim comes from the DAN CRT that had an intervention arm composed of divers who received a pre-dive checklist which included a checklist of procedures, gas management plan, dive tips, and a post-dive log (Form-A: appendix 1) and a control arm with divers who received a control form which only had a post-dive log (Form-B: appendix 2). Diving mishaps were assessed using a post-dive outcomes questionnaire (Appendix 3). Incidence of diving mishaps – that can be addressed by the intervention, were compared from both the groups.

2. To evaluate the relationship between a diver's own pre-dive checklist use and the incidence of diving mishaps in recreational scuba divers.

Rationale: Several training agencies advocate diving safety by promoting the use of checklist that they develop themselves. However, these checklists are not uniform, not evaluated and include different degrees of detail. The control group data from the CRT was used to examine the total effect of all the pre-dive checklists in the field with an aim to appreciate and quantify the effect of their use on the incidence of pre-dive mishaps.

Method: Data was collected for the use of a self-pre-dive checklist (training agency developed, self-developed; physical or mental) and the incidence of diving mishaps with the help of a post-dive outcomes questionnaire. The incidence of diving mishaps incidence among those who use their own pre-dive checklist (physical) was compared with those who do not use any pre-dive checklist of their own. This analysis was conducted in the control group participants, only.

3. To evaluate the factors affecting the adherence to the pre-dive checklist.

Rationale: A pre-dive checklist is a tool that may improve diving safety. However, when a pre-dive checklist is provided to divers, some adhere to the checklist, while others do not. Divers who do not adhere to the provided pre-dive checklist may have different risk perceptions than those who do. Identifying the individual and environmental factors related to diving adherence may provide insight about groups that require greater persuasion to help them continue using a pre-dive checklist.

Method: Adherence to pre-dive checklist was measured and a binary variable for adherence was created. The relationship of individual and environmental factors like age, sex, dive location, previous use of own pre-dive checklist, and average annual dives with adherence to pre-dive checklist was examined using exploratory regression analysis.

III. DATA COLLECTIONS METHODS AND MATERIALS

A. Study design

By utilizing a cluster randomized trial (CRT) design, this research intended to evaluate the effectiveness of using a pre-dive checklist immediately before diving on the incidence of diving mishaps among recreational scuba divers. The intervention was randomly assigned by location-day such that each day all enrolled participants at same location were either all control or all intervention group participants. This prevented bias due to cross-contamination. Each diver could participate in the study only once. The dive shops and boat crew were informed about the study in advance and advised not to disclose study information to the divers.

B. Instruments

There were four instruments utilized in the study: Pre-dive Checklist (intervention – Form-A), Control form (Form-B), Contact-Information form, and Outcomes Questionnaire. The pre-dive checklist included a checklist of procedures, a gas management plan, and a post-dive log (appendix 1). The control form was given to the control group participants and included only a post-dive log (appendix 2). The contact-information form was used to enroll and track participants, this form also noted the participant's age, gender and racial/ethnic background (appendix 4). The outcomes questionnaire was given to both intervention and control group participants at the end of their dive day (appendix 3). It included information on incidence of mishaps among divers, information on height, weight, brief medical history and diving history. Participant identifiers were collected while taking consent for participation. We are interested to see if reminding the divers to conduct proper pre-dive checks reduces the incidence of diving mishaps.

The intent of using pre-dive checklists is to prevent injuries. To do so, precursors of injuries i.e., mishaps and unsafe conditions must be prevented. Hence, the outcomes of interest in this study were mishaps and unsafe conditions. Besides diving-related injury is a rarer outcome. It would require larger sample size to obtain conclusive evidence of checklist effectiveness on dive-related injuries, rendering the study expensive and time consuming.

C. Interns and training

Four trained interns were hosted by busy dive shops located at 4 coastal sites – one in North Carolina, two in Cozumel (Mexico), and one in Cayman Islands. Interns collected data at these sites from June 1 to August 17, 2012. Interns were college students from different universities across the United States pursuing a bachelor's degree in science. Each of them had advanced diving experience, some previous experience with observational research, and excellent communication skills. They were recruited via a competitive application and interview process. They received one week of training prior to study. Training included ethical principles of research, understanding the study design, the importance of randomization in research studies, information on the study materials, skills to recruit participants and conduct the study, online data entry, and maintenance of study records. DAN Education staff trained and certified the interns in Basic Life Support and First Aid, Oxygen First Aid for Scuba Diving injuries, and First Aid for Hazardous Marine Life Injuries. All interns completed DAN research ethics training modules. All the above training was provided at DAN's headquarters in Durham, NC. Interns also received two-day field training at Wilmington, before being sent to their specific locations for data collection. All the study related training was provided by the PI.

D. Administration and data collection

For each location-day separate packets of study materials were made. Half of the packets were intervention packets and the remaining half were control packets. Each packet contained 30 sets of consent forms, laminated Form-A (intervention) or Form-B (control), outcomes questionnaire, marker-pens and one contact-information-form (Appendix 4). Packets were randomized beforehand at DAN using a SAS random number generator and then sequentially numbered. An excel-spreadsheet of the randomized and numbered packets was made in which the study arm for each numbered packet was noted. This spreadsheet was used to cross check the intervention and control arms of the collected data.

Interns who administered the study had to pick one sequentially numbered packet every day before going to work.

Divers were briefed about the study and those who agreed to participate were asked to provide consent. At this time, interns also collected the participant's name, contact information, age, gender and race using the Contact-Information Form (Appendix 4). Name and contact information allowed for censoring repeat participation on other days. Participants received either Form-A, or Form-B and explanation for its use; interns noted the form-number/ participant number on the Contact-Information Form. When the participants completed their dives, or upon divers' return to the pier, interns collected the study form (A or B) and asked the participants to answer the outcomes questionnaire; this questionnaire had the same number as the participant's form (Form-A or Form-B). Interns then collected back completed outcomes questionnaire at the same time.

E. Study Population

1. Eligibility

Any participating diver had to be more than 18 years of age. They had to have a valid diver certification, had to be planning to dive the day they were recruited in the study, had to be deemed fit for diving by the dive operator, and had to have working knowledge of English.

The checklist was pretested at one of the study locations two months prior to the CRT, so that lessons learned from the pretesting would help the planning of CRT implementation. Investigators only wanted to use the information from the pretesting to plan out the CRT and did not intend to report / publish the data otherwise. An IRB application for this was submitted to DAN IRB, which determined the pretesting to be exempt.

2. Pretesting

i. Recruitment

Participants for pretesting were recruited by the study PI at the pier of Aquatic Safaris dive shop at Wilmington, NC, before they board the charter boat that takes them to the sea for diving. Aquatic Safaris had two dive boats going out. Sixteen divers were enrolled for pretesting from both the boats. All the sixteen divers were asked to complete the pre-dive checklist before their dives and an outcomes questionnaire when they returned back to the pier. There was no follow-up of these divers after the pretesting.

ii. Consent and processes

The PI informed the participants about the instruments and explained the goals, risks, benefits, and the voluntary nature of participation. The PI distributed the pre-dive checklist, and explained its use. The PI then went on-board on one of the boats to observe the divers during their diving trip. On their return to the pier, participants were asked to answer the outcomes questionnaire. The PI recorded the events of the day and participants attitudes towards the checklist.

The Pre-dive checklist and the outcomes questionnaire were then refined based on the lessons learnt from pretesting. Pretesting also helped us establish best practices for recruitment and implementation of the study.

A complete study plan was decided upon and an IRB application was submitted to DAN IRB for full review, and was approved on March 29, 2012. An amendment was submitted to the DAN IRB, which was reviewed and approved on May 8, 2012. A concurrent application was submitted at UNC non-biomedical IRB with a request to defer to DAN IRB; this was approved on May 29, 2012.

3. Group Randomized Trial

i. Recruitment

Interns recruited the participants while travelling with the divers on a charter boat or before the divers boarded the boat. Data collection continued from June 1st through August 17th for a total of 70 location-days (40 intervention days and 30 control days). On average, interns collected 29.19 dives per location-day (range 15-50 dives) by recruiting on an average of 15.43 divers/ location (range 8-25 divers). It must be noted that the interns were out in the field longer than the location-day of data collection. This was due to bad weather and days with little or no recruitment due to non-participation or repeat divers. In total 1080 divers completed the study. Those who completed the study contributed total of 2043 dives, 1205 intervention dives and 838 control dives. Total number of divers present on each dive boat at the time of enrollment is not known; hence, calculating participation rate may be difficult.

ii. Consent

Interns informed the subjects about the goals and objectives of the study, explained the risks, benefits, and voluntary nature of participation including participants' right to withdraw from the study at any time. Subjects were also be informed that non-participation or withdrawal would not result in any penalty or loss of services that they were otherwise entitled to receive from DAN or the partner dive shop. Those who volunteered were asked to sign a consent form (Appendix 5).

iii. Data management/ Quality control

Data was collected from three different sites using the same pre-dive checklist and outcomes questionnaire. All the interns were trained to enter data to online forms, which were identical to the pre-dive checklist and outcomes questionnaire. All the records are numbered and contain identification and contact information of participants. This ensured that pre-dive checklist and outcomes questionnaire from the same participant are entered together. Data was monitored on weekly basis by the PI.

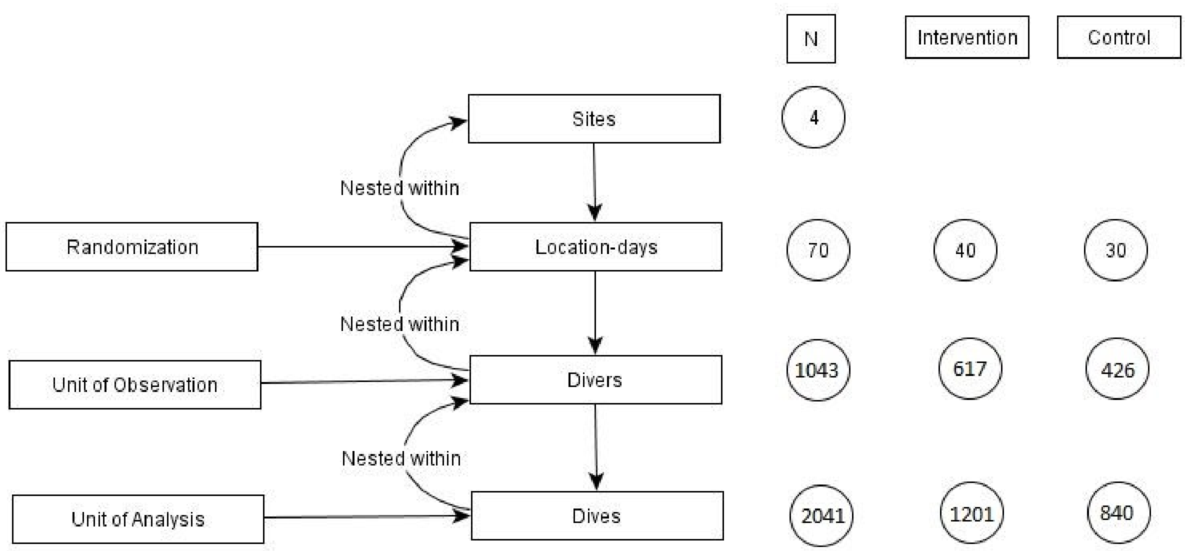
This study was approved by the institutional review boards (IRB) at DAN # 009-12 on 03/27/2012 and the University of North Carolina (UNC) # 12-1051 on 05/29/2012, and further renewed by DAN IRB on 02/06/2013 and UNC IRB on 02/25/2013.

F. Data

The distribution of divers and the dives at the four study sites is shown below (table 3.1). Study sites 1 and 2 had more intervention group participants as compared to control group. The two groups were balanced at study site 3 and 4. Site 1 and Site 2 had more intervention dives than control dives; however, the number of dives in the intervention and the control group were almost equal at site 3 and 4.

This imbalance between intervention and control groups was because of the location-days were not block randomized. Instead interns were given materials that would last them for 40 days (20 intervention packets and 20 control packets). These 40 days were randomized beforehand at DAN using SAS random number generator. However, interns were not able to complete all 40 days of data collection. Interns at sites 3 and 4 completed 18 envelopes each while intern at site 1 completed 19 envelopes and the intern at site 2 completed 15 envelopes only. Due to randomization, sites 1 and 2 had more intervention packets earlier as compared to the control packets, and the control packets that were to be used later could not be used. Secondly, the number of divers enrolled on any given study day (intervention / control) were not the same. Interns enrolled between 8-25 divers (mean=15.43) for a range of 15-50 dives (mean=29.19). Due to these two factors, the number of intervention days and control days varied and so did the number of divers enrolled in both the groups. A schematic representation of the data collection process shows the distribution of data between the intervention and the control arms (figure 3.1).

Figure 3.1: Nested structure of the data



There were more males in the study than females at all the study sites; 68% vs 32% overall. Majority of participants were Caucasians or White (94.8% overall) at all the study sites, followed by Hispanic population, especially in Cozumel (2.5% overall), followed by African American / Black population (1.5%) followed by Asians (1.1%).

Table 3.1: Demographic distribution of the data

		Location									
		Site 1		Site 2		Site 3		Site 4		Total	
		N	%	N	%	N	%	N	%	N	%
Location-days	**Intervention**	9	60.0	13	68.4	9	50.0	9	50.00	40	57.14
	Control	6	40.0	6	31.6	9	50.0	9	50.00	30	42.86
Divers	**Intervention**	111	59.0	223	69.9	142	50.9	141	54.9	617	59.2
	Control	77	41.0	96	30.1	137	49.1	116	45.1	426	40.8
Dives	**Intervention**	243	56.6	423	71.3	281	51.6	254	53.67	1201	58.84
	Control	181	43.4	170	28.7	268	48.4	221	46.33	840	41.16
Gender	**Males**	103	54.8	214	67.1	189	67.7	202	78.6	708	67.9
	Females	85	45.2	105	32.9	90	32.3	55	21.4	335	32.1
Race	**White**	175	93.1	295	92.5	267	95.7	252	98.0	989	94.8
	Black	6	3.2	7	2.2	2	0.7	1	0.4	16	1.5
	Asian / PI	5	2.6	2	0.6	2	0.7	2	0.8	11	1.1
	Hispanic	2	1.1	15	4.7	8	2.9	2	0.8	27	2.5

Site 1 – Grand Cayman; Site 2 – Cozumel 1; Site 3 – Cozumel 2; Site 4 – North Carolina

Age was divided in six categories. Age group 45-54 years had highest participation (28% overall), followed by 35-44 years of age group (22% overall). The breakdown for each study site is presented in table 3.2.

Table 3.2: Age distribution of participant's at the four study locations

		Location									
		Site 1		Site 2		Site 3		Site 4		Total	
		N	%	N	%	N	%	N	%	N	%
Age	**18-24**	14	7.5	61	19.1	20	7.2	44	17.1	139	13.3
	25-34	21	11.2	56	17.6	64	22.9	39	15.2	180	17.3
	35-44	38	20.2	66	20.7	64	22.9	70	27.2	238	22.8
	45-54	57	30.3	96	30.1	78	28.0	73	28.4	304	29.1
	55-64	47	25.0	34	10.7	43	15.4	27	10.5	151	14.5
	65+	11	5.8	6	1.8	10	3.6	4	1.6	31	3.0
	Total	188	30.6	319	18.0	279	26.8	257	24.6	1043	100

Site 1 – Grand Cayman; Site 2 – Cozumel 1; Site 3 – Cozumel 2; Site 4 – North Carolina

Use of self-pre-dive-checklists is described in table 4. About 20% participants said that they do not use a self-pre-dive-checklist. Those who said that they use a self-pre-dive-checklist were further asked about the type of checklist they used. Almost 60% of all participants said that they use a memorized checklist that they made themselves. About 12% said that they use a training agency checklist that they memorized, while just over 6% participants said that they use some form of physical pre-dive-checklist (training agency or self-made). 2% participants mentioned other kinds of checklists.

Table 3.3: Use of self-pre-dive-checklist at the four study sites

Self-Checklist Use	Location								Total	
	Site 1		Site 2		Site 3		Site 4			
	N	%	N	%	N	%	N	%	N	%
None	28	14.9	79	24.8	62	22.2	34	13.2	203	19.5
Self – Mental	120	63.8	161	50.5	181	64.9	175	68.1	637	61.1
Self – Physical	8	4.3	15	4.7	4	1.4	15	5.9	42	4.0
TA* - Mental	31	16.5	52	16.3	26	9.3	25	9.7	134	12.8
TA* - Physical	1	0.5	12	3.7	6	2.2	8	3.1	27	2.6
Total	188	18.0	319	30.6	279	26.8	257	24.6	1043	100

*Training Agency; Site 1=Grand Cayman; Site 2=Cozumel 1; Site 3=Cozumel 2; Site 4= North Carolina

Note: Mental checklists - those that are memorized by the divers, are not really checklists. A checklist must be a physical written/printed tool that contains safety procedures to be followed.

G. Aim 1

Investigate the effect of administration of a pre-dive checklist at the time of diving, on the incidence of diving mishaps in recreational scuba divers.

1. Exposure Assessment:

Exposure of interest for aim 1 was the presence or absence of the intervention pre-dive checklist. This was recorded as a binary variable. The pre-dive checklist (Form A) had two parts, both of which together serve as an intervention, 1) checklist of procedures, and 2) gas management plan. On page-2 of the pre-dive checklist there were four dive tips, which are accepted diving rules that the U.S. Navy enforces among Navy divers (US Navy, 2008a; US Navy, 2008b). Also, on page 2 was a dive log where divers could record up to 4 dives for the day they participate in the study. All of this together composed the pre-dive checklist (or the intervention). There were a total of 14 safety measures. These safety measures were developed to reduce mishaps that might be caused by human errors (Acott, 1995a; Acott, 1999b; Edmonds & Walker, 1989) and/or equipment errors (Acott, 1996; Edmonds & Walker, 1991). The pre-dive gas management plan was intended for a diver to plan four aspects of their dive; the intended depth of the dive and amount of gas the diver will retain for turn-around, ascent and back-on-board reserve. Research shows that depth-time profiles and gas management errors predict the risk of diving injuries (Buzzacott et al., 2011). This was intended to get the diver to plan a dive and minimize mishaps like running low or out of gas. The post-dive log asked the participants to report the actual dive values for the same aspects they planned for.

Completing the safety check and marking it off in the checklist took 5-7 minutes of a participant's time. Divers were advised to conduct a safety check before each dive; however they checked the checklist only once. There is no way to find out if the divers actually conducted a safety check before each dive, or conducted a safety check only before the first dive, or else did not do the safety check at all and just checked the boxes on the checklist (before or after their dives). This is further discussed in limitations.

The participants in the control group received a control form (Form B), this only contained a dive log good for recording up to 4 dives for the day they participate in the study. This dive log was identical to that in the intervention pre-dive checklist (Form A).

We assessed the participants in the intervention group for adherence to the intervention pre-dive checklist. Three criteria were used to determine adherence, such that all three must be met to be adherent. The criteria were 1) a diver must have reported the starting tank pressure on the checklist, 2) a diver must have checked at least 10 procedures out of the 14 on the checklist, and 3) a diver must have added at least one of the 4 values on the gas management plan. All the participants in the control group were considered adherent.

Based on the adherence we used three approaches to data analysis for aim 1. The approaches were intent-to-treat analysis, per-protocol analysis, and marginal structural model analysis. The intent-to-treat (ITT) analysis kept all the participants randomized to the intervention in the intervention group irrespective of their adherence status. The per-protocol (PP) analysis removed the non-adherent participants from the intervention group. The marginal structural models (MSM) provides solution to the question – what would have happened if all the non-adherent would have been adherent? In doing so MSM calculated the inverse probability of being adherent for all intervention group participants, and used these inverse probabilities as weights. All the participants in the control group were given an inverse probability weight of 1. Thus the ITT analysis estimates the effect of treatment given, while the PP and MSM analysis estimate the effect of treatment received.

2. Outcome Assessment:

Outcomes were collected in this study using outcomes questionnaire. The questionnaire included a list of events that could be checked off if they occurred during any of the dives the participant made that day, with space to specify events that were not mentioned in the list. This questionnaire took about 5-10 minutes to be completed by a diver.

The questionnaire was employed when the participants completed their intended dives for the day. Depending on where the interns provided questionnaires to the participants, viz., on the dive boat or pier, there was a 15 minutes to 2 hour time lag between the dives and the time when the diver answered the questionnaire.

The questionnaire included mostly specific closed-ended questions and only a few open-ended questions where needed; this was intended to reduce errors in data collection, entry into the online system, and reduce amount of coding for open-ended questions. While the participants answered this questionnaire, interns were present at the pier / dive boat and were able to assist them, if they had difficulties. The primary outcome of interest was the number of diving mishaps.

An event is a change in condition, state, energy or health that is distinctive in space and time. An event, during the dive, may have significant impact (or be a potential threat) on the evolution of dive whether or not it causes injury. This event is called a mishap. Some events may occur in the pre-dive period and the checklist may help to detect it, and prevent a mishap during dive. Some of these can be easily rectified and the dive may be executed, while some may force the diver to not dive. These conditions that do not occur during the dive are not diving mishaps – we classified them as unsafe conditions.

To be able to classify the outcome events correctly we need to define a dive first. A dive starts when the diver enters the water equipped with scuba with an intention to submerge, and the dive ends when the diver leaves the water.

Furthermore, some mishaps may carry a relatively higher risk of causing a severe injury than others. Accordingly, the outcomes were classified in three groups: 1) Major mishaps: These are mishaps that occur during the dive and are more likely to cause injury; or the potential injury is severe. 2) Minor mishaps: These are mishaps that occur during the dive and are less likely to cause injury; or the potential injury is mild. 3) Unsafe conditions: These are conditions that exist pre-dive and if detected, may make a diver to undertake some corrective action. The diver may choose to dive as planned after correcting the condition, or the condition may be too difficult to rectify and the diver may choose to not dive. If not detected pre-dive and diver does dive with unsafe condition present, the risk of injury is increased.

The separate groups are presented in table 1 below. The effect of intervention will be assessed on each of these groups or the combination of these groups.

Table 3.4: Categories of scuba diving mishaps

Major mishaps	Minor mishaps	Unsafe conditions
Rapid ascent/ Computer recorded rapid ascent	Air used frequently to maintain buoyancy	Unable to locate alternate regulator
Entanglement/ entrapment	Changed buoyancy due to dive suit	Dive computer not turned on before dive
Lost buddy contact	Unable to clear mask	Dive tables – misread
Buddy breathing	Unable to release weights	Didn’t know how to inflate/ deflate
2nd stage regulator malfunction	Unable to clear mask/ caused panic	Confusion in inflate/ deflate buttons
Low to our of air	Weights belt/ weights dropped	Unfamiliar with the use of BCD
Spontaneous inflation	Fins lost/ loose/ dislodged	Dive computer battery problems
Free Ascent	Fins strap broke	Unit confusion on the dive gauge
Content hose rupture	Air not turned on/ not fully on	Tight/ uncomfortable dive suit
Free flowing 2nd stage	Safety Stop missed	Incorrect BCD size
	Multiple ascents	Overweight
	Equalization problems	Underweight
	O-ring problem	Not familiar with Dive computer
	Octopus reg snagged	Computer hard to understand
	Buddy mismatch	Size changed between dives
	Leaking BCD	Not used before
	Mask flooded/ Dislodged/ Panic	Unable to understand dive tables
	Computer stopped working	Fins - Caused cramp
	Mask squeeze	Max depth indicator problem
	Mask strap broke	Inaccurate dive gauge
		Inadequate buoyancy
		Tank not well secured

We listed a total of 57 mishaps and unsafe conditions in the outcomes questionnaire. These were divided under the headings – Dive Suit, Environment, Ascent, Buddy, Air & Regulator, BCD, Mask, Weights, Dive Computer, Dive Gauge, Tank, Dive Tables and Fins, each of these categories also had an ‘other’ option, where divers could specify the mishap if it was not listed by us.

Each participant could report one or more events. Each of the three types of events – major mishaps, minor mishaps, and unsafe conditions were totaled. The total number of major mishaps, minor mishaps and the unsafe conditions are count data.

For Aim 1, we only considered those outcomes events that could be addressed by the intervention (Form A). There were 28 such outcome events. These events and the explanation for their selection are given in the table below.

Table 3.5: Mishaps and unsafe conditions addressed by the intervention

Checklist message	**Mishaps / Unsafe conditions addressed**	**Explanation**
Confirm you are healthy enough to dive		Being healthy is vital for a safe dive
Review hand signals with your buddy	Buddy mismatch	Reviewing hand signals helps establish rapport between divers and the mishaps are avoided
	Lost buddy contact	
Make sure your air is turned on *(Check by breathing through the regulator). What is the starting tank pressure?*	Air not turned on/ not fully on	Checking the air in the tank, allows the diver to appreciate the amount of gas in the tank before the start of the dive, check proper reading (units) and functioning of the regulator
	Unit confusion on the dive gauge	
	Low to out of air	
Check all the hoses are connected properly and there are no leaks	Low to out of air	Leaks may cause a diver to run out of air more quickly
Secure all equipment to your body/ check all straps: □ Mask □ Buoyancy Compensator Device (BCD) □ Tank □ Fins	Mask squeeze	Securing different equipment allows the diver to appreciate the condition of the equipment, its wear and tear and to detect if the equipment needs to be repaired or replaced
	Unable to clear mask	
	Mask strap broke	
	Tank not well secured	
	Fins lost/ loose/ dislodged	
	Fins strap broke	
Make sure to have completed a buoyancy check for this suit	Changed buoyancy due to dive suit	Detecting this may allow for correction by adjusting weights

Check if the weight releases work properly	Unable to release weights	Weights help maintain buoyancy and are critical to maintain control over a dive especially descent and ascent. In emergency ascent or rescue, the release of weights makes operation easier. Inability to discard weights in some situation at surface causes drowning.
	Weights belt/ weights dropped	
<u>Test your BCD</u> □ Inflate □ Deflate □ Integrated weights (if so equipped) □ Releases	Spontaneous inflation	It is vital to know the different functions of a BCD. Many divers rent gear and may not know different capabilities and functions on a given BCD. This will avoid mishaps that may lead to severe injuries
	Didn't know how to inflate/ deflate**	
	Confusion in inflate/ deflate buttons**	
	Unfamiliar with the use**	
	Inadequate buoyancy	
	Unable to release weights	
Test the spare second stage regulator (it should not free-flow)	2nd stage regulator malfunction	Malfunctioning may lead to leak of air, which may lead to running low or out of air, cause rapid ascent, panic, etc. Regulator may not provide gas when needed.
	Unable to locate alternate regulator	
Make sure that you are satisfied with the fit of your suit		An uncomfortable diver may have problems with breathing, buoyancy or just be distracted throughout the dive.
Carry a cutting tool with you if allowed	Entanglement/ entrapment	A cutting tool may allow one to become free of

		entrapments
Familiarize yourself with your buddy's gear	Buddy breathing	Familiarizing with buddy's gear will allow a diver to be at ease, if buddy breathing has to be initiated
Make sure your depth gauge (once you start descending) and/ or computer are working □ Battery check □ Understand their use properly	Unit confusion on dive gauge Dive computer not turned on before dive Dive computer battery problems	Making sure dive gauge and computer works properly before the dive and at the beginning of descent allow the diver accurate information on depth, time and remaining gas, this will prevent many other mishaps and injuries
Once in water do a final-ok buddy check before descending		Helps diver to realize everything is working before they start descending into the water
Dive plan: *(Plan your dive before diving)*	Rapid ascent* Computer recorded rapid ascent* Buddy breathing Low to out of air	A proper dive plan conserves sufficient gas for the time and circumstances and thus prevents situation caused by running out of gas.
Dive tips: *(Important during diving)*	Lost buddy contact Rapid ascent Dive tables – misread	Dive tips provided additional tips for the diver to remember that will make themselves safer

*, ** - These outcomes corresponding are dependent on each other. Hence, if one or more of the corresponding of them are reported by a participant, it would still be counted as one outcome events.

Data was also collected for the number of dives each participant made on the day they participated in the study. This information was collected using outcomes questionnaire (Appendix 3). The number of dives formed the denominator for the incidence rate of mishaps to be compared between the intervention and the control group. Incidence rates of mishaps (major, minor, and both) were reported per 100 dives such that,

Incidence rate of mishaps in the intervention group =

$$\frac{\text{\# of mishaps in the intervention group}}{\text{\# of dives in the intervention group}} * 100$$

Incidence rate of mishaps in the control group =

$$\frac{\text{\# of mishaps in the control group}}{\text{\# of dives in the control group}} * 100$$

One of the effects of the intervention may be that a diver chooses not to dive. This outcome was a binary variable, such that if someone did not to dive then their answer was 'yes', and if someone dove then their answer was 'no.' We calculated the risk of not diving in both the groups such that,

Risk of not diving in the intervention group =

$$\frac{\text{\# of divers in the intervention group who didn't dive}}{\text{\# total number of divers in the intervention group}}$$

Risk of not diving in the control group =

$$\frac{\text{\# of divers in the control group who didn't dive}}{\text{\# total number of divers in the control group}}$$

3. Covariates

Data on covariates was collected using outcomes questionnaire as well. Participants were asked to report their weight, height, age, medical and diving history, use of other checklists, and the day (approximate date) of their last dives. Information about participant's sex and race were collected by the intern using contact-information form.

4. Analysis

i. Descriptive Analysis

Descriptive analysis on outcomes, sex, race, weight, height, age of the diver, diver's medical and diving history, and use of other checklists was carried out. Frequency and distribution (%) are presented using tables and histograms. Variable distributions were compared between the intervention and the control groups to check if randomization was able to achieve adequate balancing of the variables between both the study arms.

ii. Sample size calculation

The estimated sample size to achieve 90% power and detect a 50% reduction in the incidence of mishaps, at 10/100 dives baseline mishap rate and alpha of 0.05, with an intervention to control allocation ratio of one, was 1704 dives, 852 intervention and 852 control. Considering that each diver would make an estimated 1 or 2 dives during their enrollment, 1200 divers had to be randomly recruited; 600 interventions and 600 controls. Accounting for clustering required an average of 30 dives per location-day. Further assumptions were made for the within-location-day standard error and between-location-day standard error to be 0.1 and 0.01 respectively.

Hence, between-location-day variance for the outcome = $\sigma^2_g = (0.01)^2 = 0.0001$

Within-location-day variance for the outcome = $\sigma^2_d = (0.1)^2 = 0.01$

ICC = $\sigma^2_G / (\sigma^2_G + \sigma^2_d) = 0.0099$ m=Average daily dives = 30

Design effect = 1 + [(m-1)*ICC] = 1 + (29*0.0099) = 1.2871

Hence, a total sample size of 1704*1.2871 = 2193 dives would be needed; 1097 intervention dives, and 1097 control dives. The within-diver clustering of dives was not accounted for.

iii. Variable structure:

Exposure: It was coded as a binary variable. Those who were given the intervention pre-dive checklist were the exposed and those who were not given the intervention were un-exposed or controls.

Outcomes: The outcomes of interest were the number of mishaps (major, minor, and all) – count data, the number of unsafe conditions – count data, and not-diving – binary variable.

Written Self-checklist use: This was coded as a binary variable (Yes/ No). The participants were first asked if they used a pre-dive checklist on a regular basis or not. They were further asked if the checklist they used was a self-made-mental-checklist or a self-made-physical-checklist or a training-agency-mental-checklist, or a training-agency-physical-checklist. Those who use a physical checklist were coded as ‘yes’ for the use of written self-checklist, or those who didn’t use any checklist or used mental self-checklists were coded as ‘no’ for the use of written self-checklist.

Diving Experience (years of diving): This variable was created using the ‘year of first diving certification’ of the diver (2012 – year of first diving certification). This variable was considered on a continuous scale and categorical scale. Categories were made using tertiles or quartiles of the distribution and by consulting the literature to identify established meaningful cut-points. However, this variable was not retained in the final model.

Average annual dives: Data for this variable was collected as continuous data. Incidence of mishaps and unsafe conditions decreased with increase average annual dives up to 40 dives after which the incidence of mishaps started increasing. It was later divided into three categories 0-20 dives, 20-40 dives, and greater than 40 dives. After considering the model fit, the continuous variable was retained in the model.

Sex and Age: These were both demographic confounders. Sex was binary variable – male/ female. Age was considered as both a continuous variable, and later as a 6 category variable (18-24, 25-34, 35-44, 45-54, 55-64, and 65+ years), but was not retained in the final model.

Medical history: This consisted of multiple variables for current health issues, history of chronic diseases/ previous illnesses, BMI (continuous variable), and disability (binary). None of these were retained in the final models.

Previous dive: Information for this variable was collected as a date. However, fewer participants answered this question; consequently large data were missing for this variable. This was not retained in the final model.

Environmental factors: This represents a group of 3 variables – animal attack, low visibility, strong current. All these variables were binary (yes/no) asked using the outcomes questionnaire. Visibility and current information was also separately collected by the interns by directly asking the divers, and or dive boat captains. Interns noted visibility as a range for each day of participation, while current was noted as a categorical variable (Strong, moderate, or low to no current). The binary variables for animal attack, poor visibility, and high current were retained in the final models.

Decision for the use of appropriate variable structures for self-pre-dive-checklist use, age, annual dives, diving experience, BMI, and environmental factors such as visibility and current, were made with the help of sensitivity analysis using QIC tests.

iv. Regression modeling:

The outcome is a count measure – number of mishaps. Poisson regression will be used to model the incidence density ratios of diving mishaps that compares the intervention group with the control group. To account for correlated data due to multiple divers diving on the same location-day, generalized estimating equations (GEE) will be used (Hanley, Negassa, & Forrester, 2003). Robust variance estimator generated from the models will be used to compute the 95% confidence intervals for the effect of the intervention on the incidence of diving mishaps. This analysis will provide us the relative effect of intervention on the outcome as compared to the controls. The analysis will be conducted using SAS 9.2/9.3 (SAS Institute Inc., Cary, NC).

v. Confounding:

The exposure is randomized and hence all the covariates are expected to be balanced between both the arms (intervention and control), which should be sufficient to control for confounding (Kaufman, Kaufman, & Poole, 2003). However, there is a possibility that randomization may not have appropriately balanced the covariates among the intervention and the control arm (Rothman, 1977) which may lead to confounding especially as it pertains to a CRT (Murray, Varnell, & Blitstein, 2004). Previous researchers have also suggested that it is prudent to investigate if the randomized arms are balanced as randomization does not always remove all of the confounding (Poole, 1987; Rothman, 1977). Hence all the covariates were investigated for confounding. Any covariate that was seen favorably in bias-variance trade-off was included in the model (Greenland, 2008). Bias-variance suggests that if the square of the bias controlled due to adjustment is less that the variance lost (or loss of precision) then adjustment is favored; however if variance lost is greater than the correction of bias, the trade-off and adjustment is not favorable.

vi. Effect Measure Modification:

All the variables were investigated for effect measure modification by including exposure-covariate interaction terms in the model and assessing the goodness of fit of the newer model compared with the simpler model using QIC. The interaction term for written self-checklist and intervention was retained in the final models.

Results from the trial were reported in a format consistent with consolidated standards of reporting trials (CONSORT) 2010 (Moher et al., 2010).

H. Aim 2:

Investigate the effect of a diver's own pre-dive checklist on the incidence of diving mishaps in recreational scuba divers.

This was a nested study. For this aim only the data from the control group was analyzed. Since this group was not intervened on and dove with minimal impact of the study this group is closest to the day-to-day recreational diving situation. Analyzing this arm alone would be the best way to answer the question at hand.

1. Exposure assessment:

Exposure of interest for aim 2 was the participant's self-pre-dive-checklist use. On the outcomes questionnaire that was administered at the end of the diving day, participants were asked if they used any pre-dive safety protocol or checklist. This was a binary (yes/no) response. If the participant answered 'yes', the response was further evaluated using a multi-response question, which asked them to specify the type of checklist used. Options were 1) Mental checklist that I memorized, 2) Physical checklist that I made myself, 3) Training agency checklist (memorize), 4) Training agency checklist (physical / written), and 5) Other (specify).

Using information from the above questions, a binary variable was created for a routinely used written self-checklist. Those who use a physical checklist were coded as 'yes' for the use of written self-checklist, or those who didn't use any checklist or used mental self-checklists were coded as 'no' for the use of written self-checklist.

A third exposure variable was created which has 3 categories, viz., use of a physical (written) checklist, use of a mental (memorized) checklist, and no checklist use. If the participant responded affirmative to using a physical checklist they made themselves, or a training agency physical checklist, or a physical checklist enlisted in the 'others' option, they were categorized to the 'use of physical checklist' group. If participant responded affirmative to using a mental checklist that they memorized, or a training agency checklist (memorized), or a memorized checklist enlisted in the 'others' option, they were categorized to the 'use of a mental checklist' group. Those who responded 'no' to the first binary question about the use of any pre-dive protocol or checklist were categorized as 'no checklist use' group.

Note that the definition of a pre-dive protocol or checklist may vary from diver to diver, and training agency to training agency. These checklists may also vary widely in terms of the extent of information they provide and their scope in terms of prevention of mishaps, injuries or even fatalities. We did not evaluate the exact nature of their checklist. This limits our ability to provide recommendations for specific use of checklists, and good diving practices.

2. Outcome assessment:

Outcome for aim 2 was the number of mishaps, and unsafe conditions. Mishaps were further divided into major and minor mishaps, like in aim 1. However, unlike aim 1, we accounted for all the major and minor mishaps and unsafe conditions for this aim. This was because the extent and the scope of the exposure were unknown for this aim. In simpler sense, it is hard to determine which mishaps might be addressed as the exact nature of each self-pre-dive-checklist is unknown. Not-diving was also an outcome of interest.

3. Analysis:

i. Variable Structure and Directed Acyclic Graph (DAG):

The exposure outcome relationship and their associations with covariates are depicted by a directed acyclic graph (figure 3.2).

Exposure: Exposure was a binary variable for the use of written self-checklist. Incidence rate ratios comparing the categories those who use written self-checklist versus those who did were reported.

Outcome: The outcomes – major mishaps, minor mishaps, all mishaps, and unsafe conditions were coded as count data. The mishaps rates are reported per 100 dives. Not-diving was coded as a binary variable. Outcome was affected by the exposure/ self-pre-dive-checklist use and other confounders/ predictors.

Covariates: Diving Experience (years of diving): This variable was created using the 'year of first diving certification' of the diver (2012 – year of first diving certification). This variable was considered on a continuous scale and categorical scale. Categories were made using tertiles or quartiles of the distribution and by consulting the literature to identify established meaningful cut-points. However, it was not retained in the final model.

Average annual dives: Data for this variable was collected as continuous data. Incidence of mishaps and unsafe conditions decreased with increase average annual dives up to 40 dives after which the incidence of mishaps started increasing. It was later divided into three categories 0-20 dives, 20-40 dives, and greater than 40 dives. This three category variable was retained in the model. More annual dives may make a diver more likely to have a mishap simply by the virtue of greater exposure, consequently it can make the diver more experienced and hence less susceptible to a mishap. This variable was affected by 'years of diving/ diving experience'. It may have predicted the incidence of mishaps and may also affect the previous dive.

Sex and Age: These were both demographic confounders. Sex was binary variable – male/ female. Age was considered as both a continuous variable, and later as a 6 category variable (18-24, 25-34, 35-44, 45-54, 55-64, and 65+ years), but was not retained in the final model.

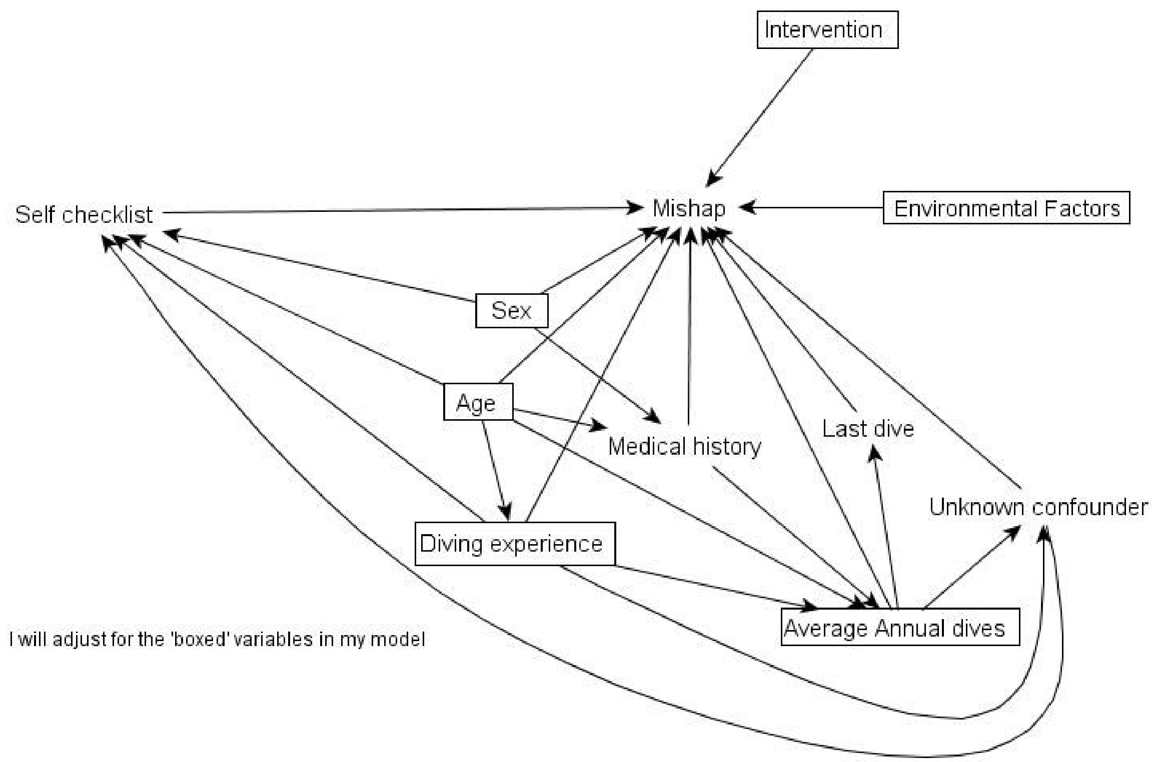
Medical history: This consisted of multiple variables for current health issues, history of chronic diseases/ previous illnesses, BMI (continuous variable), and disability (binary). None of these were retained in the final models.

Previous dive: Information for this variable was collected as a date. However, fewer participants answered this question; consequently large data were missing for this variable. This was not retained in the final model.

Environmental factors: This represents a group of 3 variables – animal attack, low visibility, strong current. All these variables were binary (yes/no) asked using the outcomes questionnaire. Visibility and current information was also separately collected by the interns by directly asking the divers, and or dive boat captains. Interns noted visibility as a range for each day of participation, while current was noted as a categorical variable (Strong, moderate, or low to no current). The binary variables for animal attack, poor visibility, and high current were retained in the final models.

Decision for the use of appropriate variable structures for self-pre-dive-checklist use, age, annual dives, diving experience, BMI, and environmental factors such as visibility and current, were made with the help of sensitivity analysis using QIC tests.

Figure 3.2: Directed Acyclic Graph for the effect of self-checklist on mishaps



ii. Regression modeling:

The primary outcomes of interest mishaps and unsafe conditions were count data, hence, Poisson regression was used to model the incidence density ratios of diving mishaps and unsafe conditions (and their 95% confidence intervals) to compare the effect of use of one's own pre-dive checklist. To account for correlated data due to multiple divers diving on the same location-day, generalized estimating equations (GEE) was used (Hanley et al., 2003). Robust variance estimator generated from the models was used to compute the 95% confidence intervals for the effect of the intervention on the incidence of diving mishaps. The analyses were conducted using SAS 9.2/9.3 (SAS Institute Inc., Cary, NC).

iii. Confounding:

Considering all the pathways from the DAG (figure 3.2), the minimum sufficient set to control for confounding includes sex, age, diving experience, and annual dives. Environmental factors and exposure to DAN's pre-dive checklist (intervention) were also controlled for.

A backward elimination method was used to assess confounding for all DAG and non-DAG indicated variables. Any potential confounder that was seen favorably in bias-variance trade-off was included in the model (Greenland, 2008). Environmental factors (current, visibility and animal attack) were not confounders, but they were strong predictors of mishaps. We controlled for these variables in our analyses by including them in the final model.

The final models included the use of written pre-dive checklist, gender, race, poor visibility, high current, age, and average annual dives.

I. Aim 3

Evaluate the factors affecting the adherence to the pre-dive checklist.

Pre-dive checklist was provided to the intervention group participants only. Hence, for this aim only the data from the intervention group was analyzed.

1. Outcomes:

The outcome for this study was the adherence to pre-dive checklist. Three criteria were used to determine if a participant was adherent to the checklist. First, a diver was considered non-adherent, if they did not report the starting tank pressure of their first dive, on the checklist. Then they must have made a written pre-dive plan on the checklist. Lastly, they must have checked at least 10 checkboxes on the checklist. Adherence to checklist was defined as a binary variable where meeting all of the aforementioned criteria would deem a diver adherent.

2. Covariate structure:

Divers reported the use of self-checklists as a three category response - no-checklist use, use of a written checklist, or the use of a memorized checklist. A binary variable for the use of a written self-checklist (yes/ no) was created, where the 'no' includes no checklist use and use of a memorized self-checklist.

Gender (male/ female), race (white/ non-white), and location (North Carolina/Caribbean) are all binary variables.

Sensitivity analyses were conducted to explore the effect of average annual dives, and age on the adherence. Based on which, average annual dives were categorized them into five categories - 0-5 dives, 6-10 dives, 11-15 dives, 16-20 dives, and more than 20 dives per year; and age was categorized as a binary variable where divers between from 18-35 years of age formed the 'younger' divers group, and divers with age 36 years and above formed the 'older' divers group.

3. Statistical Analysis:

Descriptive statistics of the collected variables were discussed using tables and frequencies. Exploratory analyses, using logistic regression models, were used to evaluate the odds of being adherent. The best fitting model included age, gender, race, diving experience (average annual dives), use of a self-checklist, and dive location. Since the participants that participated on the same day faced similar environmental conditions, their outcomes may not have been independent, leading to clustering of effects in our data. Generalized estimating equations were used to address the non-independence of dives within a cluster that generate a robust variance estimator to account for change in variance due to the clustering.[10]

Odds ratios of comparison are reported for gender, age, race, diving experience, use of self-checklist, and diving location. SAS 9.3 (SAS Inc., Cary, NC) was used for all statistical analysis.

IV. RESULTS CHAPTER 1: The effect of using a pre-dive checklist on the incidence of diving mishaps in recreational scuba diving: A cluster randomized trial

A. Introduction:

Recreational scuba diving is a widely popular sport. US census 2000 estimated that there are about 2.5 million scuba divers in the United States (US Census Bureau, 2000). The Professional Association of Diving Instructors (PADI) alone certified more than 11.5 million divers during 1999-2008 (Richardson, 2010). The mainly self-regulated recreational scuba diving industry includes training agencies, dive operators, dive resorts, and equipment and travel industries. Training is provided in small modules, and divers are certified for life after completion of the first basic module; advanced training is not mandatory. During the few days of training potential divers learn about diving physiology, equipment, and the skills required to operate underwater and manage pressure changes. The minimum age limit for diving, as set by training agencies, is 12 years of age with no upper limit. Health and physical fitness related exclusion criteria are few and lenient, usually enforced by local dive operators.

The overall injury rate from self-reported data is a little over 3/100 dives (Ranapurwala et al., 2014). Diving injuries amount to a significant financial burden due to treatment costs, residual disability, loss of productivity, and/or death (Buzzacott, 2012). Divers Alert Network (DAN) reports between 80-90 diving related deaths among US and Canadian divers every year (Denoble et al., 2008). The fatality rate among DAN membership is estimated at 16.4/100,000 person-years (Buzzacott, 2012; Denoble et al., 2008). Analyses of diving fatalities suggest that most are triggered by preventable mishaps (Denoble et al., 2008). One or more mishaps act as a trigger to begin a sequence of triggers, disabling agent and disabling injury, that ultimately may prove fatal (Denoble et al., 2008; Lippmann, 2010).[9,10] Mishaps further can be classified as human errors, equipment failures, or adverse environmental factors (Acott, 1995a; Acott, 1996; Acott, 1999b; Edmonds & Walker, 1989; Edmonds & Walker, 1991). Thirty percent of reported diving mishaps lead to diving injuries (Acott, 2003). In one study, the incidence of three most common mishaps – low to out of air, rapid ascent, and loss of buoyancy control, was found to be about

2.17/100 dives (Buzzacott et al., 2009). Forgetting, omitting, or neglecting adequate pre-dive preparation lead to human errors and equipment failure causing mishaps. The probability of human errors increases with increasing levels of stress, complexity of the equipment and lack of practice (Acott, 1995a; Acott, 1996; Acott, 1999b; Acott, 2003; Jablonski, 1965; Sexton et al., 2000). The lack of practice is evident by the fact that most divers do not need to undergo refresher training even when they have not been diving since a long time. Interventions aimed at preventing mishaps could potentially reduce the injuries and fatalities (Denoble et al., 2008; Lippmann, 2010; Willamson & Feyer, 1990).

A checklist is a simple and effective tool to reduce human error and safeguard against equipment problems. Pre-dive checklists are used in diving, but mostly only during training, and their use is not well promoted. Moreover, different training agencies use different checklists, none of which has been evaluated for its efficacy.

The purpose of this study was to evaluate efficacy of pre-dive checklists to prevent the incidence of scuba diving mishaps in recreational divers. Since there is no gold standard pre-dive checklist, we developed a generic checklist for this study.

B. Materials and Methods:

This research utilized a grouped randomized trial (CRT) design. Randomization was done by day. Each day all enrolled participants at the same location were either all control or all intervention group participants. This prevented cross-contamination of the intervention. Each diver could participate only once. The dive shops and boat crews were informed about the nature of the study and advised not to disclose it to the participants. Interns who administered the study had to pick one sequentially numbered packet every day before going to work to enroll participants.

There were four study instruments: Intervention form for the intervention group, control form for the control group, contact-information form, and outcomes questionnaire. The intervention form included a pre-dive checklist safety procedures and a post-dive log. The control form included the post-dive log only. The contact-information form was used to enroll and track participants and note their age, gender and racial/ethnic background. The outcomes questionnaire was given to both intervention and control group participants at the end of their dives; it included a list of potential mishaps, information on height, weight, brief medical history, and diving history.

The study was conducted at one location in North Carolina, two locations in Cozumel, Mexico, and one location in the Cayman Islands. Four trained interns, one at each study, were placed and hosted by a total of 7 dive shops. For each location, separate packets of study materials were assembled at DAN, which was the study headquarters. Half of the packets were intervention. Each packet contained 30 sets of consent forms, laminated intervention or control forms, outcomes questionnaire, marker-pens and one contact-information-form. Packets were randomized beforehand by the principal investigator (PI) at DAN using a SAS random number generator and then sequentially numbered. The study arm of each randomly numbered packet was noted on a spreadsheet. The spreadsheet was used for cross checking at the end of data collection.

The estimated sample size, to achieve a 90% power to detect a 50% reduction in the incidence of mishaps, for a baseline mishap rate of 10/100 dives, at alpha level of 0.05, for equal allocation of intervention and control (allocation ratio = 1), was 1704 dives; 852 intervention and 852 control. Considering that each diver would make an estimated 1 or 2 dives during their enrollment, we estimated that we would need to recruit at least 1200 divers in the study; 600 randomized to intervention and 600 to control. We accounted for clustering of dives per location-day. We expected to collect 30 dives per location-day on an average. We further assumed that the within-dive standard error for the outcome would be 0.1, and the within-location-day standard error would be 0.01. Based on these assumptions, we calculated the intra-class correlation (ICC) and design effect that allowed us to adjust our sample size to account for clustering.

Hence, Within-dive variance for the outcome = $\sigma^2_d = (0.1)^2 = 0.01$

Within-location-day variance for the outcome =$\sigma^2_g = (0.01)^2 = 0.0001$

ICC = $\sigma^2_G / (\sigma^2_G + \sigma^2_d) = 0.0099$ m=Average daily dives = 30

Design effect = 1 + [(m-1)*ICC] = 1 + (29*0.0099) = 1.2871

Based on this, we would need a total sample size of 1704*1.2871 = 2193 dives; 1097 intervention dives, and 1097 control dives. We did not account for clustering of dives for the participant per day.

Any participating diver had to be more than 18 years of age. They had to have a valid diver certification, had to be planning to dive the day of their recruitment, had to be deemed fit for diving by the dive operator, and had to have working knowledge of English.

The divers were briefed about the study; those agreeing to participate were asked to provide signed consent. At this time, interns noted participant names, contact information, age, gender, race, and participant number on the contact-information form. The names and contact information allowed preventing repeat participation. The participants received either the intervention or the control form and explanation for its use. When the participants completed their dives, or upon divers' return to the pier, interns collected the study form (intervention or control) and asked the participants to answer the outcomes questionnaire. The study forms, and the outcomes questionnaire all had the same participant number for each diver; this ensured that each participant's study form and the outcomes questionnaire were entered together. The interns entered the data to the online forms, which were identical to the pre-dive checklist and outcomes questionnaire. Data were monitored weekly by the PI.

Interns informed the participants about the general study goals and objectives but the study hypothesis was kept obscured. This means that the divers were told that we are doing a study, but not that this is an interventional trial. Divers were not told that they are being randomly assigned to use a pre-dive checklist. If we had done that, the divers would have known the group they were randomized to as soon when they received the intervention or control forms. This could have changed their behavior, the control group would have become more cautious than they would otherwise be, and the intervention group could have become more compliant than they would usually be. Thus we could not have measured the true effect of the intervention. Interns also explained the risks and benefits of participation, the voluntary nature of participation, and that non-participation or withdrawal would be completely non-consequential. This allowed us to blind the participants while addressing ethical concerns. The interns were only allowed to use the envelopes in the randomized order; they did not know which envelope was intervention or control, until they opened it for recruiting participants on their subsequent work day; in effect, the allocation was concealed from the interns. The outcomes were self-reported by the already blinded participants. Given this information, this is a single-blinded trial.

This study was approved by the institutional review boards (IRB) at DAN # 009-12 on 03/27/2012 and the University of North Carolina (UNC) # 12-1051 on 05/29/2012, and further renewed by DAN IRB on 02/06/2013 and UNC IRB on 02/25/2013.

C. Statistical Methods:

Diving mishaps vary in their severity and the risk of injury may vary for different mishaps. To address this we divided the mishaps in major and minor mishaps. The major mishaps are more likely to cause injury; or the potential injury is severe. The minor mishaps are less likely to cause injury; or the potential injury is mild. The primary outcomes of interest are major mishaps, minor mishaps, and all mishaps (major plus minor). These outcomes are coded as count data. The secondary outcomes of interest are unsafe conditions and not-diving. Unsafe conditions are also count data, and not-diving is a binary variable coded yes or no.

Poisson regression models were used to compare the incidence rates of mishaps and unsafe conditions in the intervention and control groups. Since the randomization was based on location-day of participation, there was clustering in our data. To address the non-independence of dives within a cluster, we used generalized estimating equations (GEE) that generate a robust variance estimator that accounts for change in variance due to the clustering effect (Hanley et al., 2003). To compare the risks of not-diving in the intervention and control groups we used log-risk models, with GEE to address non-independence of divers within the cluster.

We took three approaches to analyzing the data – intent-to-treat (ITT), per-protocol (PP), and marginal structural models (MSM). The ITT approach retains the randomization, and analyzes the participants in their respective group, irrespective of whether they actually adhered to the intervention or not (Weiss, 2008). The crude incidence rate of mishaps for both intervention and control groups, rate difference, and rate ratios for comparison were estimated. We calculated the crude 'number needed to treat' (NNT), which is given by,

NNT = 1/ rate difference

NNT provides the number of dives that will have to be intervened on in order to prevent one mishap.

Randomization allows the ideal comparison of the intervention and control groups, because on average, randomization creates groups that are equivalent to each other in all respects except the intervention (Weiss, 2008). However, this holds true for large datasets or multiple (more than one) trials, and may fail for a single trial with small sample size (Poole, 1987; Rothman, 1977). Hence, we adjusted our models for potential confounders. The best fitting model was derived by backward elimination technique such that any variable that was seen favorably in bias-variance trade-off (Greenland, 2008), was retained in the model. Such that if the adjustment reduces more bias than the amount of increase in variance (or loss of precision) due to adjustment, adjustment is favored; however if the increase in variance is greater than the correction of bias, the trade-off is not favorable, that is, one should not adjust for the variable in question.

We also checked for interaction due to the use of a physical self-checklist. The final models for evaluating the effect of intervention on major mishaps and all mishaps included the intervention, gender, race, poor visibility, high current, animal attack, average annual dives, use of a physical self-checklist, and the interaction variable for intervention and the use of a physical self-checklist. The final models for minor mishaps and unsafe conditions are identical to the one stated above, except it does not include the binary variable for animal attack, as the participants who were attacked by an animal (n=4) in the study only reported major mishaps. The model to evaluate the effect of intervention on not-diving only includes race and gender variables, as the models did not converge with addition of any other variables.

Poor adherence could mask the true effects of intervention. Hence, an adherence variable was developed using three criteria. First, a diver must have reported the starting tank pressure of their first dive, on the checklist, to be considered adherent. If first condition is satisfied, then the diver must have made a written pre-dive plan on the checklist. If the second condition is met, then the diver must have checked at least 10 checkboxes on the checklist. All control group participants were considered adherent. Crude and adjusted per protocol analysis were conducted by removing the non-adherent divers from the analysis.

We also used marginal structural models to account for non-adherence. We calculated inverse probability weights for the intervention group participants. All the control group participants got a weight of one. The weighting for adherence among the intervention group participants is given by:

w = p(complying) / p(complying | gender, age, race, poor visibility, high current, animal attack, average annual dives, history of hypertension, history of high cholesterol)

Where w = weight.

These probabilities were derived using logistic regression. Crude and adjusted Poisson regression models were then weighted using the newly created weights to assess the effect of intervention on the incidence of diving mishaps. SAS 9.3 (SAS Inc., Cary, NC) was used for all statistical analysis.

Covariate structure: Intervention, gender, race, poor visibility, high current, and use of physical self-checklist are binary variables. Intervention variable can be described as intervention or control, gender as male or female, race as white or non-white, poor visibility as yes or no, high current as yes or no, and use of physical self-checklist as a yes or no.

Average annual dives were reported as a continuous variable. We conducted sensitivity analysis to explore the effect of average annual dives on the incidence of mishaps, observed that the incidence of mishaps decreased for increasing number of dives up to 40 dives per year, after which it increased. Using this information we categorized them into three categories - 0-20 dives, 21-40 dives, and more than 40 dives per year.

D. Results:

Data were collected between June 1, 2012 and August 17, 2012. We ended the data collection because we had limited funds to support the interns, and the diving season was slowing down as reflected from less and less divers participating in diving.

At the four study locations, we collected data on 70 random location-days – 40 intervention and 30 control (intervention allocation ratio: 1.33), 1160 participants were enrolled, 9 participants withdrew, 31 participants did not want to complete the study and were subsequently removed by the investigator, and 77 participants were lost to follow-up. The study was completed by 1043 participants (figure 4.1). Self-withdrawal indicates that participants voluntarily asked to be withdrawn from the study. The investigator removed some participants from the study because they refused to complete the outcomes questionnaire citing lack of time, or being uninterested completing additional paperwork. Some participants were lost to follow-up because the interns were not able to contact them after the diving day and their study forms were not returned.

Over two-thirds of the participants were males, 94.8% were white, and the median age was 43 years (table 4.1). Only 6.6% of all participants reported regularly using a self-checklist. Divers made a total of 2041 dives ranging from 0 to 6 dives per day. 89.5% divers dove twice and 43 divers chose to not dive; 22 in the control group and 21 in the intervention group.

About a quarter of all participants (n=260) reported either a major or minor mishap ranging from 1 to 7 mishaps per person. The overall rate of major mishaps was 8.6/100 dives; most common being rapid ascent (3.6/100 dives), lost buddy contact (2.5/100 dives), and low-to-out-of-air (1.0/100 dives). The overall rate of minor mishaps was 8.5/100 dives; most common being changed buoyancy due to dive suit (3.1/100 dives), mask squeeze (2.4/100 dives), and unable to clear mask (0.8/100 dives). None of the enrolled divers was injured during the study (table 4.2).

The crude ITT rate of major mishaps in the intervention group was 7.5 per 100 dives, and 10.2 per 100 dives in the control group (table 4.2) for a crude rate difference of 2.7 mishaps per 100 dives and an adjusted ITT rate ratio (RR) of 0.64 (95% CI: 0.46, 0.87) (table 4.4). The number needed to treat (NNT) was 36.9 dives indicating that one major mishap was prevented by using the checklist prior to 37 dives. The crude ITT rate of all mishaps in the intervention group was 15.2 per 100 dives, and 19.0 per 100 dives in the control group for a crude rate difference of 3.8 mishaps per 100 dives and an adjusted ITT RR of 0.68 (95% CI: 0.50, 0.93); the NNT was 26.3 dives.

The most common unsafe conditions were poorly secured gas tanks, unfamiliarity with the use of BCD, and battery problems with the dive computer (table 4.3). The crude ITT rate of unsafe conditions in the intervention group was almost the same as that in the control group, approximately 2.6 per 100 dives, suggesting that one may not be at any special advantage to receive the intervention when one wants to control the unsafe conditions. The risk of not-diving in the intervention group is lower than in the control group by 1.8% (table 4.3). This means that more diving took place in the intervention group as a result of using a pre-dive checklist. The NNT is 55.6 divers.

The adjusted rate ratios (table 4.4) suggest that there was heterogeneity of effects based on self-checklist use. Among those who used a self-checklist the ITT RR of major mishaps for the intervention was 1.03 (95% CI: 0.52, 2.03), while among those who did not use self-checklist the ITT RR was 0.57 (95%CI: 0.41, 0.80). The ITT and MSM analysis suggest that the intervention reduced the incidence of major mishaps by 36% and the incidence of all mishaps by 32%, among those who did not use self-checklists.

The ITT and MSM analysis suggest that the intervention reduced the incidence of major mishaps by 43% and that of all mishaps by 36%. The use of a physical self-checklist also reduced the incidence of minor mishaps however this effect may be small.

Unlike the crude rates the adjusted ITT and MSM rate ratios for the incidence of unsafe conditions suggests that there may actually be a reduction of 22-28 % due to the intervention. The ITT and MSM risks ratios for not-diving suggest that the intervention group divers dive about 35-70% more as compared to the control group. Although, these analysis were prone to greater degree of random error due to small sample sizes.

E. Discussion:

We can appreciate the difference between number of location-days, number of participants, and the number of dives between the intervention and the control groups (figure 4.1, table 4.1). The imbalance in number of location days is because each intern was given materials for 20 intervention days and 20 control days. These 40 days were randomized beforehand at DAN using SAS random number generator. However, interns were not able to complete all 40 days of data collection. Randomization allowed more intervention days in the beginning at some locations, allowing more intervention days data collection than control days. The number of divers and dives in the two groups differed because the number of divers enrolled on any given study day (intervention/ control) were not the same. Interns enrolled between 8-25 divers (mean=15.43) for a range of 15-50 dives (mean=29.19) per location-day.

We see that the reported minor mishaps and the unsafe conditions are fewer than the reported major mishaps (table 4.2, table 4.3). However, in reality one would assume otherwise. It takes a lot more to go wrong for a major mishap to occur, and they cannot be corrected that easily. Major mishaps usually force a diver to shorten the dive, or take special measures or help of buddy or others to overcome the situation. A diver would regard these mishaps of more importance and report them. On the other hand the unsafe conditions and minor mishaps are readily correctable. Divers may have actually had them more frequently than they reported, but they were more prompt to correct them and move on, and hence did not report them often in this study. Besides an unsafe condition or a minor mishap may highlight a greater degree of neglect on the part of the diver than in case of a major mishap; reporting such mistakes may not look good, especially to divers who are more experienced. This may also result in underreporting of unsafe conditions and minor mishaps.

We also see that the crude rates of unsafe conditions in the intervention and control groups are same. This may be because the unsafe conditions exist before the dive, and are too obvious to note to begin with. The checklist may help detecting some, but the basic training that divers receive may do it equally well without a checklist, because with such mistakes, diving would commonly be hard to undertake. Most of the time these mistakes are promptly corrected even before the dive starts and the diver would then proceed to diving. Unlike the crude rates, the adjusted rate ratios for unsafe conditions show a reduction in the intervention group, however, the sample sizes are too small to appreciate the effect precisely.

The adjusted rate ratios of mishaps suggest that there is no effect of intervention among those who had their own physical pre-dive checklist. This could suggest that there is a ceiling effect of using a checklist, and using more checklist than one may be as good as using any. However, the numbers of participants that use their own checklist in both the groups are very small, and this measure is greatly vulnerable to random error.

The NNT for major mishaps is 36.9; this suggests that had the intervention group not received the intervention, they could have had about 33 more major mishaps – given by the total number of dives in the intervention group divided by the NNT (1201/36.9). In other words, by intervening with a pre-dive checklist we prevented 33 major mishaps in the intervention group. Similarly we prevented about 47 total mishaps in the intervention group. On the other hand, 11 more people dove in the intervention group due to intervention. This may be because by using a pre-dive checklist the divers may feel more prepared, safer, and more confident, hence diving often. This may be a good reason for the diving industry to promote checklists.

The adjusted results suggest that there is in fact a greater effect of the checklists than that suggested by the crude measures. The use of a pre-dive checklist reduces the incidence of diving mishaps by 35-40%. A pre-dive checklist reduces human and equipment errors by enforcing the basics of safety. Diving studies have long noted that a large number of injuries occur as a result of preventable mishaps (Acott, 1995a; Denoble et al., 2008; Lippmann, 2010). A pre-dive checklist encompasses the principles of basic safety and may prevent diving specific and non-specific injuries by reducing the incidence of diving mishaps. We can compare this scuba diving intervention with other diving interventions and also with the use of checklists in other fields.

Scuba diving got popularized as a recreational activity after the world-war-II. However, diving injuries and fatalities were a big problem at that time. Injuries and fatalities mainly resulted from diving specific injuries like decompression sickness (DCS), pulmonary barotrauma (PBT), or arterial gas embolism (AGE). Hence, traditionally, all injury prevention efforts in scuba diving have been targeted towards diving specific injuries like decompression sickness (DCS), arterial gas embolism (AGE), and other barotraumas. Interventions and education up until the recent past e.g., dive computers, oxygen-enriched-air, decompression schedules, flying after diving guidelines, conservative diving practices, first-aid surface oxygen, banning emergency ascent technique, etc. – are all geared toward reducing DCS and AGE. However, during the last 20 years 80-90% fatalities have occurred due to non-diving specific causes (Buzzacott, 2012). Behavioral interventions can allow divers to play a more active role in ensuring their safety. A pre-dive checklist, when used immediately prior to the dive, may control mishaps that cause most of the diving injuries, specific and non-specific.

Other high risk areas have also benefitted from the use of checklists. Checklists foster a safety culture in aviation; its use since more than seven decades has made aviation the most popular form of transcontinental travel. Today pilots are required to complete checklists for their equipment, flying procedures, and even their individual health and mental status (Hales & Pronovost, 2006). Checklists are enforced upon pilots and crew members of armed forces and commercial airliners alike (Helmreich, 2000). This also allows a continuous scrutiny and amendment of all procedures (Scriven, 2000). Similarly pre-operative and post-operative checklists in surgery are slowly becoming the norm. Randomized trials investigating the effect of these checklists have found a large reduction in the post-operative mortality and morbidity (Haynes et al., 2009).

Limitations: Randomization of intervention based on location-days allowed the investigators to restrict cross-contamination of the intervention; however it introduced clustering. The outcomes thus observed by participants diving on same location-day are not independent. This non-independence could bias our results. Each location-day cluster has 8-25 divers. If we do not account for clustering, we will be assuming that each observation is independent, resulting in spuriously small standard errors, wrongly providing us with greater power, and tighter confidence intervals. To account for this non-independence we used GEE, which accounts for the within cluster correlation in the data (Hanley et al., 2003). The results thus obtained had a robust standard error that removes the falsely generated power in the study and provides confidence intervals that are more realistic. However, there is also clustering on the level of the diver because most of the divers dove more than once. This is a limitation that we could not account for because we do not have separate outcome information for each of the dives. The outcome information is available only at the diver level. Even some of the covariate information that is likely to change from dive to dive like the environmental factors (current and visibility) is available for the participant and not for each dive.

When the study was conducted, no special measures were taken to record non-compliance, and address it. An intent-to-treat analysis assesses a participant based the treatment they are randomized to, irrespective of whether the participant adhered to it or not. Inability to address adherence to treatment may either mask or accentuate the effect of the treatment. Three criteria were used to assess adherence among the intervention group participants; 187 participants (30.3%) were non adherent. We conducted a per-protocol analysis where we eliminated all the non-adherent subjects from the analyses. We also used marginal structural models that use inverse probability weighting to weight the effect of intervention in the non-adherent participants based on their compliance. However, both these approaches yielded similar results to that of the ITT analysis, which may reflect that the incidence of mishaps among the adherent and non-adherent participants was similar.

Like most studies, this study suffers from limitations due to external validity. The study was conducted in the Atlantic and Caribbean waters, and the current, visibility and wild animal populations in other regions may vary greatly. Diving in colder Norwegian waters is different than diving in warm tropical or equatorial waters. Also, this study was conducted during summer, and diving conditions differ greatly during other seasons. Besides, this study was conducted in recreational scuba divers; it cannot be generalized to technical divers, lobster and other seafood harvesters, scientific divers, or the navy divers. However, it cannot be argued that pre-dive checklists promote safety, they would be safe to use in any environment, season, or type of diving, and could only make a diver safer as long as the checklist conforms to the training agency and general diving guidelines.

F. Conclusion:

In this study, using a pre-checklist can prevent the incidence of mishaps by 30-40%, which could translate into quite considerable reduction in injuries, and fatalities. Although more studies would be needed to be able to calculate the conversion rate of mishaps to injuries and injuries to fatalities, it is however conceivable that pre-dive checklist is an important tool to reduce all of them. Diving training agencies must promote the use of checklist among their divers, and pre-dive checklists should become a cornerstone of safety culture.

Figure 4.1: Distribution of participants based on the assigned group

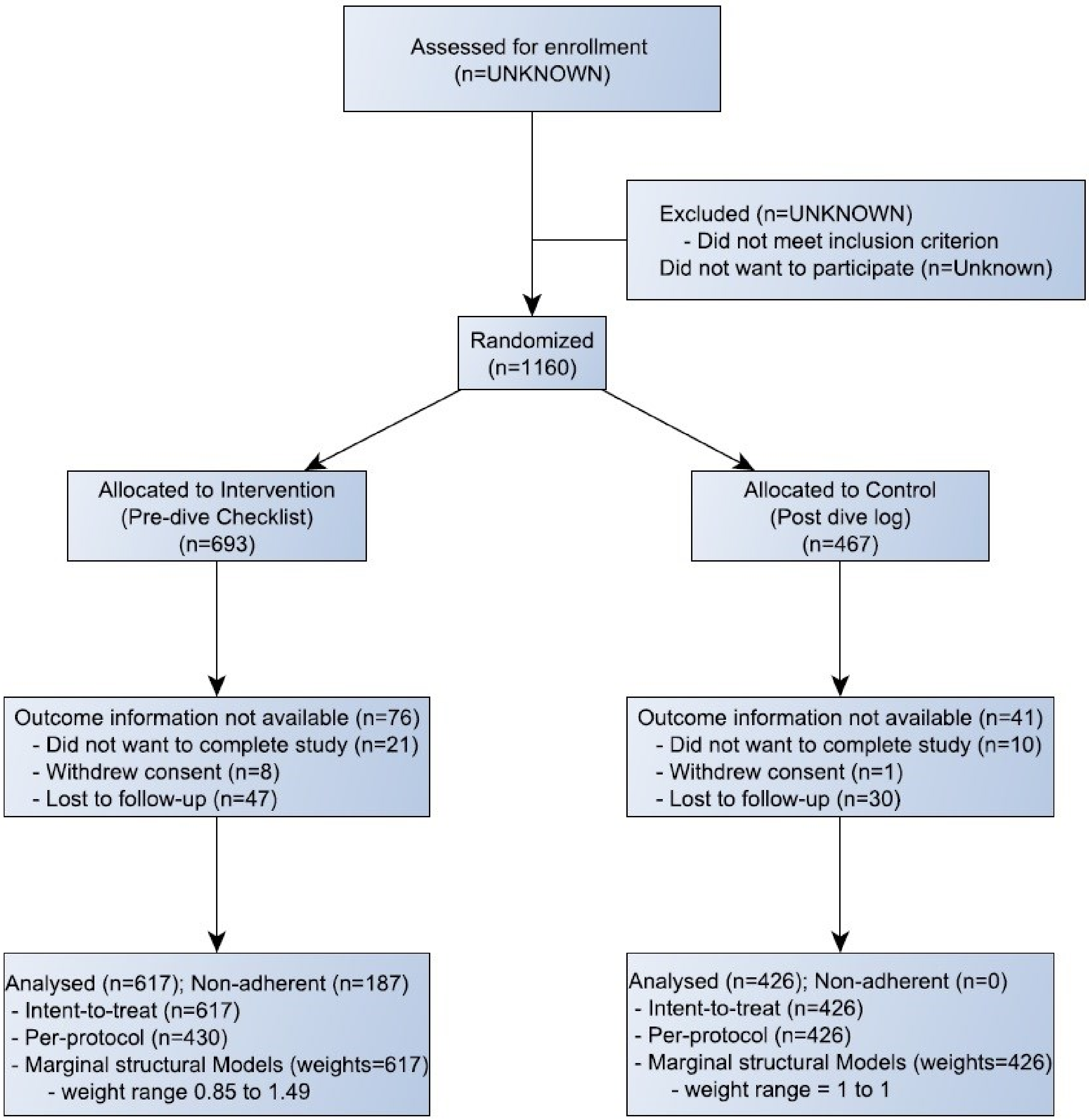


Table 4.1: Demographics and distribution of covariates in the assigned groups

	Intent-to-treat		Per-protocol	
	Intervention	**Control**	**Intervention**	**Control**
Total Divers	617	426	430	426
Total Dives	1201	840	840	840
	Mean (median)	**Mean (median)**	**Mean (median)**	**Mean (median)**
Average Annual Dives	22.8 (10)	37.0 (10)	24.6 (10)	37.0 (10)
BMI	26.4 (26)	26.6 (26)	26.4 (26)	26.6 (26)
Age	41.5 (43)	42.4 (44)	42.1 (43)	42.4 (44)
	%	**%**	**%**	**%**
Males	66.1	70.4	67.7	70.4
White	93.8	96.2	94.7	96.2
Self-checklist	5.8	7.7	7.2	7.7
Animal Attack	0.5	0.2	0.5	0.2
High Current	18.8	17.8	17.9	17.8
Poor visibility	9.9	6.8	9.1	6.8

% – per 100 divers

Table 4.2: Crude rates of major and minor mishaps by the assigned groups

Types of Mishaps	No. of mishaps	Rate per 100 dives	
		Intervention	Control
Major Mishaps	**176**	**7.5**	**10.2**
Rapid ascent*	74	3.1	4.4
Lost buddy contact	51	2.4	2.6
Low to out of air	20	0.9	1.1
Entanglement/ entrapment	11	0.2	1.1
Buddy breathing	8	0.5	0.2
Spontaneous inflation	6	0.1	0.6
2nd stage regulator malfunction	6	0.3	0.2
Minor Mishaps	**173**	**7.9**	**9.3**
Changed buoyancy due to dive suit	64	2.9	3.5
Mask squeeze	49	2.2	2.7
Unable to clear mask	17	0.9	0.7
Buddy Mismatch	15	0.7	0.8
Fins lost/ loose/ dislodged	10	0.3	0.7
Air not turned on/ not fully on	7	0.3	0.4
Fins strap broke	7	0.4	0.2
Weights belt/ weights dropped	4	0.2	0.2
Mask strap broke	0	0.0	0.0
Unable to release weights	0	0.0	0.0
Total Mishaps (Major + Minor)	**349**	**15.4**	**19.5**

* includes computer recorded rapid ascent

Table 4.3: Crude rates of unsafe conditions and crude risks of not-diving by the assigned groups

Types of Unsafe Conditions	N	Rate per 100 dives	
		Intervention	Control
Tank not well secured	22	1.08	1.07
Unfamiliar with BCD use*	14	0.67	0.71
Dive computer battery problems	8	0.42	0.36
Inadequate buoyancy due to BCD	4	0.17	0.24
Dive computer not turned on before dive	2	0.08	0.12
Unable to locate alternate regulator	1	0.08	0.00
Unit confusion on dive gauge	1	0.08	0.00
Dive tables – misread	1	0.00	0.12
Total Unsafe Conditions	**53**	**2.58**	**2.62**
		Risks of not-diving (%)	
Not-Diving	**43**	**3.4%**	**5.2%**

*includes confusion on BCD inflate/ deflate, & didn't know how to inflate/ deflate the BCD

Table 4.4: Estimates comparing the intervention and control groups for the incidence of mishaps, unsafe conditions, and not-diving

Outcome	Analysis Approach	Adjusted rate ratio* (95% CI)	Adjusted rate ratio** (95% CI)		Crude rates / per 100 dives (95% CI)	
			No Self-checklist	Written Self-checklist	Intervention	Control
Major Mishaps	ITT	0.64 (0.46, 0.87)	0.57 (0.41, 0.80)	1.03 (0.52, 2.03)	7.40 (6.06, 9.04)	10.11 (7.77, 13.17)
	PP	0.64 (0.46, 0.90)	0.61 (0.43, 0.86)	0.76 (0.29, 1.95)	7.51 (5.93, 9.50)	10.11 (7.76, 13.18)
	MSM	0.63 (0.46, 0.87)	0.58 (0.41, 0.80)	1.00 (0.50, 2.01)	7.35 (6.00, 8.99)	10.12 (7.80, 13.14)
Minor Mishaps[$]	ITT	0.74 (0.48, 1.13)	0.71 (0.46, 1.08)	0.85 (0.29, 2.54)	7.83 (6.39, 9.58)	8.91 (6.25, 12.71)
	PP	0.74 (0.48, 1.15)	0.71 (0.46, 1.10)	0.83 (0.23, 2.96)	7.66 (5.85, 10.03)	8.83 (6.20, 12.59)
	MSM	0.74 (0.48, 1.12)	0.71 (0.46, 1.08)	0.85 (0.29, 2.47)	7.86 (6.37, 9.71)	8.93 (6.24, 12.78)
All mishaps	ITT	0.68 (0.50, 0.93)	0.64 (0.46, 0.88)	0.96 (0.47, 1.98)	15.21 (12.90, 17.94)	19.03 (14.74, 24.57)
	PP	0.69 (0.50, 0.95)	0.66 (0.47, 0.91)	0.80 (0.32, 2.02)	15.22 (12.39, 18.68)	18.97 (14.68, 24.51)
	MSM	0.68 (0.50, 0.93)	0.64 (0.46, 0.88)	0.94 (0.45, 1.95)	15.20 (12.81, 18.03)	19.10 (14.83, 24.60)
		Adjusted rate ratio (95% CI)				
Unsafe conditions[$]	ITT	0.68 (0.29, 1.63)			2.67 (1.87, 3.80)	2.85 (1.48, 5.47)
	PP	0.67 (0.27, 1.63)			2.62 (1.77, 3.89)	2.85 (1.48, 5.48)
	MSM	0.67 (0.28, 1.62)			2.58 (1.79, 3.73)	2.85 (1.48, 5.49)
		Adjusted risk ratio[#] (95% CI)			Crude risks (95% CI)	
Not diving	ITT	0.65 (0.35, 1.22)			3.43% (2.16, 5.44)	5.19% (3.30, 8.16)
	PP	0.62 (0.33, 1.17)			3.26% (2.09, 5.08)	5.16% (3.28, 8.14)
	MSM	0.30 (0.15, 0.62)			1.63% (0.91, 2.93)	5.16 % (3.28, 8.13)

*Adjusted for sex, race, poor visibility, high current, animal attack, average annual dives, use of a physical self-checklist other than the intervention; **Adjusted for sex, race, poor adjusted for animal attack. [#]Adjusted for race, sex, visibility, high current, animal attack, average annual dives, use of a physical self-checklist other than the intervention, and the interaction of intervention and the use of physical self-checklist; [$]Minor mishaps and unsafe conditions were not

V. RESULTS CHAPTER 2: The effect of using a self-pre-dive checklist on the incidence of diving mishaps in recreational scuba diving

A. Introduction

Recreational scuba diving is an activity that involves complex instruments, specialized skills, and an unforgiving environment. This increases the risks of injuries and fatalities, especially because of the uncontrollable nature of the environment in which diving is carried out.

The all-cause diving fatality rate in the United States and Canada is 16.4/100,000 diver-years (Denoble et al., 2008). The number of recreational scuba diving fatalities in the United States and Canada vary between 80-90 deaths per year (Denoble et al., 2008). The incidence of all self-reported diving-related injuries is reported to be 3.1 per 1000 dives among Divers Alert Network members from United States (Ranapurwala et al., 2014). All cause diving mortality studies from divers and occupational cohorts suggest that most fatalities occur due to precursor events, also called as incidents, errors, triggers or mishaps (Denoble et al., 2008; Lippmann, 2010).

Mishaps are unwanted unplanned events that occur during diving and increase the risk of an injury. They are precursors of injuries that may be contained given proper preparation and training. Based on the potential of causing an injury, and the severity of the injury caused, mishaps can be divided into major and minor mishaps. Major mishaps have a high potential of causing an injury and the injury thus caused may be severe, or life-threatening. In comparison, minor mishaps have less potential to cause an injury, and they cause less severe injuries, if any. There may be some conditions that occur prior to diving and render diving unsafe. These are called unsafe conditions. A diver may take corrective actions if unsafe conditions, if detected before dive, may make a diver take corrective action. If a diver dives with an unsafe condition the risk of a mishap and injury is increased.

Diving mishaps are caused by human errors, equipment problems, or adverse environmental factors (Edmonds & Walker, 1989; Edmonds & Walker, 1990; Edmonds & Walker, 1991). Most common mishaps are out-of-air scenarios, rapid ascent, equipment problems and entrapment (Acott, 1999b; Denoble et al., 2008). An extensive list of diving mishaps is published in the 'diving incident report form,' an ongoing self-reporting online survey by Divers Alert Network (DAN) Asia-Pacific (Acott, 1994). It is suggested that 30% of the mishaps may lead to injuries (Acott, 2003). The incidence of three mishaps, viz., low to out of gas, rapid ascent, and buoyancy problems - together, has been reported to be about 2/100 dives (Buzzacott et al., 2009).

Preventing diving mishaps may prevent the incidence of injuries and fatalities (Acott, 1994; Denoble et al., 2008). However, there is very little information on the incidence rates of mishaps and there is no information on the factors affecting them. It has been suggested that pre-dive checklists may prevent the incidence of human errors and help detect equipment problems, although, the prevalence of checklist use among divers is not known and is assumed to be low (Acott, 1995b; Denoble et al., 2008). Different training agencies have different checklist that may differ in content and practice. To remember them they promote the use of different mnemonics. There is some evidence that when performing equipment check procedures without using a written checklist, most recreational divers may not be able to detect all the problems with their equipment (Acott, 1995b). Additionally, using mnemonics may inadvertently lead to reduced use of written checklist among divers who choose to remember the checklist rather than having them in print. Some divers prefer to make their own personal written checklists with varying content and information. Thus, the actual use of checklist varies in form – written or memorized, and (depending on the source) in content, too.

This paper investigates the incidence of diving mishaps and unsafe conditions and their association with the routine use of a self-checklist. A self-checklist is a written pre-dive checklist used by a diver irrespective of its content, and source.

B. Materials & Methods

This was a nested study that utilized a prospective observational study design to evaluate the effect of using a written self-checklist on the incidence of mishaps among the control group of the cluster randomized trial (aim 1). There were three study instruments: A post-dive log, a contact-information form, and an outcomes questionnaire. The post-dive log was meant to record the depth and time of dives, and the pressure of breathing gas at different points of the dive. The contact-information form was used to enroll and track participants and record their age, gender, and racial/ethnic background. The outcomes questionnaire was given to the participants at the end of their dives; it included a list of potential mishaps, information on height, weight, brief medical history, diving history, and use of self-checklists.

The study was conducted at one location in North Carolina, two locations in Cozumel, Mexico, and one location in the Cayman Islands. Four trained interns, one at each location, were placed and hosted by a total of 7 dive shops. Twenty packets of study materials were assembled for each location. Each packet contained 30 sets of consent forms, post-dive logs, outcomes questionnaire, marker-pens, and one contact-information-form.

Each diver could participate only once, that is on only one location-day. The study participants usually traveled in boats together to dive, besides they were all guided by same boat operator, and they dove at the same locations; hence all participants participating on the same location at a particular day may not have independent outcomes. Hence, only one packet was used on a given day to enroll the participants, allowing identification of clustering units by location and participation day or location-day.

Any participating diver had to be more than 18 years of age, had to have a valid diver certification, had to be planning to dive the day of their recruitment, had to be deemed fit for diving by the dive operator, and had to have working knowledge of English.

The divers were briefed about the study; those agreeing to participate were asked to provide signed consent. At this time, interns noted participant names, contact information, age, gender, race, and participant number on the contact-information form. The names and contact information allowed preventing repeat participation. The participants received the post-dive log and explanation for its use. When the participants completed all their dives for the day or upon divers' return to the pier, interns collected the logs and asked the participants to answer the outcomes questionnaire. The dive logs and the outcomes questionnaire all had the diver's participant number which allowed them to be recorded together. The interns recorded the data to the online forms, which were identical to the dive logs and the outcomes questionnaire.

This study was approved by the institutional review boards (IRB) at DAN # 009-12 on 03/27/2012 and the University of North Carolina (UNC) # 12-1051 on 05/29/2012, and further renewed by DAN IRB on 02/06/2013 and UNC IRB on 02/25/2013.

Outcomes: The primary outcomes of interest are major mishaps, minor mishaps, and all mishaps (major plus minor). Mishaps are coded as count data. The secondary outcomes of interest are unsafe conditions and not-diving. Unsafe conditions are also coded as count data, and not-diving is a binary variable coded yes or no.

Covariate structure: Use of self-checklist was coded as a binary variable for the use of a written self-checklist (yes/ no), where the 'no' includes no checklist use and use of a memorized self-checklist. We collapsed divers who reported no checklist use with divers who reported the use of a memorized checklist because on analysis, these two groups were not any different. Besides, our definition of pre-dive checklist means that it must be a written checklist used on a routine basis by the diver.

The potential confounders were gender (male/ female), race (white/ non-white), poor visibility (yes/ no), high current (yes/ no); all binary variables. Additionally the variable for average annual dives, coded as a continuous variable, was also considered for confounding.

C. Statistical Methods

Poisson regression models were used to compare the incidence rates of mishaps and unsafe conditions among different self-checklist use groups. Since the participants on a location-day faced similar environmental conditions, their outcomes are not independent. To address the non-independence of dives within a cluster, we used generalized estimating equations (GEE) that generate a robust variance estimator that accounts for change in variance due to the clustering effect (Hanley et al., 2003).

The crude incidence rates of mishaps for the self-checklist use and no self-checklist use were estimated. The best fitting model was derived by backward elimination technique such that any variable that was seen favorably in bias-variance trade-off was retained in the model (Greenland, 2008). Bias-variance trade-off suggests if the square of the bias controlled due to adjustment is greater than the amount of increase in variance (or loss of precision) due to adjustment, adjustment is favored; however if the increase in variance is greater than the correction of bias, the trade-off is not favorable, and the adjustment is not favored.

The final models for evaluating the effect of self-checklist use on major mishaps and all mishaps included the self-checklist use, sex, race, age, poor visibility, high current, and average annual dives. The final models for minor mishaps and unsafe conditions are identical to the one stated above, except they do not include race as inclusion of race led to non-convergence.

SAS 9.3 (SAS Inc., Cary, NC) was used for all statistical analysis.

D. Results

Between June 1st and August 17th 2012, 467 divers were enrolled in the study. One participant withdrew, 10 participants did not complete the outcomes questionnaire and were removed by the investigator, and 30 participants were lost-to-follow-up. The lost-to-follow-up occurred because at each location there was only one personnel collecting data, and at the end of the day when divers are in a rush to leave some of the participants missed completing the outcomes questionnaire. Overall, 426 divers completed the study during 30 location-days. The average number of participants per location-day was 14.2 (range: 8-20), and the average number of dives per location-day was 28 (range: 15-42). Divers made a total of 840 dives ranging from 0 to 6 dives each; 22 divers chose not to dive (5.2%) and 84.5% divers dove twice.

More than two-thirds of the participants (n=300) were males, the median age was 44 years (range 18 to 81 years), and 96.2% of the participants (n=410) identified their race as White (table 5.1). Seventy percent of the participants dive 0-20 dives per year, 10% dive 21-40 dives per year, and 20% dive more than 40 dives per year. The median average annual dives were 10 per diver (range 0 to 300). Fewer than eight percent of participants (n=33) used a self-checklist (written pre-dive checklist). More than 17% of participants (n=78) reported facing high current while diving, but only 6.8% (n=29) reported bad visibility.

About 36% of all participants (n=153) reported either a major or minor mishap ranging from 1 to 11 mishaps per diver. Rapid ascent and lost buddy contact were the most frequently observed major mishaps, and change in buoyancy due to dive suit, equalization problems, and mask problems were the most frequently observed minor mishaps. The overall rate of major mishaps was 11.2 per 100 dives, the rate of minor mishaps was 18.2 per 100 dives and the rate of all the mishaps was 29.4 per 100 dives. The crude rate of major mishaps for those who used a written self-checklist was 5.1 per 100 dives and was 11.7 per 100 dives for those who did not use a written self-checklist (table 5.2), for a crude rate difference of 6.6 major mishaps per 100 dives. The crude rate difference for minor mishaps was 5.0 per 100 dives, and the crude rate difference of all mishaps was 11.6 per 100 dives.

Almost 18% participants (n=80) reported at least one unsafe condition. One diver reported 8 unsafe conditions, while all others reported between 1 to 3 unsafe conditions. Being underweight, i.e., positively buoyant, and overweight, i.e., negatively buoyant in the water, were the most common unsafe conditions observed. The overall crude rate of unsafe conditions was 12.9 per 100 dives. The crude rate of unsafe conditions for those who used a written self-checklist was 6.8 per 100 dives, as compared to 13.3 per 100 dives for those who did not use a written checklist (table 5.3), for a crude rate difference of 6.5 unsafe conditions per 100 dives. The proportion of divers who did not dive was 6.1% among those who used a written self-checklist as compared to 5.1% among those who did not use a written self-checklist.

The adjusted rate ratios for mishaps and unsafe conditions suggest that the use of a written self-checklist was associated with a decrease of major mishaps by two thirds, all mishaps by half, and unsafe conditions by more than a half (table 5.4).

E. Discussion:

The use of self-checklist among the control group divers was associated with decreased incidence of mishaps and unsafe conditions. Those who routinely use self-checklists had 69% fewer major mishaps, 53% fewer all mishaps, and 56% fewer unsafe conditions. However, less than eight percent participants used a written pre-dive checklist. This suggests the low prevalence of written pre-dive checklist use.

Among the major mishaps, rapid ascent and lost buddy contact were most common. Rapid ascent can be due to many reasons. This may have something to do with the diver's general health, some critical equipment failure, running out of air, panicking during dive, or simply because the diver did not pay attention to their ascent rate (Buzzacott, Rosenberg, & Pikora, 2009b). This is indicative of lack of proper training. A lost buddy contact may have also resulted from similar conditions. The conventional rule in case of lost buddy contact is to search for the buddy for one minute and if not found, start a controlled ascent back to the surface. This rule is taught by diving agencies consistently, but the compliance is questionable, because ascending back to the surface, especially when one hasn't been underwater for long, means terminating your own dive without getting your money's worth. Losing buddy contact is one of the most frequently encountered features in diving-related fatalities (Denoble et al., 2008; Walker, Lippmann, Lawrence, Houston, & Fock, 2009). While rapid ascent increases the diver's risk of having decompression sickness, losing a buddy may deny critical assistance to the diver when in need. Entanglement/ entrapment and low-to-out-of-air were the next most common major mishaps. All cause diving mortality studies suggest that insufficient gas and entrapment are the leading triggers in diving fatalities (Denoble et al., 2008). Despite these major mishaps no injuries were observed in this study.

Many individuals carried inappropriate weights and were underweight – positively buoyant or overweight – negatively buoyant (table 5.3); this may reflect inexperience or lack of training. There were more minor mishaps than the unsafe conditions reported (tables 5.2 and 5.3). However, conventionally, one would expect to observe the contrary. Unsafe conditions can be identified and corrected easily before the dive starts. The diver may correct some of the unsafe conditions and hence not report it leading to fewer reported unsafe conditions overall.

In our study the use of a written self-checklist is associated with a 50% decrease in the incidence of all mishaps as compared to not using a written checklist. In addition a written checklist is associated with 66% fewer major mishaps and 55% fewer unsafe conditions. Although the extent and contents of these written self-checklists are not known, it is conceivable that any written checklist that directs an individual to do particular tasks would prove to be safe. Use of checklists is supported by other high risks areas like aviation and surgery, where the checklists focus on individual tasks and ensure safety (Haynes et al., 2009; Helmreich, 2000).

The findings are consistent with a 1995 study, where 55 divers who attended a dive equipment exhibition were asked to perform a pre-dive check on a pre-assembled scuba gear from their memory and experience without using a written checklist. The researchers had deliberately left nine equipment faults for the divers to find. Only 2 out of 55 divers could find all nine errors (Acott, 1995b).

Limitations: This study may not be generalizable to the entire diving population. The study was conducted in the Atlantic and Caribbean waters, and the current, visibility and wild animal populations in other regions may vary greatly. Also, this study was conducted during summer, and diving conditions differ greatly during other seasons. All the participants were recreational scuba divers; results cannot be generalized to technical divers, seafood harvesters, or navy divers. However, it is uncontended that pre-dive checklists promote safety; that they would be safe to use in any environment, season, or type of diving; and that they could only make a diver safer as long as the checklist conforms to the training agency and general diving guidelines.

The source and contents of the self-checklist used by participants in this study may vary greatly. This nested study makes an assumption that the effect of any and all such checklists is similar which may not be true.

F. Conclusions:

Our study suggests that the incidence of mishaps may be higher than previously thought. The prevalence of pre-dive checklist use among recreational scuba divers may be low. The use written pre-dive checklists, irrespective of the source and content of the checklist, may lead to fewer mishaps as compared to not using a written pre-dive checklist, including the use of a memorized checklist. Since most of the memorized checklists are memorized using mnemonics and mnemonics do not provide focused instructions, divers may only remember the mnemonic and the main items, but forget or overlook the specific actions to be taken. The use of memorized checklists should be discouraged in favor of written checklists. A written checklist provides step by step instructions to perform specific actions for checking the equipment and the diver’s readiness to dive.

Table 5.1: Aim 2 covariate distribution

Variables	Categories	Self-checklist		No self-checklist	
		N	%	N	%
Sex	**Male**	26	78.8	274	69.7
	Female	7	21.2	119	30.3
Age	**17-35**	4	12.1	117	29.8
	36-55	23	69.7	210	53.4
	> 55	6	18.2	66	16.8
Race	**White**	410	93.9	379	96.4
	Non-White*	2	6.1	14	3.6
Average yearly dives	**0-20**	20	60.6	278	70.7
	21-40	5	15.2	38	9.7
	> 40	8	24.2	77	19.6
Bad visibility	**Yes**	6	18.2	23	5.9
	No	27	81.8	370	94.1
High current	**Yes**	3	9.1	73	18.6
	No	30	90.9	320	81.4
All participants		33 (7.8%)		393 (92.2%)	

* includes African American, Asian, and Hispanic

Table 5.2: Crude rates of mishaps among divers who used a written self-checklist vs not

	N	Rate per 100 dives		
		Total	Written	None
Major mishaps	**94**	**11.2**	**5.1**	**11.7**
Rapid ascent	37	4.4	0.0	4.7
Lost buddy contact	22	2.6	3.4	2.6
Entanglement/ entrapment	9	1.1	0.0	1.2
Low to out of air	9	1.1	0.0	1.2
Free Ascent	8	1.0	0.0	1.0
Spontaneous inflation	5	0.6	0.0	0.6
Buddy breathing	2	0.2	1.7	0.1
2nd stage regulator malfunction	2	0.2	0.0	0.3
Content hose rupture	0	0.0	0.0	0.0
Free flowing 2nd stage	0	0.0	0.0	0.0
Minor mishaps	**153**	**18.2**	**13.6**	**18.6**
Changed buoyancy due to dive suit	29	3.5	3.4	3.5
Equalization problems	26	3.1	0.0	3.3
Mask squeeze	23	2.7	0.0	2.9
Mask flooded/ Dislodged/ Panic	17	2.0	1.7	2.0
O-ring problem	9	1.1	3.4	0.9
Buddy mismatch	7	0.8	1.7	0.8
Unable to clear mask	6	0.7	0.0	0.8
Fins lost/ loose/ dislodged	6	0.7	0.0	0.8
Safety Stop missed	6	0.7	0.0	0.8
Leaking BCD	6	0.7	1.7	0.6
Air used frequently to maintain buoyancy	5	0.6	0.0	0.6
Air not turned on/ not fully on	3	0.4	0.0	0.4
Computer stopped working	3	0.4	1.7	0.3
Weights belt/ weights dropped	2	0.2	0.0	0.3
Fins strap broke	2	0.2	0.0	0.3
Multiple ascents	2	0.2	0.0	0.3
Octopus reg snagged	1	0.1	0.0	0.1
Unable to release weights	0	0.0	0.0	0.0
Mask strap broke	0	0.0	0.0	0.0
All mishaps	**247**	**29.4**	**18.6**	**30.2**

Table 5.3: Crude rates of unsafe conditions and risk of not-diving among divers who used written self-checklist vs not

Outcome	N	Rate per 100 dives		
		Total	**Written**	**None**
Underweight	26	3.1	3.4	3.1
Overweight	24	2.9	1.7	2.9
Not familiar with Dive computer	10	1.2	0.0	1.3
Tank not well secured	9	1.1	0.0	1.2
Unfamiliar with the use of BCD*	8	1.0	0.0	1.0
Tables Not used before	6	0.7	0.0	0.8
Tight/ uncomfortable dive suit	5	0.6	0.0	0.6
Dive computer battery problems	3	0.4	0.0	0.4
Incorrect BCD size	3	0.4	0.0	0.4
Size changed between dives	3	0.4	0.0	0.4
Fins - Caused cramp	2	0.2	0.0	0.3
Inaccurate dive gauge	2	0.2	1.7	0.1
BCD Inadequate buoyancy	2	0.2	0.0	0.3
Dive computer not turned on before dive	1	0.1	0.0	0.1
Dive tables – misread	1	0.1	0.0	0.1
Computer hard to understand	1	0.1	0.0	0.1
Unable to understand dive tables	1	0.1	0.0	0.1
Max depth indicator problem	1	0.1	0.0	0.1
Unable to locate alternate regulator	0	0.0	0.0	0.0
Unit confusion on the dive gauge	0	0.0	0.0	0.0
Total Unsafe conditions	**108**	**12.9**	**6.8**	**13.3**
		Risk per 100 divers (%)		
Did not dive	**22**	**5.2%**	**6.1%**	**5.1%**

*includes confusion on BCD inflate/ deflate, & didn't know how to inflate/ deflate the BCD

Table 5.4: Crude and adjusted rate ratios comparing the use of written checklist with none

Outcomes	**Self-checklist versus No Self-checklist**			
	Crude RR	**95% CI**	**Adjusted RR***	**95% CI**
Major mishaps	0.43	0.13, 1.41	0.31	0.10, 0.93
Minor mishaps	0.64	0.30, 1.35	0.62	0.29, 1.29
All mishaps	0.55	0.27, 1.13	0.47	0.27, 0.83
Unsafe conditions	0.52	0.28, 0.98	0.44	0.22, 0.87

RR – Rate ratio; CI – Confidence interval; *Adjusted for sex, race, age, poor visibility, high current, and average annual dives

VI. RESULTS CHAPTER 3: Factors affecting adherence to the intervention in a cluster randomized trial of pre-dive checklist among recreational scuba divers.

A. Introduction:

The importance of using checklists for injury prevention has been justified time and again (Acott, 1995a; Hales & Pronovost, 2006; Scriven, 2000). While the aviation industry is the innovator, early adopter, and most dedicated proponent of checklist, surgery is the newest and most emphatic champion for checklist use (Haynes et al., 2009; Helmreich, 2000). Pre-flight and pre-surgical checklists are integral parts of their respective areas. A pre-dive checklist is a written set of actions a scuba diver must perform immediately before diving in order to ensure safety. Vast majority of scuba diving fatalities are caused by preventable mishaps (Denoble et al., 2008; Lippmann, 2010). The use of pre-dive checklist in recreational scuba diving has been shown to decrease the incidence of diving mishaps, and hence may also prevent against injuries and reduce fatalities (Ranapurwala, Wing, & Denoble, 2013). But, the prevalence of pre-dive checklist use in recreational scuba diving seems low (Ranapurwala, 2014a; Ranapurwala, 2014b).

The use of pre-dive checklists may not increase by mere communication of their good effects. The widespread adoption of pre-dive checklists depends on how well the idea is promoted by dive training organizations and industry partners like dive shop operators and equipment manufacturers. At present, training curriculums include familiarizing divers with pre-dive checklist, however their use is not mandatory and there is very little emphasis for their continued use, if any. Commercialization drives different training agencies to come up with their own checklists all of which vary considerably, thus further complicating the pre-dive checklist scenario. Training agencies publish checklists in their diving manuals but the onus of reproducing it and putting it to regular use is solely on the diver. The majority of instructors, dive masters, and senior divers do not use pre-dive checklists, and hence are not very likely to mandate their students or those who dive alongside to use them. Divers prefer to depend on their experience and training alone and consider using checklist a time-drain rather than an important safety tool.

It is vital to know the groups that do not prefer to use the pre-dive checklist, so called non-adherent groups, so that their motivations for doing so can be studied and remedied. The factors that distinguish these divers may be individual or environmental. In this study the authors provided divers with a pre-dive checklist to use and observed the proportion of people that adhere to the pre-dive checklist. The authors also examine the role of age, gender, race, average annual dives, using their own written checklist (self-checklist), and dive location, in the adherence to the pre-dive checklist provided by the authors.

B. Methods:

This was a nested study conducted among the intervention group participants of the cluster randomized trial (aim1) that utilized a prospective observational study design to assess the factors affecting the adherence to the interventional pre-dive checklist. There were three study instruments: A pre-dive checklist, a contact-information form, and a post-dive questionnaire. The pre-dive checklist contained a list of actions divers were asked to undertake before diving, it included checking tank pressure, checking the diving equipment, assessing their own preparedness for diving, a gas management plan, four dive tips and a post-dive log to record the depth and time of dives, and the pressure of breathing gas at different points of the dive. The contact-information form was used to enroll and track participants and note their age, gender and racial/ethnic background. The post-dive questionnaire was given to the participants at the end of all their dives on the day of participation; it included a list of potential mishaps, information on height, weight, brief medical history, and diving history including the use of their own pre-dive checklists (self-checklist).

The study was conducted at one location in North Carolina, two locations in Cozumel, Mexico, and one location in the Cayman Islands. Four trained interns, one at each study, were placed and hosted by a total of 7 dive shops. Each diver could participate only once. All participants participating on a same location may not have independent outcomes. Hence, a separate contact information sheet was used to enroll participants on each location-day, and the completed study instruments for a particular location-day were kept separately along with the contact information sheet. Each diver received a unique identifier based on their location-day, and enrollment number on that day. The enrollment number was noted on their pre-dive checklist and the outcomes questionnaire; this ensured that each participant's pre-dive checklist, post-dive questionnaire, and contact information were kept together.

The participants had to be more than 18 years of age, had to have a valid diver certification, had to be planning to dive the day of their recruitment, had to be deemed fit for diving by the dive operator, and had to have working knowledge of English.

The divers were briefed about the study; those agreeing to participate were asked to provide signed consent. At this time, the interns noted participant names, contact information, age, gender, race, and participant number on the contact-information form. The names and contact information allowed preventing repeat participation. The participants received the pre-dive checklist and explanation for its use. When the participants completed all their dives for the day or upon divers' return to the pier, interns collected the checklists and asked the participants to answer the post-dive questionnaire. The interns entered the data to the online forms, which were identical to the pre-dive checklist and post-dive questionnaire.

This study was approved by the institutional review boards (IRB) at DAN # 009-12 on 03/27/2012 and the University of North Carolina (UNC) # 12-1051 on 05/29/2012, and further renewed by DAN IRB on 02/06/2013 and UNC IRB on 02/25/2013.

Outcomes: The outcome for this study was the adherence to pre-dive checklist. Three criteria were used to determine if a participant was adherent to the checklist. First, a diver was considered non-adherent, if they did not report the starting tank pressure of their first dive, on the checklist. Then they must have made a written pre-dive plan on the checklist. Lastly, they must have checked at least 10 checkboxes on the checklist. Adherence to checklist was defined as a binary variable where meeting all of the aforementioned criteria would deem a diver adherent.

Covariate structure: Divers reported the use of self-checklists as a three category response - no-checklist use, use of a written checklist, or the use of a memorized checklist. A binary variable for the use of a written self-checklist (yes/ no) was created, where the 'no' includes no checklist use and use of a memorized self-checklist. Gender (male/ female), race (white/ non-white), and location (North Carolina/Caribbean) are all binary variables.

Sensitivity analyses were conducted to explore the effect of average annual dives, and age on the adherence. Based on which, average annual dives were categorized them into five categories - 0-5 dives, 6-10 dives, 11-15 dives, 16-20 dives, and more than 20 dives per year; and age was categorized as a binary variable where divers between from 18-35 years of age formed the 'younger' divers group, and divers with age 36 years and above formed the 'older' divers group.

C. Statistical Methods:

Descriptive statistics of the collected variables are discussed using tables and frequencies. Exploratory logistic regression models were used to evaluate the odds of being adherent. The best fitting model included age, sex, race, diving experience (average annual dives), use of a self-checklist, and dive location. Since the participants that participated on the same day faced similar environmental conditions, their outcomes may not have been independent, leading to clustering of effects in our data. Generalized estimating equations were used to address the non-independence of dives within a cluster that generate a robust variance estimator to account for change in variance due to the clustering (Hanley et al., 2003).

Odds ratios of comparison are reported for gender, age, race, diving experience, use of self-checklist, and diving location. SAS 9.3 (SAS Inc., Cary, NC) was used for all statistical analysis.

D. Results:

From June 1st to August 17th 2012, 693 divers were enrolled, during 40 location-days, to use the pre-dive checklist. Of the 693, eight participants withdrew, 21 did not complete the outcomes questionnaire and were removed by the investigator, and 47 participants were lost-to-follow-up. Overall, 617 participants completed the study.

The characteristics of these participants are presented in table 3.1. About two thirds of the participants (66.1%) were males, the median age was 43 years (range 18 to 77 years) with 67.9% older divers (> 35 years of age), and the majority of participants identified their race as White (93.8%). Most of the divers perform between 0-5 dives a year (42.8%), and almost a fifth of the divers (19.4%) perform more than 20 dives a year. The median average annual dives were 10 per diver (range 0 to 300). Only 5.8% participants (n=36) used a written self-checklist.

Of the 617 participants who completed the study, 430 (69.7%) participants adhered to the pre-dive checklist. Factors influencing the adherence to the pre-dive checklist are explained in table 6.2. Those who routinely use self-checklists had about 2.5 times the odds of adhering to the intervention checklist as compared to those who do not use a self-checklist. Participants who described themselves as African-Americans, Hispanics, Asian, and others (Non-white) had 49% fewer odds of being adherent to the intervention pre-dive checklist as compared to those who described them as White. Females had 23% lower odds of adhering to the intervention checklist than males. However, the model effects of self-checklist, race, and sex are imprecise due to small sample sizes. As compared to the younger divers (18-35 years of age), older divers (> 35 years of age) had 1.67 times the odds of adhering to the intervention pre-dive checklist. Diving experience is denoted by the number of average annual dives a diver makes. As compared to divers who dive 0-5 dives a year, divers who dive more had higher odds of being adherent to pre-dive checklist, however, there was a bi-nodal effect, such that divers who dive 6-10 dives and 16-20 dives had the highest adherence odds.

Divers who dove in North Carolina had 59% less adherence odds to the intervention checklist than divers in the Caribbean.

E. Discussion:

Although in excess of 30% participants were non-compliant, there may be different levels or kinds of non-compliance issues here. Some divers may not have referred to the checklist at all, and some divers may have read it but did not note or write on it. The prevalence of written self-checklist use was very low among the participants.

Those who routinely use self-checklist had 2.5 times the odds of adhering to the checklist as compared to those who do not use self-checklist. This makes sense because divers who already use checklists may have experienced the benefits of it first-hand, and were happy to use a checklist that comes of a professional diving safety organization.

Divers who dove in North Carolina had lower odds of adhering to the pre-dive checklist than those who dove in the Caribbean. Diving in both these places is different. The Atlantic coast of North Carolina is known for wreck diving, while the Caribbean is home to reef diving. Even though all these divers were recreational, it can be assumed that Caribbean, being a major tourist location and having a larger tourism industry, sees influx of divers with a wide range of experience and certification level. These may first timers who want to try diving on their vacation or they may be experienced divers who came to the Caribbean specially to dive. North Carolina diving on the other hand is dominated by local divers, who know the diving conditions well, and dive more often because it is cost-effective. This is supported by the fact that the median average annual dives for the Caribbean participants was 8 dives (range 0-300 dives), while that for the North Carolina participants was 15 dives (range 1-149 dives).

The data also suggests that divers above 35 years of age had 67% higher odds of being adherent to the pre-dive checklist as compared to divers between the ages of 18-35. Younger adults are known to take more risks than older adults, it may be due to their low risk perceptions, a sense of being invulnerable, or due to the experimentation behavior (Irwin, Cataldo, Matheny, & Peterson, 1992; Otani, Leonard, Ashford, Bushroe, & Reeder, 1992). Hence, younger divers may be less careful than the older divers and may not understand the importance of pre-dive checklist well, which led them to be less adherent.

Limitations: Our study had a small sample size to assess the associations all the variables we used with adherence to pre-dive checklist. Only 36 (5.8%) participants had a self-checklist, and only 5 of those were non-adherent. When more variables were added to the regression model the sample size in each cell became smaller, leading to wide confidence intervals in the analysis. Hence the accuracy of the measures may be questionable. However, the univariate for self-checklist use had enough power, and after multivariate adjustment the odds ratio did not decrease much. Hence, it may be safe to say that those who used a self-checklist adhered more. As for race, again, there were very few non-white participants to allow any accurate estimation of the odds ratio.

This study was conducted in the Atlantic and Caribbean waters. Diving conditions, water temperature, current, and other environmental factors may vary greatly with diving in other parts of the world. Besides this was a very small group of divers that may not represent all of the diving population; also, each of the divers was observed for only a few dives. Hence, the results of this study may not be generalizable to the complete diving population.

There may be other unknown factors that may have affected the divers to not adhere to the provided pre-dive checklist. The diver's perception of risk may be the single most important factor that would motivate them to adapt to safety behaviors. Besides, there may be many facilitators and barriers of behavior. Facilitators like a dive buddy who uses self-checklist, or a proven checklist provided by a safety organization might motivate a diver to use a pre-dive checklist. Conversely barriers like lack of time, a mismatched buddy, improper training may make a diver to not use a checklist, or use it improperly. To emphasize the point, many of these behaviors towards adherence to the checklist may be conditional; divers may adhere to the checklist when they are more comfortable and have more time and may not adhere at another instance. Interpretation of the study results warrant consideration of these factors which the authors did not investigate.

F. Conclusions:

This study informs future research about the target populations to improve checklist compliance. Such target population may be younger divers, who do not use pre-dive checklists routinely, and know the diving location or conditions all too well.

Future studies should evaluate risk perceptions of divers and its association with facilitators and barriers of pre-dive checklist use, using focus group studies, online likert scale based questionnaires, or using qualitative interview based studies. These studies would help determine the best way to promote the use of pre-dive checklist by improving industry involvement, and making pre-dive checklist a part of diving safety culture.

Table 6.1: Aim 3 covariate distribution

Variables	Categories	Divers			
		Adherent	Non-adherent	Total	%
Sex	**Male**	291	117	408	66.1
	Female	139	70	209	33.9
Age	**18-35 years**	120	78	198	32.1
	> 35 years	310	109	419	67.9
Race	**White**	407	172	579	93.8
	Non-White*	23	15	38	6.2
Location	**North Carolina**	81	60	141	22.8
	Caribbean	349	127	476	77.2
Average Yearly Dives	**0-5 dives**	173	91	264	42.8
	6-10 dives	81	23	104	16.9
	11-15 dives	44	21	65	10.5
	16-20 dives	48	16	64	10.4
	>20 dives	84	36	120	19.4
Written self-checklist	**Yes**	31	5	36	5.8
	No	399	182	581	94.2
All participants		430	187	617	100

Table 6.2: Adherence Odds Ratio (AOR) for factors influencing adherence to pre-dive checklist

Variables	Categories	Adherence Odds ratio (AOR)	
		Univariate AOR (95% CI)	**Multivariate* AOR (95% CI)**
Self-Checklist (ref= None)	**Written**	2.67 (1.05, 6.74)	2.48 (0.95, 6.44)
Race (ref = White)	**Non-White**	0.59 (0.30, 1.11)	0.54 (0.27, 1.09)
Sex (ref=Male)	**Female**	0.81 (0.57, 1.15)	0.77 (0.54, 1.12)
Age (ref=18-35 years)	**> 35 years**	1.86 (1.31, 2.64)	1.67 (1.15, 2.42)
Average yearly dives (ref=0-5 dives)	**6-10 dives**	1.76 (1.03, 2.99)	1.87 (1.09, 3.21)
	11-15 dives	1.20 (0.67, 2.12)	1.17 (0.62, 2.20)
	16-20 dives	1.74 (1.05, 2.89)	1.59 (0.95, 2.67)
	> 20 dives	1.24 (0.78, 1.96)	1.14 (0.69, 1.89)
Location (ref = Caribbean)	**North Carolina**	0.46 (0.23, 0.91)	0.42 (0.20, 0.85)

*The best fitting multivariate model included age, sex, race, diving experience (average annual dives), use of a self-checklist, and dive location

VII. DISCUSSION

A. Summary

The prevalence of pre-dive self-checklist use among the participants was low, only 6.6% overall. Overall 349 mishaps were reported in the intervention and the control groups combined; 176 major mishaps and 173 minor mishaps. Among the major mishaps rapid ascent, lost buddy contact, and low to out of air mishaps were most common, while among the minor mishaps changed buoyancy due to dive suit, mask squeeze, and unable to clear mask were most common.

The crude ITT rate of major mishaps in the intervention group is 7.5 per 100 dives, and that in the control group is 10.2 per 100 dives for a rate difference of 2.7 mishaps per 100 dives. The number needed to treat (NNT) is 36.9 dives. Thus we prevented 33 major mishaps in the intervention group. The ITT rate of all mishaps in the intervention group is 15.2 per 100 dives, and that in the control group is 19.0 per 100 dives for rate difference of 3.8 mishaps per 100 dives; the NNT is 25.6 dives. Thus we prevented a total of 47 mishaps (major + minor) in the intervention group.

The most common unsafe conditions were poorly secured gas tanks, unfamiliarity with the use of BCD, and battery problems with the dive computer. The crude ITT rate of unsafe conditions in the intervention group was almost the same as that in the control group, approximately 2.6 per 100 dives, suggesting that one may not be at any special advantage to receive the intervention when one wants to control the unsafe conditions. The risk of not-diving in the intervention group is lower than in the control group by 1.8% (risk difference). This means that more diving took place in the intervention group as a result of using a pre-dive checklist. The NNT is 55.6 divers.

The ITT and MSM analysis suggest that the intervention reduced the incidence of major mishaps by 41% and that of all mishaps by 35%.

Unlike the crude rates the adjusted ITT and MSM rate ratios for the incidence of unsafe conditions suggests that there may actually be a reduction of 22-28% due to the intervention. The ITT and MSM risks ratios for not-diving suggest that the intervention group divers dive about 35-70% more as compared to the control group. Although, these analysis were prone to greater degree of random error due to small sample sizes.

The aim 2 analyses were conducted among the control group participants only. Since the scope and content of self-checklists may vary greatly, all reported mishaps were accounted for in aim 2 analyses, unlike aim 1 where a selected group of mishaps were accounted for (table 3.5).

About 36% of all control group participants (n=153) reported either a major or minor mishap ranging from 1 to 11 mishaps per diver. Rapid ascent and lost buddy contact were the most frequently observed major mishaps, and change in buoyancy due to dive suit, equalization problems, and mask problems were the most frequently observed minor mishaps. In the control group, the overall rate of major mishaps was 11.2 per 100 dives, the rate of minor mishaps was 18.2 per 100 dives and the rate of all the mishaps was 29.4 per 100 dives. The crude rate of major mishaps for those who used a written self-checklist was 5.1 per 100 dives and was 11.7 per 100 dives for those who did not use a written self-checklist, for a crude rate difference of 6.6 major mishaps per 100 dives. The crude rate difference for minor mishaps was 5.0 per 100 dives, and the crude rate difference of all mishaps was 11.6 per 100 dives.

Almost 18% participants (n=80) reported at least one unsafe condition. One diver reported 8 unsafe conditions, while all others reported between 1 to 3 unsafe conditions. Being underweight and overweight were the most common unsafe conditions observed. The overall crude rate of unsafe conditions was 12.9 per 100 dives. The crude rate of unsafe conditions for those who used a written self-checklist was 6.8 per 100 dives, as compared to 13.3 per 100 dives for those who did not use a written checklist (table 5.3), for a crude rate difference of 6.5 unsafe conditions per 100 dives. The proportion of divers who did not dive was 6.1% among those who used a written self-checklist as compared to 5.1% among those who did not use a written self-checklist.

The adjusted rate ratios for mishaps and unsafe conditions suggest that the use of a written self-checklist was associated with a decrease of major mishaps by two thirds, all mishaps by half, and unsafe conditions by more than a half.

In the aim 3 analyses, the factors influencing adherence to the intervention were assessed. Of the 617 intervention group participants who completed the study, 430 (69.7%) participants adhered to the pre-dive checklist. Those who use written self-checklist adhered to the pre-dive checklist about 2.5 times more as compared to those who do not use a written self-checklist. Participants who described themselves as African-Americans, Hispanics, Asian, and others (Non-white) adhered to the pre-dive checklist 49% less as compared to those who described them as White. Females adhered to the pre-dive checklist 23% less as compared to males. However, the effects of self-checklist, race, and sex on the adherence to the intervention checklist is not precise. As compared to the younger divers (18-35 years of age), older divers (> 35 years of age) were 1.67 times likely to adhere to the pre-dive checklist. Diving experience is denoted by the number of average annual dives a diver makes. As compared to divers who dive 0-5 dives a year, divers who dive more than that adhered more, however, there was a bi-nodal effect, such that divers who dive 6-10 dives and 16-20 dives had the highest adherence.

Divers who dove in North Carolina showed 59% less adherence to the checklist than divers in the Caribbean.

B. Strengths

A pre-dive checklist is a simple tool that can increase safety and provide a better diving experience. This idea is simple and logical, especially as they has been proved to be effective in other high risk fields like aviation and surgery (Hanley et al., 2003; Helmreich, 2000).

Diving injuries are uncommon outcomes, and divers often do not report mild symptoms of injuries (Ranapurwala et al., 2014). Hence, assessing the effectiveness of checklists in reducing the injuries would be harder as it would require a large sample size, greater resources, and a long time to collect the adequate data. This study used diving mishaps, which are more common than injuries, as outcomes of interest. This reduced the needed sample size, and the need for greater resources and time.

Using a randomized study design to assess the effectiveness of pre-dive checklist use on the incidence of diving mishaps is also the strength of the study. This design allowed establishing a causative relationship between the pre-dive checklist use and the incidence of diving mishaps (Weiss, 2008).

Cluster randomization is also one of the strengths of this study. Divers dive together on a dive boat. Randomizing individuals to intervention within a dive boat would have led to cross-contamination of the intervention and control groups. By randomizing location-days this cross-contamination was avoided.

Using per-protocol analyses and marginal structural models allowed accounting for non-compliance in the intervention group participants. These two methods provide the effect of ‘treatment received’ as opposed to ‘treatment given’ from the intent-to-treat approach, thus providing the true effectiveness of pre-dive checklist use in reducing the incidence of mishaps.

C. Limitations

Randomization of intervention based on location-days allowed the investigators to restrict cross-contamination of the intervention; however it introduced clustering. GEE was used to control the within-location-day clustering. However, there is also clustering on the level of the diver because most of the divers dove more than once. This is a limitation that as this does not account for separate outcome information for each of the dives. The outcome information is available at the diver level. Even some of the covariate information that is likely to change from dive to dive like the environmental factors (current and visibility) is available only at the participant level.

This study did not utilize block randomization. Hence there was staggering of more intervention location-days in the beginning of the trial at two locations. This resulted in participants getting randomized to more intervention location-days early on and fewer control location days by the time the sample size was reached. This resulted in greater number of location days, divers, and dives in the intervention group as compared to the control group.

This study may not be generalizable to the entire diving population. The study was conducted in the Atlantic and Caribbean waters, and the current, visibility and wild animal populations in other regions may vary greatly. Also, this study was conducted during summer, and diving conditions differ greatly during other seasons. All the participants were recreational scuba divers; results cannot be generalized to technical divers, seafood harvesters, or navy divers. However, it is uncontended that pre-dive checklists promote safety; that they would be safe to use in any environment, season, or type of diving; and that they could only make a diver safer as long as the checklist conforms to the training agency and general diving guidelines.

The source and contents of the self-checklist used by participants in this study may vary greatly. The nested study in Aim-2 makes an assumption that the effect of any and all such checklists is similar which may not be true.

There may be other factors influencing adherence to the provided pre-dive checklist that are not accounted in this study. The diver's perception of risk may be the single most important factor that would motivate them to adapt to safety behaviors. Besides, there may be many facilitators and barriers of behavior. Facilitators like a dive buddy who uses self-checklist, or a proven checklist provided by a safety organization might motivate a diver to use a pre-dive checklist. Conversely barriers like lack of time, a mismatched buddy, improper training may make a diver to not use a checklist, or use it improperly. To emphasize the point, many of these behaviors towards adherence to the checklist may be conditional; divers may adhere to the checklist when they are more comfortable and have more time and may not adhere at another instance.

This study did not have enough power to assess some of the factors that influence adherence to the provided checklist or to assess the association of using written self-checklists with the incidence of mishaps in divers.

D. Recommendations

The use of pre-dive checklists in recreational scuba diving must be promoted and pre-dive checklists should become a cornerstone of the scuba diving safety culture. An action oriented written pre-dive checklist may be the best way forward. This means that the checklist should focus on individual tasks rather than topics, that could be written as commands starting with verbs like check, examine, record, ensure, remember, do, do not, etc. For example, check weight releases, or record the starting tank pressure, or ensure that the air is turned on. Breaking down safety topics in individual tasks provides the best opportunity to reduce human error and draw appropriate attention to equipment problems.

Administration of such checklists immediately before dive at focal points such as piers, dive boats, and dive shops may be most beneficial. This means, not in mail, not through a seminar or at a conference, not online on a website, but at dive sites where divers are preparing to dive and taking the plunge. This will require involvement of industry stakeholders like instructors, dive shop owners, boat operators and captains, etc. Training agencies must promote the use of checklists more vigorously. Not only put it in their manuals, but print laminated slates and provide them to the participants. Instructors and dive shop owners may provide checklists for their divers at a miniscule cost, e.g., paste an oversized checklist on dive boats and /or piers, or have small laminated paper checklists available at the shops and dive boats that the divers could carry and use individually.

The adoption and promotion of checklists is a matter of urgency for the diving community. Pre-dive checklists should become a cornerstone of the scuba diving safety culture.

APPENDIX 1: Form A – Intervention - Pre-dive checklist

Study Form

(This form has two parts: a checklist of procedures and a post-dive log. Please follow the procedures below before every dive but fill out the checklist only before your first dive. Fill out the post-dive log after every dive. Note tank pressure, depth and time where asked, and check the applicable boxes.)

□ Confirm you are healthy enough to dive

□ Review hand signals with your buddy

Primary gas tank:

□ Make sure your air is turned on *(Check by breathing through the regulator)*

What is the starting tank pressure? _______ □psi □bar

□ Check all the hoses are connected properly and there are no leaks

Secure all equipment to your body/ check all straps:

□ Mask □ BCD □ Tank □ Fins

□ Make sure to have completed a buoyancy check for this suit

□ Check if the weight releases work properly

Test your BCD:

□ Inflate □ Deflate □ Integrated weights (if so equipped) □ Releases

□ Test the spare second stage regulator (it should not free-flow)

□ Make sure that you are satisfied with the fit of your suit

□ Carry a cutting tool with you if allowed

□ Familiarize yourself with your buddy's gear

□ Make sure your depth gauge (once you start descending) and/ or computer are working

- □ Battery check
- □ Understand their use properly

□ Once in water do a final-ok buddy check before descending

Dive plan: *(Plan your dive before diving)*

Maximum depth you plan to go to during your dives today: _____ □ feet □ meters

Amount of gas you will keep for your

a. Return / Turnaround _____ □ psi □bar
b. Ascent _____ □ psi □bar
c. Back-on-board reserve _____ □ psi □bar

Dive tips: *(Important during diving)*

1. Stay close to your buddy; in case of lost contact with buddy, search for one minute and ascend if you do not find your buddy
2. Equalize early and often during descent
3. Do not ascend more than 30-60 feet/min (9-18 meters/min)
4. Understand the dive tables/computers and follow proper safety stop guidelines

Post-dive log: *(Enter the information below after completing each dive)*

Dive 1: □ psi □bar
______ depth of dive □ ft □m ______ total dive time
______ tank pressure before dive ______ tank pressure when started return/turnaround
______ tank pressure when started ascent ______ tank pressure after dive

Dive 2: □ psi □bar
______ depth of dive □ ft □m ______ total dive time
______ tank pressure before dive ______ tank pressure when started return/turnaround
______ tank pressure when started ascent ______ tank pressure after dive

Dive 3: □ psi □bar
______ depth of dive □ ft □m ______ total dive time
______ tank pressure before dive ______ tank pressure when started return/turnaround
______ tank pressure when started ascent ______ tank pressure after dive

Dive 4: □ psi □bar
______ depth of dive □ ft □m ______ total dive time
______ tank pressure before dive ______ tank pressure when started return/turnaround
______ tank pressure when started ascent ______ tank pressure after dive

APPENDIX 2: Form B – Control form – Post-dive log

Study Form

(This form has one part: a post-dive log. Please fill out this post-dive log after every dive. Note tank pressure, depth and time of your dives and check the applicable boxes.)

Dive 1: □ psi □bar

_____ depth of dive □ ft □m _____ total dive time

_____ tank pressure before dive _____ tank pressure when started return/turnaround

_____ tank pressure when started ascent _____ tank pressure after dive

Dive 2: □ psi □bar

_____ depth of dive □ ft □m _____ total dive time

_____ tank pressure before dive _____ tank pressure when started return/turnaround

_____ tank pressure when started ascent _____ tank pressure after dive

Dive 3: □ psi □bar

_____ depth of dive □ ft □m _____ total dive time

_____ tank pressure before dive _____ tank pressure when started return/turnaround

_____ tank pressure when started ascent _____ tank pressure after dive

Dive 4: □ psi □bar

_____ depth of dive □ ft □m _____ total dive time

_____ tank pressure before dive _____ tank pressure when started return/turnaround

_____ tank pressure when started ascent _____ tank pressure after dive

APPENDIX 3 – Outcomes Questionnaire

1. Weight _____ lbs__ kg__
2. Height ___ ft ___ in
3. Age _____ yr
4. Do you take medications for any of the following? (Check all that apply)
   ___High BP ___ Diabetes___ Asthma ___High Cholesterol
   ___Other (specify) ____
5. Do you have a history of any of the following?
   ___ Heart failure (MI) ___Angina ___Stroke ___Asthma ___High cholesterol
   ___Cardiac surgery ___ Cardiac pacemaker implant
   ___Other chronic illness (specify) ______________________________
6. Do you have any disability? ___ Yes ___ No
7. How many dives did you make today? _________
8. On a regular basis, do you use any pre-dive safety protocol or checklist?
   _____ Yes _____ No

a. **If yes**, what kind of checklist is it?

i. Mental checklist that I memorized ___

ii. Physical checklist that I made myself ___

iii. Training agency checklist (memorized) ___

iv. Training agency checklist (physical / written) ___

v. Other (specify) _______________________

9. What year was your first diving certification? __________ (example: 1983)
10. On an average, how many dives do you make every year? ______ dives
11. When was your last dive before today? _____________
12. Did you find this checklist helpful? ___ Yes ___ No
13. From the following group of diving mishaps / errors, please check the ones that occurred to you, during the dives you made today.

DIVE SUIT
___Tight / Uncomfortable
___Changed buoyancy
___ Other (Specify) _______________
____

ASCENT
___Rapid ascent
___Computer recorded rapid ascent
___Free ascent
___Multiple ascents
___Safety stop missed
___Equalization problems on ascent/ descent
___ Other (Specify) _______________
____

ENVIRONMENT
___Poor visibility
___Strong current
___Entanglement/ Entrapment
___Animal attack
___ Other (Specify) _______________
____

BUDDY
___Buddy mismatch
___Lost buddy contact
___Buddy breathing
___ Other (Specify) _______________
____

AIR & REGULATOR

___Low to out of air
___Air not turned on / not fully on
___Content gauge hose rupture
___2nd Stage malfunction
___Free flowing 2nd stage
___O-ring problem
___Unable to locate alternate regulator
___'Octopus' reg snagged
___ Air used frequently to maintain buoyancy
___ Other (Specify) _______________
____

MASK

___Squeeze
___Flooded /Dislodged
___Flooding / Dislodging caused panic
___Unable to clear
___Clearing caused panic
___Strap broke
___ Other (Specify) _______________
____

DIVE COMPUTER

___Not familiar with
___Not turned on before the dive
___Battery problems
___Stopped working
___Hard to understand
___ Other (Specify) _______________
____

DIVE TABLES

___Not used before
___Misread
___Unable to understand
___ Other (Specify) _______________
____

BCD

___Spontaneous inflation
___Didn't know how to inflate/ deflate
___Confusion in inflate/deflate buttons
___Unfamiliar with use
___Inadequate buoyancy
___Leak
___Incorrect size
___ Other (Specify) _______________
____

WEIGHTS

___Overweight
___Underweight
___Unable to release weights
___Weight belt / weights dropped
___ Other (Specify) _______________
____

DIVE GAUGE

___Units confusion
___Max depth indicator problem
___Inaccurate
___ Other (Specify) _______________
____

TANK

___Not well secured
___Size change between dives
___ Other (Specify) _______________
____

FINS

___Lost / Loose / Dislodged
___Strap broke
___Caused cramp
___ Other (Specify) _______________
____

APPENDIX 4: Contact information Form

Envelope Number : XX-NN **Date:**

Sr. No.	**Last Name**	**First Name**	**Phone Number**	**Email**	**Age**	**Gender**	**Race**
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							
21							
22							
23							
24							
25							
26							
27							
28							
29							
30							

How many divers were recruited today? ______ (write a number)

How many divers returned the study form (version blue/ yellow)? ______ (write a number)

How many divers answered the outcomes questionnaire? ______ (write a number)

Answer from hear-say information:

What was the visibility during the dives today? ________ maximum (number of feet)

How was the current in the sea today? ___ Strong ___ Moderate ____ low to no current

How were the waves in the sea today? ____ High ____ Moderate ____ Calm sea

Weather.com

Today's temperature: ______ Low, _____ High

Average winds: _____ mph

APPENDIX 5: Consent form

INTRODUCTION

You are asked to volunteer for a research study that aims to evaluate common practices in recreational diving. In order to decide whether or not you wish to be in the study, you will need to consider information about the study provided in this document. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You can ask any questions you might have at any time. This study is being sponsored by **Divers Alert Network (DAN)** who pays the primary investigator's (PI's) and co-PI's salaries. The out-of-pocket expenses and expenses for interns are being paid by private donations to DAN research.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate common practices in recreational diving.

BACKGROUND

Diving practices may influence health outcomes associated with diving e.g., mishaps and injuries. This research is designed to study recreational diving safety.

HOW THE STUDY WORKS

You may volunteer for this study if you are 18 years or older, have a valid diving certification and are able to give self-consent for participation. Participation in the study is completely voluntary and you can choose to stop participating whenever you want at any time. You can participate in the study only if your dive buddy participates. You and your buddy both must provide separate consent for participation.

Prior to participation you and your buddy will be fully oriented to the study procedures and informed about all the benefits and potential harmful effects of the study (mentioned below). If you choose to participate, we will collect information including your name, age, gender, race, and contact information. We will then provide you an additional study form and instruct you how to use it. We will ask you to record data about the dives you make today in the study form. This may take 5-15 minutes. We do not ask you to make any modifications to your dive plan for the sake of the study. You should dive as you may have otherwise planned in accordance with safe diving practices. At the end of your diving day, we will ask you to answer a questionnaire which may take anywhere between 5-10 minutes to complete. Completion and return of all materials will complete your participation in the study.

You can participate in the study only once. There will be no follow-up or email notifications. Your contact information will be used to contact you only if we need more clarification on any of the comments or events that you might have reported in the study forms.

We ask for your complete cooperation and diligence once you decide to volunteer for this study.

RISKS TO YOU

Mishaps and injuries are usual diving risks; these may occur during participation in this study, however, we do not expect an increase in mishaps or injuries as a result of participation. Participation exposes you to minimal additional risks that include potential loss of private data, such as identification information and contact information. However, we will not share participant's private data, unless required by law.

Apart from this there may be some risks that are currently unforeseeable.

PHYSICIAN AVAILABILITY

For the purpose of this study there will be no appointed physician or other medical professional at the dive site. You must have other arrangements for the coverage of your dive.

BENEFITS TO YOU

There is no direct benefit to you for participation in this study. The results of the study may benefit recreational divers in general.

WITHDRAWALS

You can withdraw from this study at any time, without penalty or loss of benefits to which you are already otherwise entitled. If after consenting to be in the study, you later voluntarily want to withdraw from the study, you must simply let the DAN intern know about your decision and the intern will mark your records as being withdrawn from the study.

CONFIDENTIALITY

All of this paperwork is being done only because you are in this study.

Your study record may be reviewed in order to meet federal or state regulations. Reviewers may include, for example, representatives from the Food and Drug Administration, and/or the DAN Institutional Review Board (IRB).

After the data collection has been completed, any identification information from the electronic or paper data will be deleted/ destroyed. The paper copies of all study forms will be sealed and kept in locked cabinets for three years at DAN, after which they will be destroyed. Your name will not be used in journal articles or at meetings when the results of this study are reported.

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, telephone number, email or any other direct personal identifier in study records disclosed outside of DAN. For records disclosed outside of DAN, your record will be assigned a unique identification number (UIN).

COMPENSATION/COSTS

No compensation will be provided to participate in this study. You are responsible for your diving costs. There is no additional cost for participation in the study.

RESTRICTIONS

Please, do not share details of the study with your peers who have not yet participated in the study, as this may affect our study results.

YOUR RIGHTS

It is necessary that you read and understand several general principles that apply to everyone who takes part in this study:

1. Taking part in this study is entirely voluntary. You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes. You may withdraw your authorization for us to use your data that have already been collected (other than data needed to keep track of your withdrawal), but you must do this in writing. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled. If you do decide to withdraw, we ask that you contact the study PI Mr. Shabbar I Ranapurwala or Co-PI Dr. Petar Denoble in writing and let them know that you are withdrawing from the study. At that time we will ask your permission to continue using all of your information that have already been collected as part of the study prior to your withdrawal.
2. There will not be a charge to you for taking part in this study.
3. Research records are maintained according to confidentiality requirements, but authorized reviewers such as representatives from the Food and Drug Administration and/or DAN IRB may examine your records. Thus, complete confidentiality cannot be guaranteed.
4. If you sustain acute injuries during participation in this research study there is no provision for free medical care or for monetary compensation for such injury by the research team or DAN. There are not any provisions for chronic conditions or injuries sustained after the completion of the study. You are responsible for your emergency plan and all possible costs that may arise in case of your injury.

QUESTIONS

Should you have any questions with regard to this research, you are urged to contact the principal investigator, Shabbar I Ranapurwala, Research Assistant, DAN, 919-684-2948, ext. 237 or email at sranapurwala@dan.org. You may also contact Dr. Petar Denoble, Sr. Research Director, DAN, 919-684-

2948, ext. 261 or email at pdenoble@dan.org. Information concerning the rights of subjects in research can be obtained from the DAN IRB (919-684-2948; irb@dan.org).

AUTHORIZATION

The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask the questions I have, and my questions have been answered to my satisfaction. I have been told whom to contact if I have additional questions. I have fully disclosed my complete medical history. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed copy of this consent form.

____

Signature of subject

____

Date

____

Printed name of subject

____

Person obtaining consent

____

Date

BIBLIOGRAPHY

Abdel-Galil, K. (2010). The WHO surgical safety checklist: Are we measuring up? *Br J Oral Max Surg, 48*(5), 397-398.

Acott, C. (1994). Diving incident monitoring study update 1993. *SPUMS J, 24*(1), 42-49.

Acott, C. (1995a). Diving incidents: Errors divers make. *SPUMS J, 25*(3), 155-162.

Acott, C. (1995b). A pre-dive check; an evaluation of a safety procedure in recreational diving: Part 1. *SPUMS J, 25*(2), 76-77.

Acott, C. (1996). An evaluation of buoyancy jacket safety in 1,000 diving incidents. *SPUMS J, 26*(2), 89-94.

Acott, C. (1999a). A brief history of diving and decompression illness. *SPUMS J, 29*(2), 98-109.

Acott, C. (1999b). Equipment malfunction in 1,000 diving incidents. *SPUMS J, 29*(3), 122-126.

Acott, C. (2003). Recreational scuba diving equipment problems, morbidity and mortality: An overview of the diving incident monitoring study and project stickybeak. *SPUMS J, 33*(1), 26-37.

American Academy of Underwater Sciences. (2009). *The american academy of underwater sciences standards for scientific diving*

Billinger, M., Zbinden, R., Mordasini, R., Windecker, S., Schwerzmann, M., Meier, B., & Seiler, C. (2011). Patent foramen ovale closure in recreational divers: Effect on decompression illness and ischaemic brain lesions during long-term follow-up. *Heart, 97*(23), 1932-1937.

Blake, G., Velikonja, D., Pepper, V., Jilderda, I., & Georgiou, G. (2008). Evaluating an in-school injury prevention programme's effect on children's helmet wearing habits. *Brain Inj, 22*(6), 501-507.

Böhmer, A., Wappler, F., Tinschmann, T., Kindermann, P., Rixen, D., Bellendir, M., . . . Gerbershagen, M. (2012). The implementation of a perioperative checklist increases patients' perioperative safety and staff satisfaction. *Acta Anaesthesiol Scand, 56*(3), 332-338.

Boorman, D. (2001). Today's electronic checklists reduce likelihood of crew errors and help prevent mishaps. *International Civil Aviation Organization Journal, 56*(1), 17-20.

Buzzacott, P. (2012). The epidemiology of injury in scuba diving. In T. Heggie, & D. Caine (Eds.), *Epidemiology of injury in adventure and extreme sports* (pp. 57-79) Med Sport Sci. Basel, Karger.

Buzzacott, P., Denoble, P., Dunford, R., & Vann, R. (2009). Dive problems and risk factors for diving morbidity. *Diving Hyperb Med, 39*(4), 205-209.

Buzzacott, P., Rosenberg, M., Heyworth, J., & Pikora, T. (2011). Risk factors for running low on gas in recreational divers in western australia. *Diving Hyperb Med, 41*(2), 85-89.

Buzzacott, P., Rosenberg, M., & Pikora, T. (2009a). Western australian recreational scuba diving fatalities, 1992 to 2005. *Aust NZ J Publ Heal, 33*(3), 212-214.

Buzzacott, P., Rosenberg, M., & Pikora, T. (2009b). Using a delphi technique to rank potential causes of scuba diving incidents. *Diving Hyperb Med, 39*(1), 29-32.

CDC. (2010). Behavioral risk factor surveillance system. center for disease control and prevention. 2005-2010. Retrieved February, 2011, from http://www.cdc.gov/brfss/questionnaires.htm

Civil Air Patrol, U. (June 2004). *CAPR 60-1 Attachment—IM SAFE checklist: Attachment 8, p1*. Maxwell AFB, AL: National Headquaters, United States Air Force.

Conley, D., Singer, S., Edmondson, L., Berry, W., & Gawande, A. (2011). Effective surgical safety checklist implementation. *Journal of the American College of Surgeons, 212*(5), 873-879.

Denoble, P., Pollock, N., Vaithiyanathan, P., Caruso, J., Dovenbarger, J., & Vann, R. D. (2008). Scuba injury death rate among insured DAN members. *Diving Hyperb Med, 38*(4), 182-188.

Denoble, P., Caruso, J., Dear, G. d. L., Pieper, C. F., & Vann, R. (2008). Common causes of open-circuit recreational diving fatalities. *Undersea Hyperb Med, 35*(6), 393-406.

Denoble, P., Ranapurwala, S., Vaithiyanathan, P., Clarke, R., & Vann, R. (2012). Per-capita claims rates for decompression sickness among insured divers alert network members. *Undersea Hyperb Med, 39*(3), 709-715.

Edmonds, C., & Walker, D. (1989). Scuba diving fatalities in australia and new zealand. part 1. the human factor. *SPUMS J, 19*(3), 94-104.

Edmonds, C., & Walker, D. (1990). Scuba diving fatalities in australia and new zealand. part 2. the environmental factor. *SPUMS J, 20*(1), 2-4.

Edmonds, C., & Walker, D. (1991). Scuba diving fatalities in australia and new zealand. part 3. the equipment factor. *SPUMS J, 21*(1), 2-4.

Edwards, J., Feldman, P., Sangl, J., Polakoff, D., Stern, G., & Casey, D. (2007). Sustainability of partnership projects: A conceptual framework and checklist. *Joint Commission Journal on Quality and Patient Safety, 33*(Supplement 1), 37-47.

Egstrom, G. (2004). Diving equipment. In A. Bove (Ed.), *Bove and davis' diving medicine* (4th ed., pp. 37-51). Philadelphia, PA: Saunders Elsevier Inc.

Fourcade, A., Blache, J., Grenier, C., Bourgain, J., & Minvielle, E. (2012). Barriers to staff adoption of a surgical safety checklist. *BMJ, 21*(3), 191-197.

Frick, R. (1989). Explanations of grouping in immediate ordered recall. *Memory & Cognition, 17*(5), 551-562.

G.Morrow, V., Leirer, J., Andrassy, C., Hier, W., & Menard, D. (1998). The influence of list format and category headers on age differences in understanding medication instructions. *Experimental Aging Research, 24*(3), 231-256.

Golemboski, K. (2011). Improving patient safety: Lessons from other disciplines. *Clin Lab Sci, 24*(2), 114.

Greenland, S. (2008). Invited commentary: Variable selection versus shrinkage in the control of multiple confounders. *Am J Epidemiol, 167*(5), 523-529.

Hales, B., & Pronovost, P. (2006). The checklist—a tool for error management and performance improvement. *Journal of Critical Care, 21*(3), 231-235.

Hamilton, R. (2004). Mixed-gas diving. In A. Bove (Ed.), *Bove and davis' diving medicine* (4th ed., pp. 95-126). Philadelphia, PA: Saunders Elsevier Inc.

Hanley, J., Negassa, A., & Forrester, J. (2003). Statistical analysis of correlated data using generalized estimating equations: An orientation. *Am J Epidemiol, 157*(4), 364-375.

Haynes, A., Weiser, T., Berry, W., Lipsitz, S., Breizat, A., Dellinger, E., . . . Lapitan, M. (2009). A surgical safety checklist to reduce morbidity and mortality in a global population. *New England Journal of Medicine, 360*(5), 491-499.

Healy, J. (2012). How hospital leaders implemented a safe surgery protocol in australian hospitals. *International Journal for Quality in Health Care, 24*(1), 88-94.

Helmreich, R. (2000). On error management: Lessons from aviation. *BMJ, 320*(7237), 781-785.

Irwin, C., Cataldo, M., Matheny, A., & Peterson, L. (1992). Health consequences of behaviors: Injury as a model. *Pediatrics, 90*(5), 798-807.

Jablonski, E. (1965). *Flying fortress: The illustrated biography of the B-17s and the men who flew them* Doubleday.

Kaufman, J., Kaufman, S., & Poole, C. (2003). Causal inference from randomized trials in social epidemiology. *Social Science & Medicine, 57*(12), 2397-2409.

Kindwall, E. (2004). A short history of diving and diving medicine. In A. Bove (Ed.), *Bove and davis' diving medicine* (4th ed., pp. 1-9). Philadelphia, PA: Saunders Elsevier Inc.

Klingmann, C., Rathmann, N., Hausmann, D., Bruckner, T., & Kern, R. (2012). Lower risk of decompression sickness after recommendation of conservative decompression practices in divers with and without vascular right-to-left shunt. *Diving Hyperb Med, 42*(3), 146-150.

Ko, H., Turner, T. J., & Finnigan, M. A. (2011). Systematic review of safety checklists for use by medical care teams in acute hospital settings-limited evidence of effectiveness. *BMC Health Serv Res, 11*(1), 211-1. doi:9

Lafère, P., Germonpré, P., & Balestra, C. (2009). Pulmonary barotrauma in divers during emergency free ascent training: Review of 124 cases. *Aviat Space Envir Med, 80*(4), 371-375.

Lippmann, J. (2010). Diving deaths down under. *Recreational Diving Fatalities Workshop Proceedings,* Durham, NC, USA. 86-98.

Moher, D., Hopewell, S., Schulz, K., Montori, V., Gotzsche, P., Devereaux, P., . . . Altman, D. (2010). CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials. *J Clin Epidemiol, 63*(8), e1-e37.

Moon, R. (2004). Treatment of decompression illness. In A. Bove (Ed.), *Bove and davis' diving medicine* (4th ed., pp. 195-223). Philadelphia, PA: Saunders Elsevier Inc.

Murray, D., Varnell, S., & Blitstein, J. (2004). Design and analysis of group-randomized trials: A review of recent methodological developments. *Am J Public Health, 94*(3), 423-432.

National Association of Underwater Instructors. (2000). *NAUI scuba diver manual: Appendix C: Checklists*

Nielsen, D. (2010). Behavioral self-monitoring for safe driving. *Giornale Italiano Di Medicina Del Lavoro Ed Ergonomia, 32*(1 Suppl A), A35-A36.

Otani, H., Leonard, S., Ashford, V., Bushroe, M., & Reeder, G. (1992). Age differences in perception of risk. *Perceptual and Motor Skills, 74*(2), 587-594.

Poole, C. (1987). Critical appraisal of the exposure-potential restriction rule. *American Journal of Epidemiology, 125*(2), 179-183.

Professional Association of Diving Instructors. (2008). *PADI open water diver manual* (2.10th ed.)

Ranapurwala, S. (2014a). *The effect of using a pre-dive checklist on the incidence of diving mishaps in recreational scuba diving: A cluster randomized trial. dissertation paper 1.* Unpublished manuscript.

Ranapurwala, S. (2014b). *Use of a self-pre-dive checklist and the incidence of diving mishaps in recreational scuba diving. dissertation paper 2.* Unpublished manuscript.

Ranapurwala, S., Bird, N., Vaithiyanathan, P., & Denoble, P. (2014). *Scuba diving injuries among divers alert network members in 2010-2011.* Unpublished manuscript.

Ranapurwala, S., Wing, S., & Denoble, P. (2013). Prevention of scuba diving mishaps by using a pre-dive checklist: A grouped randomized trial. Paper presented at the *AMERICAN JOURNAL OF EPIDEMIOLOGY, , 177* S14-S14.

Richardson, D. (2010). Training scuba divers: A fatality and risk analysis. *Recreational Diving Fatalities Workshop Proceedings,* Durham, NC, USA. 119-158.

Rothman, K. (1977). Epidemiologic methods in clinical trials. *Cancer, 39*(S4), 1771-1775.

Scriven, M. (2000). The logic and methodology of checklists. *Интернет–ресурс Http://Www.Wmich.Edu/Evalctr/Checklists/Papers/logic&methodology_dec07.Pdf,*

Sexton, J., Thomas, E., & Helmreich, R. (2000). Error, stress, and teamwork in medicine and aviation: Cross sectional surveys. *BMJ, 320*(7237), 745-749.

Sharps, M., Wilson-Leff, C., & Price, J. (1995). Relational and item-specific information as determinants of category superiority effects. *J Gen Psychol, 122*(3), 271-285.

Takala, R., PAUNIAHO, S., Kotkansalo, A., Helmiö, P., Blomgren, K., Helminen, M., . . . Katila, A. (2011). A pilot study of the implementation of WHOSurgical checklist in finland: Improvements in activities and communication. *Acta Anaesthesiol Scand, 55*(10), 1206-1214.

United States Air Force. (1969). In OV-10A Bronco Association (Ed.), *Pilots' abbreviated flight crew Checklist—USAF series: OV-10A aircraft*

US Census Bureau. (2000). Parks, recreation, and travel: Participation in sports activity statistics: 1998, table no. 435. Retrieved December 2, 2011, from http://www.allcountries.org/uscensus/435_participation_in_selected_sports_activities.html

US Navy. (2008a). Air diving operations. *US navy diving manual volume 2* (pp. 6:50-6:52)

US Navy. (2008b). Air diving operations. *US navy diving manual volume 2* (pp. 8-24)

Van Klei, W., Hoff, R., Van Aarnhem, E., Simmermacher, R., Regli, L., Kappen, T., . . . Peelen, L. (2012). Effects of the introduction of the WHO "Surgical safety checklist" on in-hospital mortality: A cohort study. *Ann Surg, 255*(1), 44-49.

Vann, R. (2004). Mechanisms and risks of decompression. In A. Bove (Ed.), *Bove and davis' diving medicine* (4th ed., pp. 127-164). Philadelphia, PA: Saunders Elsevier Inc.

Vann, R., Gerth, W., Denoble, P., Pieper, C., & Thalmann, E. (2004). Experimental trials to assess the risks of decompression sickness in flying after diving. *Undersea Hyperb Med, 31*(4), 431-444.

Vann, R., Pollock, N., Freiberger, J., Natoli, M., Denoble, P., & Pieper, C. (2007). Influence of bottom time on preflight surface intervals before flying after diving. *Undersea Hyperb Med, 34*(3), 211-220.

Walker, D., Lippmann, J., Lawrence, C., Houston, J., & Fock, A. (2009). Provisional report on diving-related fatalities in australian waters 2004. *Diving Hyperb Med, 39*(3), 138-161.

Weiss, N. (2008). Clinical epidemiology. In K. Rothman, S. Greenland & T. Lash (Eds.), *Modern epidemiology* (3rd ed., pp. 641-651). Philadelphia, PA: Lippincott Williams & Wilkins.

Willamson, A., & Feyer, A. (1990). Behavioural epidemiology as a tool for accident research. *Journal of Occupational Accidents, 12*(1), 207-222.

Wilmshurst, P. (1998). Technological advances in scuba diving do not always increase safety. *Br J Sports Med, 32*(1), 4-4.

World Health Organization. (2008). WHO surgical safety checklist. Retrieved January 12, 2012, from http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Checklist_finalJun08.pdf

World Health Organization. (2009). WHO guidelines for safe surgery 2009: Safe surgery saves lives. *Ginebra: World Health Organization,*