A Comparison of Five Different Hypothermia Enclosure Systems in a Cold Environment

by

Ramesh Dutta

A Thesis submitted to the Faculty of Graduate Studies of

The University of Manitoba

in partial fulfillment of the requirements of the degree of

MASTER OF SCIENCE

Faculty of Kinesiology and Recreation Management

University of Manitoba

Winnipeg

ABSTRACT

This study compared the thermal physiological and subjective responses of five subjects (1 female) to five hypothermia enclosure systems (HES) (with chemical heat sources) during 60 minutes of exposure to a -22°C climate. The five systems were: 1) user-assembled (Control); 2) Wiggy's Victims Casualty Hypothermia Bag (W); 3) Doctor Down® Rescue Wrap® (DD); 4) MARSARS Hypothermia Stabilizer Bag (M); 5) Hypothermia Prevention and Management Kit (HPMK®). Total heat flux was significantly higher with the HPMK, W and M compared to the Control and DD ($p<0.05$). Net heat gain was higher with the Control and DD compared to W and M ($p<0.05$). Although all systems provide insulation and heat, the user-assembled and DD HES were more effective.

ACKNOWLEDGEMENT

I would like to take this opportunity to express my profound gratitude and deep regards to my advisor, Dr. Gordon G. Giesbrecht for giving me the opportunity to work in his laboratory. His exemplary guidance, valuable feedback, and constant encouragement helped me gain critical scientific skills and, most importantly, the ability to carry out good research. Working under him was an extremely knowledgeable experience for me.

I would also like to thank my research committee members Dr. Phillip F. Gardiner and Dr. Alan M. Steinman for their valuable suggestions, time and assistance with this study.

My colleague, Kartik Kulkarni continuously supported me with his time and advice. I wish him all the best in his future endeavors.

I also thank Natural Sciences and Engineering Research Council of Canada (NSERC) for providing financial support required to run this project. I would like to thank the Faculty of Kinesiology and Recreation Management and the Faculty of Graduate Studies for providing me funding through teaching assistantship, UMGF and Duff Roblin Fellowship.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

INTRODUCTION

Care for patients who are exposed to a cold austere environment for an extended period have been of concern for humans since they started living and working in extreme environmental conditions. Rewarming of cold patients and preventing cooling of normothermic patient is difficult in field conditions. One recent study showed 200,000 deaths per year due to cold in 13 countries between 1985 and 2012 [1]. Other studies showed that mortality and morbidity are also increased in cold seasons [2, 3]. Cold exposure can be outdoor exposure or indoor exposure. While most indoor environments can be kept relatively constant, outdoor exposure basically depends on the external environment (i.e., temperature, the wind, and precipitation) [4].

People living and working in cold countries are more exposed to cold and can be at potential health risks due to cold. Exposure to cold can occur in many activities like occupational and leisure time. Outdoor exposure to cold is common among those who work in forestry, agriculture and construction industries while people working in some food industries are considered as cold indoor workers. The elderly, homeless, and those who have psychiatric or substance abuse problems are often victims of cold injuries (frostbite and hypothermia) which occur as a result of prolonged exposure to cold [4]. Trauma patients when exposed to cold are at greater risk of heat loss and are thereby more at risk from hypothermia [5, 6]. Cold also increases the mortality and morbidity for traumatic injuries. Therefore, it is essential to minimize loss of body heat, and preferably add heat to the body, in trauma patients during prehospital evacuation [6, 7].

Cold exposure leading to excessive heat loss from the body increases discomfort and, if not prevented or treated, can lead to systemic hypothermia [8]. Heat loss occurs by four

mechanisms: conduction, evaporation, radiation, and convection. In normal room temperature conditions with minimal air movement, the average contributions of heat loss from the body are: radiation (55%), conduction (15%), and evaporation (30%). There is minimal loss via convection [9].

Thermoregulation is the physiological process by which the human body maintains core temperature (T_{co}) either by increasing heat production and/or reducing heat loss. The three phases of thermoregulation are: afferent thermal input, central integration and control, and cold and warm efferent responses [10]. The hypothalamus is the primary thermoregulatory center [11]. It receives information (afferent thermal input) from various peripheral and core sensors of environmental temperature via afferent nerves. It integrates (central integration) these inputs and then generates required efferent responses. Peripheral vasoconstriction is one of the immediate autonomic responses of the body due to cold exposure resulting in a reduction of blood flow to the periphery to prevent heat loss. Shivering is another response of the body to increase heat production in the body and thus prevent a decrease in core temperature [12]. The other physiological responses to shivering are increased heart rate, ventilation and cardiac output [13].

Various pathophysiological processes are also associated with cold stress. Cold stress decreases blood volume due to the combined effect of cold-induced renal diuresis and extravascular plasma shift. It also affects cognitive function and increases confusion and lethargy [13]. Cooling reduces the power, velocity and force production properties of muscles [14].

Protection from cold and prevention of heat loss are essential parts of prehospital care. Rescuers and first responders should start prehospital management in the following order: rescue, examine, insulate/treatment and transport to the hospital. Prehospital treatment includes safety of

rescuers, handling of the patient, decreasing heat loss, protection from wet and/or windy conditions and if possible, field rewarming [15]. Lying on the cold ground increases conductive heat loss. Thus, the patient should be insulated from the cold ground surface [16, 17]. A foam pad or an insulated spine board can be used for this purpose during prehospital evacuation [16, 18]. The combined effect of cold air with the wind and wet clothing is more harmful than cold itself because of additional convective and evaporative heat loss, respectively [19]. Several studies have shown that cold - wet conditions can increase heat loss by 90% [20]. Henriksson et al. demonstrated that wet clothing removal, or the use of a vapor barrier, decreased shivering thermogenesis, reduced heat loss, and improved the patient's condition in a cold environment [21]. Passive rewarming of the patient is accomplished by removing wet clothes, insulating and protecting the body from the cold environment. Active rewarming is accomplished through heat applied to the patient by external sources. Active rewarming is useful in both shivering (cold stressed/mild hypothermic) and non-shivering (moderate/severe hypothermic) patients. Active rewarming is not necessary in shivering patients because the rate of core rewarming from shivering is 3-4°C/h and active rewarming provides a rate of core rewarming similar to that provided by shivering. However, addition of active rewarming has advantages because it attenuates shivering heat production and decreases energy depletion and lowers cardiac workload [15, 22]. Active rewarming is necessary in non-shivering patients. because they are not producing enough heat to spontaneously rewarm [15].

There are a variety of types and forms of insulation being used in prehospital settings to minimize further heat loss. The choice of the best insulator depends on a number of factors like insulating properties, weight and volume, cost, and the conditions of its intended used (e.g., at the scene and/or during transport). Several studies have evaluated different insulators like blankets,

rescue bags, bubble wraps, plastic covers, and quilts [23-25]. Henriksson et al. demonstrated that blankets (either in single or in multiple layers) and rescue bags might be used for protection from cold in a prehospital setting. Among the ensembles tested, those providing protection against the wind and those providing compression resistance (bubble wrap and the RC 20 rescue blanket) were more effective in high wind and extended cold exposure environments. The wind reduces effective insulation by removing an outer still layer of air surrounding the ensemble and compressing the layers of insulation [23]. Space blankets (Melinex sheet with aluminum) were developed in 1960 to prevent heat loss by reflecting radiated heat back to the body. However, a study by Chadwick in 1997 reviewed the literature and indicated that the effectiveness of space blankets in rewarming of the hypothermic patient was in doubt as very few studies (3 out of 20) demonstrated their effectiveness [26].

Many different materials and products are available for combined insulation and heat donation in a cold environment. However, the efficacy of these materials and products, either alone or in combination with each other, is not well studied. Four different commercial hypothermia enclosure systems (HES) and one user-assembled (Control) hypothermia enclosure system (HES) consisting of 3-season sleeping bag and separate internal vapor barrier with three gel chemical heat packs, were compared for their effectiveness in reducing heat loss and providing heat as follows: 1) 3-season sleeping bag (separate internal vapor barrier) with three gel chemical heat packs (Control); 2) Hypothermia Prevention and Management Kit (built-in internal vapor barrier) with dry chemical heating blanket (HPMK®); 3) MARSARS Hypothermic Stabilizer Bag (separate internal vapor barrier) with three gel chemical heat packs (M); 4) Wiggy's Victim Casualty Hypothermia Bag (built-in internal vapor barrier) with two dry chemical heating pads

(W); 5) Doctor Down® Rescue Wrap® bag (built-in internal vapor barrier) with two gel chemical heat packs (DD).

The MARSARS bag includes top and bottom insulation shells with two gel chemical heating pads - long and short. The longer one (contains two gel chemical heat packs) can cover the chest and axillae of the subject, and the shorter one (contains one gel chemical heat pack) can cover the upper back of the subject. The Doctor Down® bag provides insulation cores inside of the top and bottom shells, with two pockets at the torso level on the inside of top shell for the addition of two gel chemical heat packs. The Wiggy's bag includes an insulation shell (top and bottom) and provides a torso level pocket (mesh) on the inside of top shell for two dry chemical heating pads (Ready-Heat^{TM}) which cover the chest and abdomen areas. The HPMK® includes a waterproof heat reflecting shell and a self–heating shell liner. This shell liner is a chemical heating blanket (Ready-Heat^{TM}), with four pouches of dry chemical heat packs, which cover the chest, axillae and abdomen areas.

The effectiveness of the systems is measured by total body skin heat flux, which is the sum of all body skin heat flux (HF_{Total}) values. The HF_{Total} is affected by two properties of the systems: 1) insulation to decrease heat loss, 2) external heat to increase the heat gain by the body. The insulation and external heat also provide thermal comfort and affect metabolic response to cold. The purpose of this study is to determine and compare the effectiveness of these five systems in a cold environment by comparing thermal, physiological and subjective responses.

The hypothesis of this study is that the MARSARS system is the most effective system because it has high thickness (insulation) and gel chemical heat packs cover more high heat transfer areas (chest, both axilla and upper back) and the HPMK system is least effective because it has

low thickness (insulation) and dry chemical heating blanket covering the chest, axillae and abdomen areas. The Doctor Down, Control, and Wiggy's systems are less effective than the MARSARS system and more effective than the HPMK system.

LITERATURE REVIEW

MECHANISMS OF HEAT LOSS

Humans are found in different parts of the earth and live in the wide range of environmental temperatures. The mechanism (heat loss and heat gain) to maintain human body core temperature (T_{co}) at 37 ± 0.5°C is necessary to survive in this wide range of environmental temperature.

There are four mechanisms by which human body loses heat in the environment: conduction, convection, radiation and evaporation [27]. The average contributions to heat loss from the body in normal room temperature conditions are: radiation (55%), conduction (15%), and evaporation (30%). The contribution to heat loss by convection is minimal [9].

Conductive heat loss is the process of heat transfer from one body (higher temperature i.e. skin) to another body (lower temperature i.e. solid or liquid) when both the bodies are in contact with each other. Three factors that affect the rate of conductive heat transfer are: (i) the temperature gradient between the two contacted bodies, (ii) the size of contacted areas and (iii) thermal conductivity of two contacted bodies. The thermal conductivity of water is more compared to the thermal conductivity of the air. Therefore, human body loses heat 25 times faster in cold water compared to cold air by the process of conduction at the same temperature [27, 28]. Cold - exposed victims should be protected from conductive heat loss by placing insulation between two contacting surfaces. Conductive heat loss to the ground can also be prevented by placing an insulative ground pad between the ground and the body [21, 23].

Radiative heat loss is the heat loss from the human body in the form of infrared radiation. The largest part of heat loss by the process of radiation occurs from the body to the nearby cooler

objects and very little part to the surrounding atmosphere having a lower temperature than the human body [27]:

The heat loss through convection occurs when still fluid (gas or liquid) adjacent to the skin is heated because of the temperature gradient between skin and still fluid (lower temperature than skin). Eventually, the still fluid moves away and a new layer of fluid replaces it and gets warmed through the same process [27]. It usually occurs when the patient is inadequately insulated and increased in windy conditions. The increase in heat loss is directly proportional to the square of the velocity of the wind [9, 27, 29].

Evaporation is the process of change from a liquid phase to the vapor phase. Transcutaneous evaporation occurs at the skin and requires heat from the body to change sweat or water to vapor and thereby enhances heat loss. 0.58 kcal of heat from the body is lost when 1 gram of water evaporates [27]. Evaporative heat loss can be prevented in a cold environment through either removing wet clothes or placing a vapor barrier between wet clothes and insulation [21, 30].

MECHANISMS OF HEAT GAIN

Physiologically, heat gain is balanced by heat loss in the human body. Even in a cold environment, an excess amount of heat is generated in response to greater heat loss. There are primary means by which the body gains heat in the thermoneutral environment and cold conditions.

Metabolism

The best source of heat generation for humans is their own metabolism and this depends on the body's caloric intake. Resting energy expenditure is the amount of energy used by an

individual while resting in a relaxed position (supine) [31]. This energy is used up by organs and metabolic processes of their active cells to do normal functions at rest [31, 32]. The major consumption of this energy is by the liver which produces 1 Kcal of heat per kilogram of body weight per hour [27, 31]. Approximately 60-80% of the energy from aerobic metabolism is produced by the body as heat [31].

Muscle activity

Heat production is increased by voluntary (exercise) or involuntary (shivering) muscle activity. Exercise can increase the total metabolic rate to 15 20 times its resting state [31]. Seventy to 80% of the energy used during exercise is given off as heat [33]. The body can produce heat up to 280–350 W during mild walking and it can be increased more than 1000 W during strenuous exercise [34]. Shivering is the involuntary alternating skeletal muscle contraction and relaxation [27]. It is the primary source of body heat production in response to cold. Shivering can increase the metabolic rate and produce metabolic heat as much as 5-fold from the resting metabolic rate [33].

External heat

The heat gain process from the external environment depends on the temperature of the external environment and occurs when the temperature of the outside environment is higher than skin temperature. The process of heat gain can occur through the same mechanisms as heat loss i.e., conduction, radiation, or convection but not by evaporation [27].

The heat gain through the process of conduction occurs when heat transfers from the substance (high temperature) to the skin (low temperature) and both substance and skin are in direct contact with each other. Several studies indicated that the heat can be gained through the

conduction process when skin contacts with a higher temperature surface (e.g., chemical heat pads, charcoal heater, hot water bottle) [27, 35].

Convective heat is gained due to the flow of a warm fluid across the body surface. Studies were conducted in which the forced air warming method was used to convectively rewarm the patient [36, 37]. This method produced a rewarming rate of 3.26 ± 1.8°C/h and was comparable to shivering (3.02 ± 1.2°C/h) [36]. However, another study by Steele et al showed that forced air warming method also increased the rewarming rate about 1°C/h faster compared to the passive insulation (warmed cotton blankets) method [37]. The core rewarming rate for the forced air warming method was 2.4 ± 1.0°C/h compared to warmed cotton blankets (1.4 ± 1.0°C/h) Solar radiation is another source for gaining heat. The human body absorbs direct heat from the sun in the form of electromagnetic waves [31].

FACTORS AFFECTING HEAT LOSS

Cold stress occurs when heat loss is greater than heat gain. Heat loss and a decrease in core temperature during cold exposure depend on various factors. These factors are; environmental factors, the body's intrinsic factors, thermal factors and non-thermal factors.

Environmental factors

Heat transfer medium - Heat transfer depends on the thermal conductivity of the medium in which it takes place. The conductive heat transfer in water is relatively higher than in air. The person feels more cooling in water than in air. This is due to the higher thermal conductivity of water (25 times) than air at the same temperature. The specific heat of water is 3500 times greater than air. Therefore, the rate of cooling in water is much faster in comparison to air [38].

Temperature of the medium - Heat transfer also depends on the temperature of the medium in which it takes place. The lower the temperature of the medium (e.g. cold water or cold air), the higher will be heat loss. The conductive heat loss is governed by temperature, thermal conductivity and specific heat capacity of the surface to which body is in contact [39]. As the body also radiates heat, heat loss through the process of radiation depends on the temperature of the surrounding environment and nearby objects. If the surrounding environment has a lower temperature than the skin, then the body radiates heat or vice versa if the temperature of environment exceeds skin temperature.

Air humidity - This is defined as the relative amount of water vapor in the air. If air humidity is low (low concentration of water vapor in the atmosphere), more evaporation of sweat takes place and the person feels cooler than the actual temperature. At high air humidity, evaporation of sweat decreases. The person feels hotter than the actual temperature when there is high air humidity. Water vapour capacity depends on the air temperature. The higher the temperature, the higher will be the capacity of air to carry water vapor. Evaporative heat loss may occur as insensible perspiration if evaporation occurs fast enough [27, 39].

Fluid movement - The rate of cooling depends on the speed of wind and movement of cold water. Waves of water produce passive movement of the body which increases the heat loss [40]. Similarly, flushing of cold water through the wet clothes and swimming to avoid drowning and to maintain airway freeboard (distance between mouth and water level) are some other factors which affect core cooling [40-42]. The study has shown that water in the tank with waves increases the core cooling rate compared to calm water when a person is immersed in cold water [43]. Convective and evaporative heat loss occurs with movement of air in the cold environment. This

loss increases with increase in speed of the wind. Therefore, the wind in a cold environment is a factor which increases the rate of heat loss [39].

The body's intrinsic factors

Body morphology (size and composition) - Size or composition of the body also affects the rate of cooling. The rate of cooling increases with increase in the surface area to mass ratio [44]. Thus, a tall and small sized individual in a cold environment cools faster compared to a short and large-sized individual [44]. Children have a high ratio of body surface area to mass and cool faster compared to adults and are more prone to hypothermia [44-46]. The body's total skinfold thickness is inversely proportional to the rate of core cooling because fat beneath the skin prevents heat loss and acts as an insulator [47]. The higher fat content in the body conserves more heat and thereby less shivering thermogenesis occurs in people with higher fat content compared to people with low-fat content at a given temperature [47, 48]. Thus, in a cold environment, individuals with higher fat content attenuate the rate of core cooling and can maintain core temperature much better than the people with lesser fat content [49].

Shivering - Heat production due to shivering increases with a decrease in skin temperature to maintain core temperature (T_{co}) at 37 ± 0.5°C. Shivering is the response of the body after vasoconstriction in a cold environment to increase the metabolic heat production in the body and to attenuate the decrease in T_{co} [50]. Shivering metabolism is indirectly proportional to T_{co}. Shivering metabolism increases as T_{co} decreases from 37°C to 32°C [15]. Shivering metabolism decreases and terminates at T_{co} of 30°C [15, 51]. Studies indicate that shivering thermogenesis can rewarm an individual at a rate of 3-4°C/hr provided the individual is well insulated from the external environment [15, 22, 37].

Thermal Protection

Clothing is a good protection to prevent heat loss in cold exposure. It acts as insulation and prevents heat transfer from inside of clothing to external environment. The thickness of clothing acts as a barrier and good insulator in the cold environment [39]. The rate of core cooling is higher in a wet-suit compared to a dry - suit in cold water immersion [52]. This is because the wet-suit allows water to contact with the skin which increases the conductive heat loss.

Non-thermal factors

Physical and mental impairment occurs with alcohol consumption which results in accidental hypothermia [44]. Studies have shown that thermoregulatory impairment during cold exposure can occur with a moderate amount of alcohol consumption (50-100 mg/dl blood alcohol level) [53-55]. It decreases the vasoconstriction threshold during 28°C immersion in cold water.

THERMOREGULATION

The core temperature (T_{co}) of the human body is maintained at 37 ± 0.5°C which is not a set point rather a zone between the threshold values of core temperature for sweating and shivering thermogenesis. This is called the thermoneutral zone [56]. The hypothalamus is the thermoregulatory center in the brain which receives thermal signals (cold and warm temperature) from thermoreceptors present in the periphery (cutaneous) and core (central nervous system) [57, 58]. These thermal signals are collected and form an integrated thermal signal (ITS) [59]. There a is threshold range in the hypothalamus from which these thermal signals are compared for efferent responses. This threshold range is bounded by warm responses (first vasodilation and then sweating) at its upper end and cold responses (first vasoconstriction and then shivering) at its lower

end. This range is called the dead zone or interthreshold range. No thermoregulatory response occurs within this range [58, 60].

The first thermoregulatory response by the body is behavior changes. Removing extra clothing, dressing in light clothing or using air conditioner etc. are the behavior change responses which occur if the ITS rises. Peripheral vasodilation and sweating occur to increase heat loss from the skin if behaviour changes are not sufficient to increase heat loss and to maintain threshold temperature within the interthreshold range. The body fluid evaporates from the skin surface which causes heat loss through sweating [56, 58-61].

Similarly, the first thermoregulatory response by the body when the ITS decreases is behaviour changes. Using a heater, and putting on warmer clothes etc. are the behaviour change responses which are followed by conserving or producing mechanisms (vasoconstriction and shivering) if behaviour change responses are not sufficient to decrease heat loss and to maintain threshold temperature within the interthreshold range [56, 58-61].

The thermoregulatory system can be affected by various factors including injury of central and peripheral nervous system, drugs, alcohol, and disease (e.g., diabetes) [60, 62, 63].

PREHOSPITAL MANAGEMENT OF COLD STRESS

The primary goals of rescuers or first responders during prehospital management are outlined in the following actions: rescue, examine, insulate and transport [64].

Rescue

Patients are removed from the cold environment and kept in a horizontal position if possible. This position decreases the risk of orthostatic hypotension and increases the cerebral perfusion [65]. Physical work by the patient during rescue should be avoided [15].

Examine

The patient should be examined for airway, breathing, and circulation. Resuscitation should be initiated as soon as possible if the patient is found in cardiac arrest. All vital signs should be measured if possible - pulse, temperature and blood pressure. Mental status should be checked - the level of consciousness, able to talk and pupillary size [15].

Insulation

Prevention of heat loss and maintaining the core temperature at 37 ± 0.5^0C is an important intervention by the rescuer. It includes removing of wet clothes, insulating the exposed body and protecting from the cold environment [29]. A person using his/her own body's heat to rewarm him/herself is called passive rewarming [66]. Lying on the cold ground surface increases the conductive heat loss [16, 17]. Thus, the patient should be placed on insulation like a foam pad or insulated spine board which protects from further heat loss [16, 18]. The patient should be wrapped in blankets, vapor barrier, bubble wraps and sleeping bags, and the head and neck should be insulated as well. If passive rewarming is not sufficient, then heat is directly applied to the patient by external sources, a process which is called active rewarming [66]. The effectiveness of clothing is decreased by 90% in wet - wind condition [67]. Thus, it is necessary to remove a wet cloth or to add a vapor barrier if removal of wet cloth is not possible [21].

Blankets are generally given to victims/workers who are exposed to extreme cold, to prevent a drop-in core temperature as a pre-hospital intervention. Twelve different blankets and rescue bags were studied by Henriksson et al. to determine their properties of thermal insulation. This study showed that the ensembles (bubble wrap and RC 20 rescue blankets), which provide protection against the wind and provide compression resistance, were more effective insulation in high wind and extended cold exposure. The wind reduces the effective insulation by removing an outer still layer of air surrounding the ensemble and compressing the layers of insulation [23].

There are other different types and forms of insulators available on the market which need to be studied to determine the effectiveness of their insulating property.

Determination of Insulation properties - There are two thermal properties of insulations that determine the effectiveness of insulation on body heat exchange: thermal resistance and evaporative resistance.

Thermal resistance: This is defined as the resistance to convective, radiative, and conductive heat loss (dry) through the insulation ensembles and the ability of an insulation ensemble to retain air [63, 68]. It depends on the thickness of an insulation ensemble. The wind compresses the insulation and reduces the retained air inside the insulation ensemble. The wind also removes the still air on the outer surface of the insulation and increases the exchange of air through the fabric (this is dependent on air permeability). Therefore, wind decreases thermal resistance [68, 69].

Evaporation resistance: It is defined as the resistance to evaporative heat loss (wet) through the insulation ensembles [63, 68]. There are two phenomena: 1) real evaporation: water vapour evaporates through the insulation ensembles to the external environment, 2) heat pipe effect: water vapour condenses back to water on the inside of the outer shell of the insulation ensemble, which

occurs depending on the water vapour pressure gradient between skin surface and external environment, water vapour permeability of the insulation material and location of dew point in the layer of the fabric [70].

Transport

The patient should be transferred to a hospital or medical center as soon as possible. If transportation time is shorter than 30 minutes, then patient should be wrapped with vapor barrier and insulation to protect from cold environment. If transportation time is longer than 30 minutes, then wet clothes should be removed and wrapped with vapor barrier and insulation. All other precautions and treatment should be administered during transport. Stabilization of the injured hypothermic patient should be done as with other normothermic patients. A study by Sookram et al. was conducted in which 116 severely injured or ill patients were transported to regional referral hospital by rotary wing aircraft to determine whether hypothermia (core temperature less than 35°C) occurs while transporting. This study showed that body core temperature was maintained (mean arrival core temperature-35.5°C) with the use of simple measures (Doctor Down® Rescue Wrap®-38% trips and warmed intravenous fluid-5% trips) [71]. Active warming is recommended to prevent further core cooling and hypothermia during transportation depending on the condition of patients (severely injured nonshivering), and duration of evacuation. Henriksson et al. conducted a study in 2011 to evaluate the effectiveness of active warming (chemical heating pads) in cold stressed trauma patients (T_c-35°C) during air ambulance and road transportation. This study showed that passive warming is adequate to prevent heat loss and to reduce cold discomfort in a mild hypothermic patient during pre-hospital transportation. Active warming only adds more thermal comfort and reduces cold-induced stress response in a mild hypothermic patient [72].

FACTORS RELATED TO SELECTION OF RESCUE BAGS

The initial approach to the cold stressed patient in the emergency pre-hospital situation is to remove wet clothes, and place the patient on dry insulation like blankets, sleeping bags or rescue bags whichever is available. However, the selection of the appropriate rescue bag for search and rescue purpose is an important task for a rescuer or first responder. The choice of appropriate rescue bag depends on the following factors:

Weight and volume of rescue bag

Minimum weight and less bulk in addition to effective insulation properties are the important criteria to select a good rescue bag. A heavy-weight rescue bag increases the effort and energy of rescuers and can create a problem in search and rescue.

Effectiveness in reducing heat loss

Insulation properties are important while considering a good rescue bag for evacuation. Many studies were conducted to determine the effectiveness of various rescue bags. Three casualty bags (Bag 1 - The Fast-T Mark 2 Causality Bag, Bag 2 - The Flectalon Thermal Reflective Rescue Stretcher Blanket, and Bag 3 - Marshells of Aberdeen) were compared for the effectiveness in protecting the subject from the cold and windy environment. These bags showed no significant differences in core temperature, metabolic heat production, and heart rate. However, the mean skin temperature for Bag 1 was significantly higher than Bag 2 and Bag 3, and the mean skin temperature for Bag 3 was significantly higher than Bag 2. These bags showed limited effectiveness in protecting the subject from the cold and windy environment because of early removal of 15 subjects from the chamber and fall in core temperature [25]. Grief et al. showed that resistive heating (rate of rewarming - 0.96 ± 0.22°C/h) was more effective in rewarming the patient

and preventing the heat loss compared to metallic-foil insulation (0.41 ± 0.19°C/h) [73]. A recent study by Oliver et al. in 2016 indicated that a multi-layered metalized plastic sheet (MPS) with four large chemical heat pads is more effective (reduced cold stress and shivering thermogenesis) in treating patients during cold air exposure than a polyethylene survival bag (PSB). This study also indicated that a hot drink (flavored water) did not provide the benefit of rewarming when added with PSB. [74]. A study by Allen et al. was conducted in 2010 to compare three active warming devices and five passive warming products. Active warming devices were: (a) Hypothermia Prevention Management Kit [HPMK®] - two types of HPMK (Blizzard blanket [original] with Ready-Heat™ and Heat reflective shell [new] with Ready-Heat™), (b) Ready-Heat™ alone, and (c) Bair Hugger (forced air warming). Passive warming products were: (a) Blizzard blankets alone, (b) wool blankets, (c) space blankets, (d) Heat reflective shell alone, and (e) Human remains pouch. This study indicated that HPMK (Blizzard blanket [original]) was the most effective and maintained the higher core temperature compared to all other devices or products, including HPMK (Heat reflective shell [new]). The wool blanket was the least effective. There was no significant difference in the rate of loss of temperature between HPMK original and HPMK new [75].

Cost

The cost of purchasing, storing and maintaining a rescue bag is another important factor while selecting insulation. Washing and disinfecting the rescue bags is expensive. Nowadays, a commercially available disposable liner is cost effective in transporting, storing and maintaining rescue bags. The high-cost rescue bags, which can be more effective in providing good insulation to the victim and can prevent death, can be prohibitive to rescue teams.

Situation where it can be used

There are two situations where heat loss occurs – at the scene of the accident and during transport of the patient to the medical center [63].

1) At the scene of an accident: Patients are more exposed in the external cold environment at the scene of the accident. Many factors like improper clothing, high wind, and rain increase the heat loss and increase the chance of a patient becoming hypothermic. The windproof and waterproof properties of insulation are important property for insulation and can protect the patient from the windy cold environment [23]. If the patient is not properly insulated from the ground, a further increase in heat loss occurs [16]. A rescue bag with high insulation and thick grounded pad will decrease conductive heat loss.
2) During transport: Patients are also at potential risk to lose heat during transport. Longer duration of transportation from the site of the incident to the hospital, wind-chill effects from a helicopter's down draft during transport, and cold, wind, and wet conditions during maritime transportation are the factors which increase the heat loss and thereby could cause hypothermia [76, 77]. Several studies were performed to determine the effectiveness of various types of insulations during transportation [71, 72, 77]. The size of the warming devices, weight and electrical supply requirements for warming devices are some limitations in prehospital care during transportation of patients. A study was conducted to evaluate the efficacy of three warming methods (ChillBuster blanket, ChillBuster with a reflective blanket, and two military wool blankets) during aeromedical evacuation (simulated environment – 10 ± 0.5°C and 0.20-0.26 m/s airspeed) using an animal model (20 female swine). The ChillBuster is a battery operated/electrical and portable blanket.

This study showed that the ChillBuster with the reflective blanket was more effective than the other blankets (3 out of 6 in ChillBuster only group and 6 out of 7 in wool blankets group became hypothermic) during aeromedical evacuation for 6 hours [78].

Method of transport

There are several methods which are used to transport the patients from accident sites to a nearby hospital and or/ medical centers like a human stretcher or using a snowmobile or a helicopter. The right choice of effective insulation while transporting the patient to prevent hypothermia is very important. A study was conducted by Sookram et al. in which rescue wrap (Doctor Down, Inc., Polson, Mont.), warmed intravenous fluid and helicopter heating system were used to maintain core temperature during aeromedical transport. Body temperature was well maintained while transferring the ill or injured patient to the hospital by rotary wing aircraft using these simple measures. Therefore, this study indicate that simple measures (e.g., rescue wrap, warmed intravenous fluid and helicopter heating system) would be enough to maintain core temperature, and any major treatment or core temperature procedure in maintaining core temperature would not be required during helicopter transportation [71]. A study was conducted by Jussila and other colleagues in 2014 to determine the insulation properties of ten different casualty coverings (like blankets, bubble wraps, and rescue bags) and to evaluate whether these casualty coverings were effective during pre-hospital maritime transportation (30 minutes) against cold, wind and water splashes. It was indicated that protective coverings- rescue bags (thick windproof and waterproof) provided protection against the wind, cold and water splashes during maritime evacuation [77].

METHODS

SUBJECTS

The protocol of this study was approved by the Education/Nursing Research Ethics Board at the University of Manitoba (See Appendix A). Two questionnaires (a) "Physical Activity Readiness Questionnaire" (PAR-Q), and (b) "Medical Screening Questionnaire for Hypothermia Enclosure System Study" were provided to a group of four healthy men and one woman (aged 18-45) for screening purposes (See Appendices B and C). Potential subjects were excluded if they answered "yes" to any question in either questionnaire. Our potential subjects were not part of any vulnerable population.

Individuals were contacted who might be interested in participating in this type of study, and a recruitment script was handed over to them. Participants then signed a written informed consent prior to participation (See Appendix D).

POWER ANALYSIS

The sample size required for this study was determined by power analysis using the following equation [79]:

$n= (PI*\sigma/\mu_d)^2$

Where:

n=number of the subjects,

PI= power index, determined from the desired power of the study.

μ_d = true mean difference between two different treatment methods

σ = true standard deviation of the differences

A power of 95% was chosen for this study to find the real difference between two treatment methods. Based on this:

PI = 1.64 (0.05 α, one-tailed) + 1.64 (0.05 β, one-tailed) = 3.28

A previous study was conducted to determine effectiveness in decreasing the heat loss by one warmed or unwarmed cotton blanket and three warmed or unwarmed cotton blankets. This study detected significant differences between the decrease in heat loss by one warmed or unwarmed cotton blanket and three warmed or unwarmed cotton blankets with a mean difference of 14 W and true standard deviation of 7.5 W [80]. Therefore, the sample size required was computed as follows:

$n = (3.28 * 7.5/14)^2$

$= 3.1$

This study required at least four subjects. However, 5 subjects were studied to keep following the standard procedures in most of the studies conducted in this laboratory.

ANTHROPOMETRIC MEASUREMENT

The following variables were measured:

1) Age (yrs), weight (kg), height (m) and skinfold thickness (mm) measurements (amount of fat in the body) at four different sites (suprailiac, triceps, biceps, and subscapularis) was determined.

2) The equation of Du Bois & Du Bois was used to calculate body surface area (BSA, in m^2) [81]:

$$BSA\ (m^2) = weight^{0.425}\ (kg) \times height^{0.725}\ (cm) \times 0.007184$$

3) Body mass index (BMI) was computed based on the following equation:

$$BMI = weight\ (kg) / height\ (m^2)$$

4) Body density (BD) was calculated using equation provided by Durnin and Womersley based on the age, gender (different for male and female), and the sum of four skinfolds [82]. For example, for female (20 to 29) – BD (kg/l) = 1.1549 – 0.0717 x $\log_{base10}$ sum of four skinfolds (See Appendix E).

5) Body fat percentage (%BF) was computed according to the following equation [82]:

$$\%\ BF = (4.95/BD - 4.5) \times 100$$

INSTRUMENTATION

Subjects were prepared at an ambient temperature of 21-25°C in the laboratory. A single-channel electrocardiogram (ECG) was used to monitor the subject's heart rate (HR) throughout the experiment on a Hewlett- Packard monitor/defibrillator (model 43100A).

Core temperature (T_{co}) was measured by a disposable esophageal thermocouple which was inserted through the nose into the esophagus (T_{es}) and positioned at the level of the heart since this site provides the best non-invasive representation of core blood temperature [83, 84].

Skin temperature (T_{skin} in °C) and cutaneous heat flux (HF in W/m^2) was measured at 12 different sites (adapted from Layton et al.) using thermal flux transducers (Concept Engineering, Old Saybrook, CT) [85]. Regional heat flux was calculated using the equation:

HF_{site} (W) = HF_{disc} (W/m²) x BSA (m²) x Regional % of the site x 0.01

Or HF_{site} (W) = HF_{disc} (W/m²) x Area covered by the heat pack (m²)

The 12 sites along with their regional percentages are: forehead (9%), right lateral chest (4.5%), left lateral chest (4.5%), superior umbilicus (6%), left lateral abdomen (6%), upper back (4.5%), right axilla (4.5%), lower back (6%), left posterior upper arm (7%), right anterior forearm including hand (12%), right anterior thigh (18%), left posterior thigh (18%).

An open-circuit method was used to measure oxygen consumption (VO_2) using a metabolic cart (Vmax 229 by Sensormedics, Yorba Linda, CA) from measurements of expired minute volume and inspired and mixed expired gas concentrations. Subjects were asked to wear a face mask which was fitted snuggly with a one-way valve. This mask was connected to the metabolic cart and flow transducer by flexible light-weight tubing. Metabolic heat production (M [W]) was calculated from respiratory exchange ratio (RER) and VO_2 (in $L \cdot min^{-1}$) [86]. The respiratory exchange ratio (RER) was assumed to be 0.82 based on mixed diet [87].

$$M(W) = VO_2 \text{ (l/min)} \times 69.7(W/Kcal \cdot min^{-1}) [4.686 \text{ (Kcal/l)} + (RER - 0.707) \times 1.232(Kcal/l)]$$

CLOTHING

Four male subjects (one subject did not wear socks in all his trials) wore underwear, gym shorts, half sleeve shirt/T-shirt and socks and one female subject wore a bathing suit, gym shorts, half sleeve/T-shirt, and socks.

HYPOTHERMIA ENCLOSURE SYSTEMS (HES)

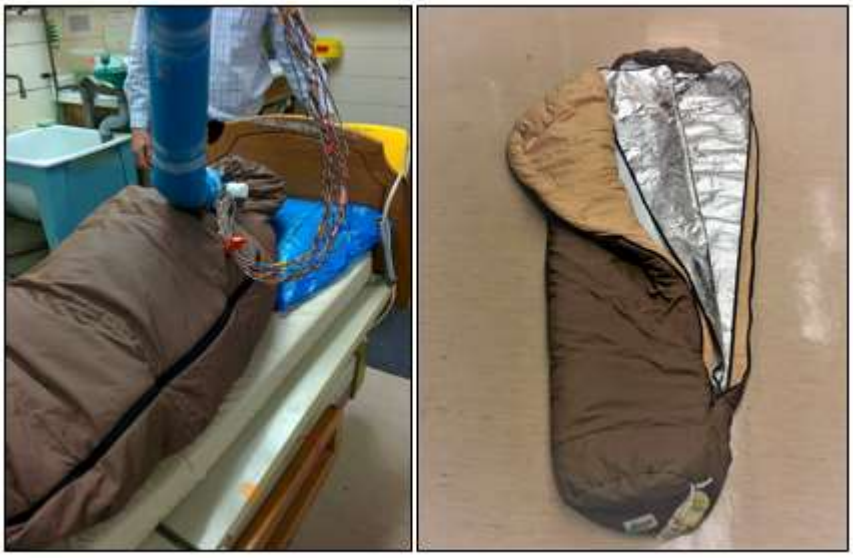
Four commercial hypothermia enclosure systems (HES) and one user assembled (3-season sleeping bag) HES was selected for use in this study. The four commercial hypothermia enclosure systems are more popular and used in rescue sites across the United States and Canada. Vapor Barrier (built-in internal or separate internal) and dry or gel chemical heat packs were used with all five systems.

Three-season sleeping bag (separate internal vapor barrier) with gel chemical heat packs (Control)

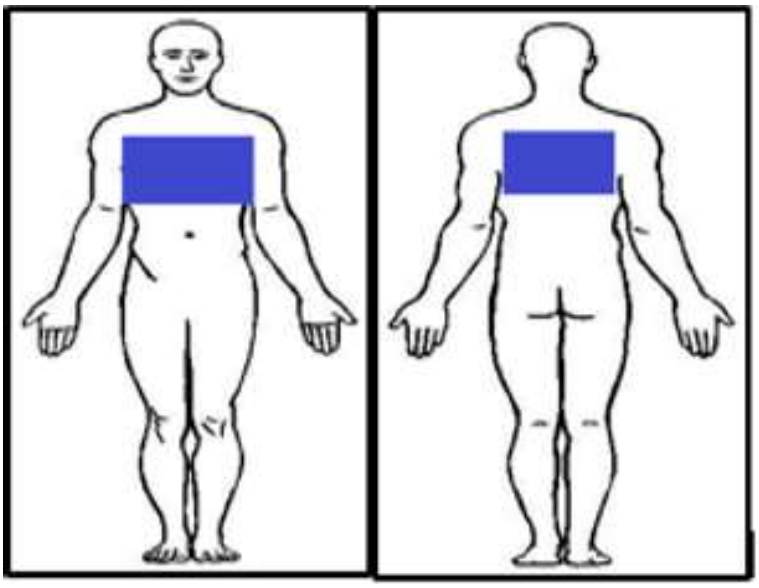
The subject was placed inside a 3-season sleeping bag in this control condition. The separate internal vapor barrier (size- 125cm x 196cm and weight- 0.39 kg) provided by Canadian Coast Guard was used with this system. The size of this bag is 70 cm x 220 cm and weighs 2.3 kg. The volume of this bag is 30 liters. The three gel chemical heat packs (ThermoPad©- Hood Thermo-Pad Canada Ltd, BC, CA) (size- 20.32 cm x 45.72 cm and weight of one heat pack-1 kg), which were included with this bag, were placed on the chest, upper back and the armpits [64]. The total cost of this bag (including the cost of vapor barrier and three gel chemical heat packs) is USD 170. A metal disk (found inside a gel heat pack) is flexed to activate until crystals formed. The metal disc activates the material (sodium acetate salt solution) of the gel heat pack to create a chemical reaction and produces heat. It needs to be heated up in boiling water for 20 minutes until all crystals dissolve for recharge. The gel chemical heat packs produce instant heat however, were activated 10 min prior to the application on the subjects to ensure maximum temperature attained by the chemical heat packs. Figure 1 shows top view and inside of the 3-season sleeping bag and placement of gel chemical heat packs on axillae, chest and upper back. Figure 6 shows the head

closure fitting for this bag. Figure 7 shows the five types of chemical heat sources for the hypothermia enclosure systems.

Figure 1. (A) Top view of the 3–season sleeping bag; (B) Inside view of the 3–season sleeping bag; (C) Placement of gel chemical heat packs on axilla, chest and upper back.



(A) (B)



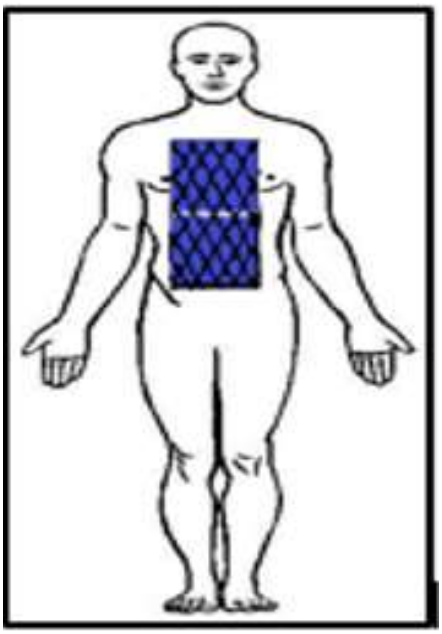
(C)

Wiggy's Victims Casualty Hypothermia Bag (Wiggy's, Inc., CO, USA) (built-in internal vapor barrier) with dry chemical heating pads

This bag has been designed to assist in casualty evacuation by search and rescue professionals. The top exterior side and the interior lining of the bag are made of 200 denier oxford nylon and the bottom side is made of 1000 denier cordora nylon. The top layer of the bag completely separates from the bottom layer which aids in easy placement of the victim. The interior and exterior of the bag are waterproof. No separate vapor barrier was used with this bag. This bag weighs 3.62 kg and measures (88 cm x 229 cm). This bag can fit into a (27.94 cm x 58.42 cm) compression stuff sack. The cost of this bag is USD 335. It has a mesh chest pocket (30 cm x 62 cm) on the inside of top layer which can hold two (15 cm x 29.5 cm) dry chemical heat pads which lay on the chest and abdomen areas of the subjects. The Wiggy's does not manufacture any chemical heat sources. Therefore, two dry chemical heating pads [Ready-Heat^{TM} (1 Panel, TechTrade LLC, NY, USA)] (size - 40.64 cm x 45.72 cm and weight – 0.19 kg) were placed inside the chest pocket. The cost of single dry chemical heating pad is USD 14. The dry chemical heat pad was exposed to air for 10–20 minutes before application on the subjects because it requires 10-20 minutes of air exposure to attain maximum temperature. Figure 2 shows top view and inside of the Wiggy's Bag and placement of dry chemical heating pads on the chest and abdomen areas. Figure 6 shows the head closure fitting for this bag. Figure 7 shows the five types of chemical heat sources for the hypothermia enclosure systems.

Figure 2 (A) Top of the Wiggy's Bag; (B) Inside of the Wiggy's Bag; (C) Placement of dry chemical heating pads on the chest and abdomen areas.

(A) (B)



(C)

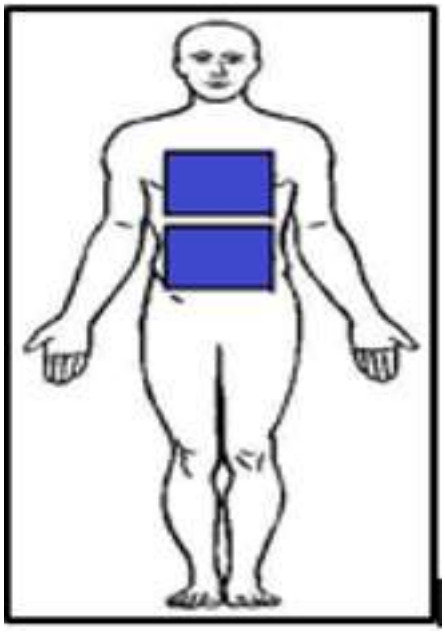
Doctor Down® Rescue Wrap® (11-1001, Doctor Down, Inc., Polson, MT, USA) bag (built-in internal vapor barrier) with gel chemical heat packs

This bag is best suited for all weather and protects from the extreme environment as per the manufacturer of this bag. The outer shell is made of storm-tech (3-layer multi-polymer) and is breathable, waterproof and windproof. It has removable PrimaLoft® insulation cores (PrimaLoft, Inc., NY, USA) which can be doubled or tripled as per requirement. It includes a disposable liner which protects the patient from infection as this provides a clean surface. All four sides have Velcro® system which allows 360° subject access. It also includes a detachable insulated hood (weight - 0.37 kg). Figure 6 shows the head closure fitting for this bag. This bag weighs 6.35 kg and measures 93.98 cm x 203.2 cm. It has solid two pockets (27.5 cm x 28 cm) inside of top layer at the chest and abdomen level for gel heat packs. The Doctor Down® provides reusable gel chemical heat packs (size - 20.32 cm x 20.32 cm and weight of one heat pack - 0.61kg). The total cost of this bag (including the cost of insulated hood and single gel chemical heat pack) is USD 1050. A metal disk (found inside a gel heat pack) was flexed to activate until crystals form. It activates the material (sodium acetate salt solution) of the gel heat pack to create a chemical reaction and produces heat. It needs to be heated up in boiling water for 20 minutes until all crystals dissolve for recharge. The gel chemical heat packs produce instant, however, were activated 10 minutes prior to application on the subjects to ensure maximum temperature attained by the chemical heat packs. Figure 3 shows top view and inside of the Doctor Down® Rescue Wrap®; and placement of gel chemical heat packs on the chest and abdomen areas. Figure 7 shows the five types of chemical heat sources for the hypothermia enclosure systems.

Figure 3 (A) Top of the Doctor Down® Rescue Wrap®; (B) Inside of the Doctor Down® Rescue Wrap®; (C) Placement of gel chemical heat packs on the chest and abdomen areas.

(A)

(B)



(C)

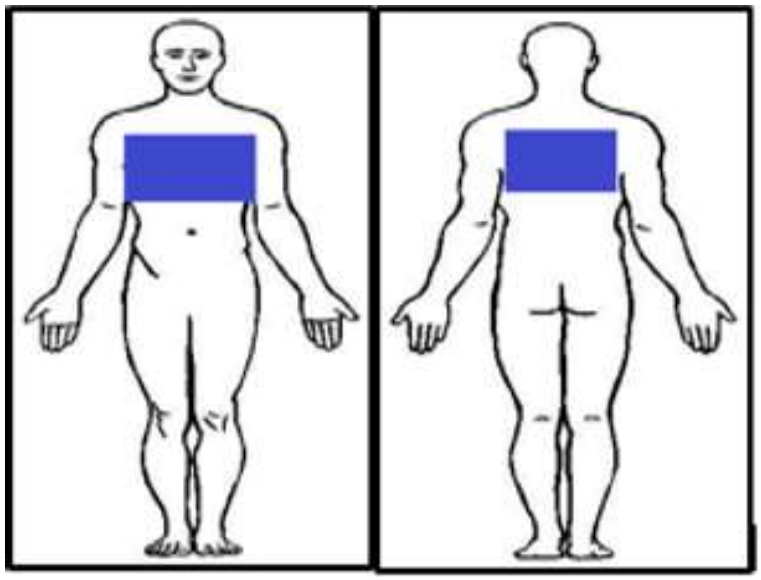
MARSARS Hypothermic Stabilizer Bag (MARSARS Water Rescue Systems, Inc., CT, USA) (separate internal vapor barrier) with gel chemical heat packs

This is a device which prevents the heat loss from a patient in a cold environment. It has a polyester–pile liner which wicks away sweat and moisture inside of the bag and maintains the insulation. The bag is waterproof and windproof. The separate internal vapor barrier (Bio-liner-Safecross® First Aid Ltd, TO, CA) (size - 142.2 cm x 228.6 cm and weight - 0.25 kg) was also used with the bag. The top insulation shell is made of 240 denier nylon and bottom insulation shell is made of 1000 denier cordora nylon. It has a double zipper on all four sides. All three sides (head end and either side) completely separate for subject access except the foot end. The top and bottom shells are attached at the foot end. This bag weighs 5.35 kg. The dimensions of the bag are 70 cm x 210 cm. This bag does not have any pocket for a chemical heat source. However, it provides two types of gel chemical heating pads (long and short). The longer one (20.32 cm x 91.44 cm) includes two gel chemical heat packs (The Heat Solution, PRISTECH products, Inc, SA, USA) and was placed on the subject's chest, and the both armpits. The shorter one (size - 20.32 cm x 45.72 cm and weight of one heat pack - 1kg) includes one gel chemical heat pack which was placed beneath the upper back of the subject. The total cost of this bag (including the cost of vapor barrier and three gel chemical heat packs) is USD 528. The gel chemical heat pack contains sodium acetate salt solution and was activated to start the chemical reaction to generate heat by flexing the metal disk inside the gel heat pack until crystals form. It needs to be heated up in boiling water for 20 minutes until all crystals dissolve for recharge. The gel chemical heat packs were activated 2 minutes prior to the application on the subjects to ensure maximum temperature attained by the chemical heat packs. Figure 4 shows top view and inside of the MARSARS Bag; and placement of gel chemical heating pads (gel chemical heat packs) on the chest, axillae, and upper back. Figure

6 shows the head closure fitting for this bag. Figure 7 shows the five types of chemical heat sources for the hypothermia enclosure systems.

Figure 4 (A) Top of the MARSARS Bag; (B) Inside of the MARSARS Bag; (C) Placement of gel chemical heating pads (gel chemical heat packs) on the chest, both axilla, and upper back

(A) (B)



(C)

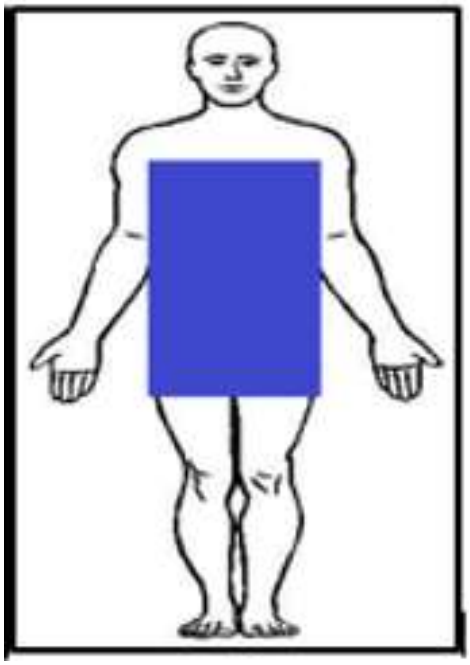
Hypothermia Prevention and Management Kit (HPMK®) (North American Rescue, LLC, SC, USA) (built-in internal vapor barrier)

This unit is recommended by the U.S. Department of Defense Committee on Combat Casualty Care (CoTCCC) for the prevention of hypothermia during casualty care. It includes a heat - reflective shell (109.22 cm x 198.12 cm) with built - in the hood and in a tapered shape. The heat - reflective shell is wind and waterproof. It is made from a polyolefin, 4 ply, composite fabric. All three sides (head end, and either side) of the heat reflective shell has Velcro® closures system (3.81 cm) except the foot end and separates completely for the victim's quick and easy placement. This kit weighs 1.58 kg. It includes self - heating shell liner called as a dry chemical heating blanket (Ready-Heat^{TM} - 4 Panel) (4 Panel, TechTrade LLC, NY, USA) (size - 86.36 cm x 121.92 cm and weight - 0.794 kg) which is the heat-generating source. The cost of HPMK is USD 108. This self - heating shell liner includes four pouches of dry chemical powder, which was placed on the subject's torso to cover the axilla, chest, and abdomen. This self-heating shell liner was exposed to air for 10–20 minutes before application on the subjects because it requires 10-20 minutes of air exposure to attain maximum temperature. Figure 5 shows top view and inside of the HPMK®; and placement of the dry chemical heat blanket on the axilla, chest and abdomen areas. Figure 6 shows the head closure fitting for this bag. Figure 7 shows the five types of chemical heat sources for the hypothermia enclosure systems.

Figure 5 (A) Top of the HPMK®; (B) Inside of the HPMK®; (C) Placement of the dry chemical heat blanket on the axilla, chest and abdomen areas.

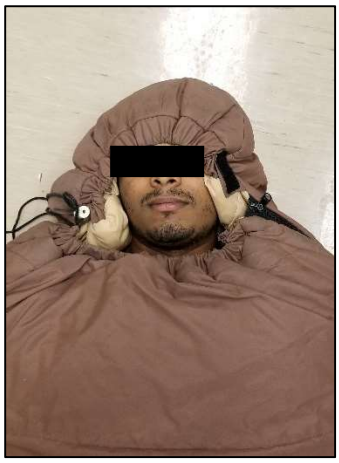
(A)

(B)



(C)

Figure 6. Head view of five hypothermia enclosure systems: A) 3-season sleeping bag; B) Wiggy's Victims Casualty Hypothermia Bag; C) Doctor Down® Rescue Wrap®; D) MARSARS Hypothermic Stabilizer Bag; E) Hypothermia Prevention and Management Kit (HPMK®)



(A)

(B)

(C)

(D)

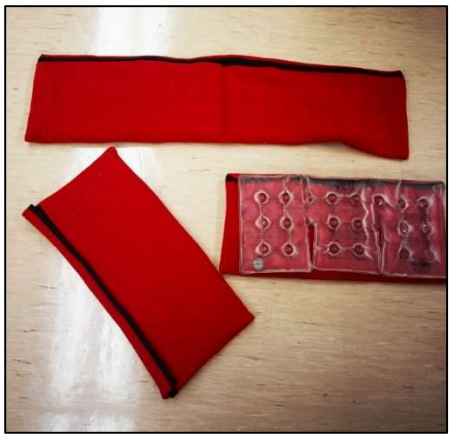
(E)

Figure 7. Chemical heat sources of five hypothermia enclosure systems: A) Gel chemical heat pack (ThermoPad) (used with Control); B) Dry chemical heating pad (Ready-Heat™) (used with W); C) Gel chemical heat pack (Doctor Down) (used with DD); D) Gel chemical heat pack (Heat Solution) (used with M); E) Dry chemical heating blanket (Ready-Heat™) (used with HPMK)

(A)

(B)

(C)



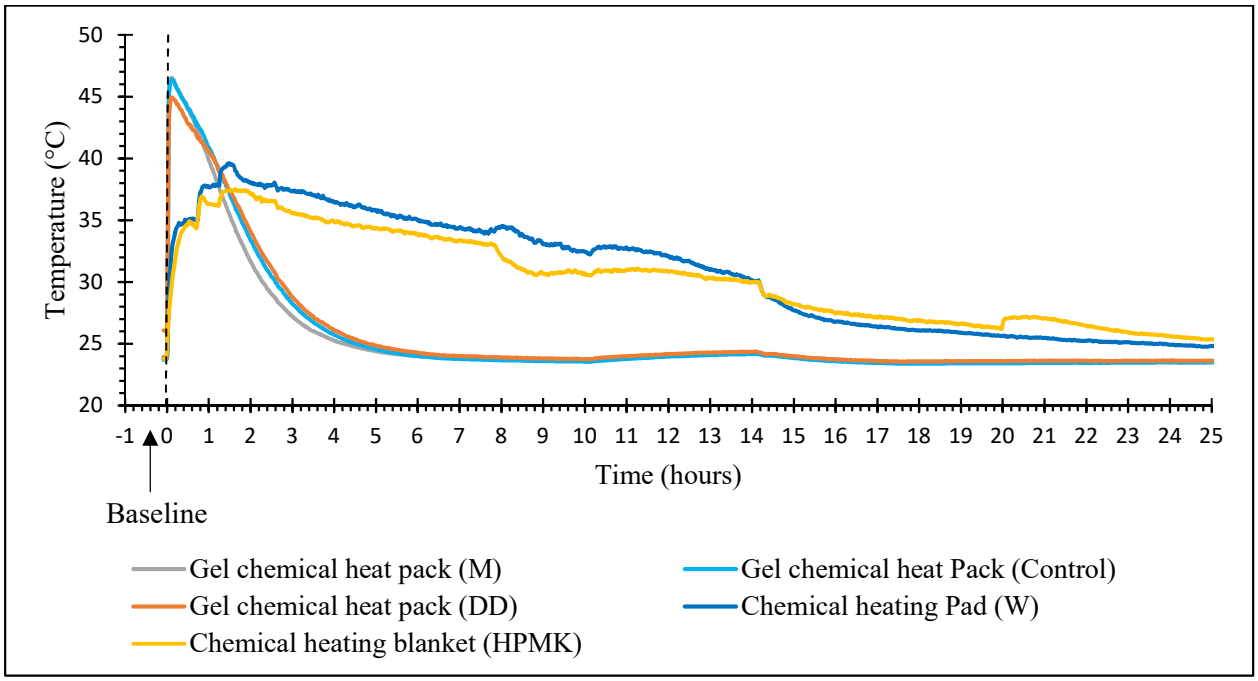
(D)

(E)

A test procedure to determine temperature profile of five chemical heat sources was performed in our laboratory (see Figures 8-9). Five chemical heat sources were: A) Gel chemical heat pack (ThermoPad) (used with Control); B) Dry chemical heating pad (Ready-Heat^{TM}) (used with W); C) Gel chemical heat pack (Doctor Down) (used with DD); D) Gel chemical heat pack (Heat Solution) (used with M); E) Dry chemical heating blanket (Ready-Heat^{TM}) (used with HPMK). A charcoal heater was also included in the test procedure. However, data for charcoal heater was not recorded.

Figure 8. Test procedure to determine the temperature profile of the five chemical heat sources Note: a charcoal heater included but data not recorded

Figure 9. Temperature profile for five chemical heat sources. Time 0 indicates activation. Note: Temperature of chemical heat sources were recorded at room temperature,



PROTOCOL

Five subjects (4 male and 1 female subjects) participated in our study. The five different trial conditions were performed on the same time of day to control for circadian effects. The subjects were supposed to be exposed to -20°C cold environment. However, we found that the climatic chamber started warming up on opening the door at every 10 minutes to get the subject response on cold discomfort. Therefore, it was decided that the four subjects would be exposed to -22°C cold environment and one subject who was already exposed to -20°C, would continue with -20°C under all the conditions. Each trial was separated by at least 48 hours. The order for five trials for each subject followed a balanced design. Subjects were advised to have adequate sleep and refrained from vigorous physical activity, alcohol or any drugs during the 24 hr before each experiment. They were not allowed any food except small breakfast within 2-3 hours before each

experiment. Forty-five minutes was designated for instrumentation to be completed. The subjects were then put on clothing mentioned above. Subjects were then asked to sit relaxed and quiet for baseline measurements. All baseline measurements were collected for 10 minutes. A Ready-Heat^{TM} (dry chemical heating blanket and pad) was exposed to air for 10 – 20 minutes before application on the subjects. The gel heat pack produces instant heat and was activated by flexing the metal disc present inside of the pack until the crystals form to generate heat.

One of the bags with built-in or separate internal vapor barrier for each trial was then placed on the bed and subject was asked to lie still on the bag. The dry chemical heating pads or blanket (Ready-Heat^{TM}) or gel chemical heat packs were applied to the subject according to their designated system. The bag was then tightly closed with zipper or Velcro® closure. The trial started when bed was pushed inside of the cold chamber (-20 or 22°C) and subject remained in the cold chamber until one of the following criteria met: a time period of 60 minutes elapsed; core temperature decreased to 36°C or decreased by 0.5°C whichever came first; a researcher terminated the experiment for safety reason, or the participant wished to exit. Subjects were asked about whole body discomfort at intervals of 10 minutes during the entire period of the experiment. They were then exited from the chamber and were asked to enter in a tank of warm water of 40 to 42°C to rewarm actively. This warm water bath was included for subjects so that core temperature could return to normal values (T_{co} – 37° ± 0.5°C) and subjects could feel comfortable. Participants were also asked about their overall preferences among all systems, overall shivering and overall cold rating at the end of each trail (See Appendix F)

DATA ANALYSIS

The change in esophageal temperature (T_{es}) was measured from the beginning of experiment period to the end, including baseline.

The area-weighted average skin temperature of all sites was calculated to compute the total body skin temperature ($T_{skTotal}$) by assigning the regional percentages to each area (described below).

The 12 sites along with their regional percentages (adapted from Layton et al.) [85] were: forehead (9%), right lateral chest (4.5%), left lateral chest (4.5%), superior umbilicus (6%), left lateral abdomen (6%), upper back (4.5%), right axilla (4.5%), lower back (6%), left posterior upper arm (7%), right anterior forearm including hand (12%), right anterior thigh (18%), left posterior thigh (18%).

Torso skin temperature ($T_{skTorso}$) was calculated from area weighted average of the right lateral chest, left lateral chest, upper back, lower back, superior umbilicus, left lateral abdomen and right axilla sites according to the percentages described above. Forehead skin temperature was represented as face skin temperature.

Metabolic heat production (M) was calculated by using the following equation from oxygen consumption (VO_2) and respiratory exchange ratio (RER):

$$M(W) = VO_2(l/min) \times 69.7(W/Kcal \cdot min^{-1}) [4.686(Kcal/l) + (RER - 0.707) \times 1.232(Kcal/l)]$$

Respiratory heat loss (RHL) was computed from metabolic heat production using the following equation [86, 88]:

$$RHL\ (W) = 0.09 \times M$$

The total body skin heat flux (HF_{Total}) was calculated by adding the heat flux values of all 12 sites ($W \cdot site^{-1}$) which were calculated from values of heat flux for each transducer using the following equation:

HF_{site} (W) = HF_{disc} (W/m^2) x BSA (m^2) x Regional % of the site x 0.01.

Or HF_{site} (W) = HF_{disc} (W/m^2) x Area covered by the heat pack (m^2)

Table 1 shows equations and regional percentages assigned to each transducer to calculate the heat flux for each site.

Torso skin heat flux (HF_{Torso}) was calculated by adding the heat flux values of all 7 sites (right lateral chest, left lateral chest, upper back, lower back, superior umbilicus, left lateral abdomen and right axilla).

Heat flux for face was calculated from flux value for forehead transducer using regional % of the face (3%).

Table 1. The skin heat flux for each site was calculated according to the equations and their regional percentages as given below:

Site	Hypothermia Enclosure Systems				
	Control	Doctor Down	MARSARS	HPMK	Wiggy's
HF_{Site} (W) = HFT_{Site} (W/m^2) x A (m^2)					
	Where A =	Where A =	Where A =	Where A =	Where A =
Forehead	BSA x 9% x 0.01	BSA x 9% x 0.01	BSA x 9% x 0.01	BSA x 9% x 0.01	BSA x 9% x 0.01
Right Lateral chest	AHS x 2/3	AHS x 1/2	AHS x 2/3	AHS x 1/2 x 2/3	AHS x 1/2
Left Lateral Chest	AHS	AHS x 1/2	AHS	AHS x 1/2	AHS x 1/2
Superior Umbilicus	BSA x 6.3% x 0.01	AHS	BSA x 6.3% x 0.01	AHS x 1/2	AHS
Left Lateral Abdomen	BSA x 6.3% x 0.01	[(BSA x 9% x 0.01) - (AHS)]	BSA x 6.3% x 0.01	AHS x 1/2	[(BSA x 9% x 0.01) - (AHS)]
Upper Back	AHS	BSA x 9% x 0.01	AHS	BSA x 12.6% x 0.01	BSA x 9% x 0.01
Right Axilla	AHS x 1/3	[(BSA x 9% x 0.01) - (AHS)]	AHS x 1/3	AHS x 1/2 x 1/3	[(BSA x 9% x 0.01) - (AHS)]
Lower Back	BSA x 12.6% x 0.01	BSA x 9% x 0.01	BSA x 12.6% x 0.01	[(BSA x 18% x 0.01) - (AHS)]	BSA x 9% x 0.01
Left Posterior Upper Arm	BSA x 7% x 0.01	BSA x 7% x 0.01	BSA x 7% x 0.01	BSA x 7% x 0.01	BSA x 7% x 0.01
Right Anterior Forearm	BSA x 12% x 0.01	BSA x 12% x 0.01	BSA x 12% x 0.01	BSA x 12% x 0.01	BSA x 12% x 0.01
Right Anterior Thigh	BSA x 18% x 0.01	BSA x 18% x 0.01	BSA x 18% x 0.01	BSA x 18% x 0.01	BSA x 18% x 0.01
Left Posterior Thigh	BSA x 18% x 0.01	BSA x 18% x 0.01	BSA x 18% x 0.01	BSA x 18% x 0.01	BSA x 18% x 0.01

A = Area allocated to each transducer; BSA = Body Surface Area (m^2); AHS = Area covered by Chemical Heat Source (length x breath) (m^2)

The net heat balance (net heat gain/loss) is the balance between heat production by the body and heat loss from the body. The net heat gain/ loss will be zero if heat production by the

body equals to heat loss from the body. Net heat gain (NHG) was calculated from metabolic heat production (M), respiratory heat loss (RHL), and total body skin heat flux (HF_{Total}).

$$NHG\ (W) = M\ (W) - RHL\ (W) - HF_{Total}\ (W)$$

Whole body cold discomfort was evaluated at 10-minute intervals during the experiment using a numerical rating scale ranging from 0 (not cold at all) to 10 (unbearably cold) [89].

Repeated measure one-way analysis of variance (ANOVA) was used to compare all the variables (core body temperature, heat flux, skin temperature, RHL, metabolic heat production, net heat gain, and whole body discomfort) for the five conditions. Post hoc analyses for significant differences between experiments was accomplished using Tukey's Post hoc test. Results were reported as means ± SD and $p<0.05$ was considered as significant differences.

RESULTS

The five subjects (4 male, 1 female) who completed the study were (mean ± SD) 29.4 ± 4.2 years old, 175 ± 7.7 cm tall, weight 83.8 ± 24.1 kg, had 2 ± 0.3 m^2 body surface area, and 18.4 ± 4.9% body fat (see Table 1).

Table 2. Descriptive data for five subjects.

Subject	Gender	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m^2)	BSA (m^2)	SFSF (mm)	Body Fat (%)
01	M	29.0	184.0	87.0	25.7	2.1	52.2	19.4
02	F	25.0	164.0	57.0	21.2	1.6	27.2	18.3
03	M	32.0	172.0	65.0	22.0	1.8	26.4	14.8
04	M	35.0	175.0	92.0	30.0	2.1	23.0	13.4
05	M	26.0	180.0	118.0	36.4	2.4	89.0	26.0
Mean		29.4	175.0	83.8	27.1	2.0	43.6	18.4
SD		4.2	7.7	24.1	6.3	0.3	27.9	4.9

BMI = Body Mass Index; BSA = Body surface area; SFSF = Sum of four skinfolds; M = Male; F = Female; SD = standard deviation

CORE TEMPERATURE

Five subjects were remained in the climatic chamber for the entire 60 minutes in 24 trials except for the one trial where the subject was taken out of the chamber and HES because the subject felt claustrophobia. The subject remained in the chamber for 44.5 minutes. Data for all the variables for that trial were extrapolated based on the trend of values before the termination of the trial. The climatic chamber failed to function in the one trial at the 30^{th} min (restarted at 45^{th} min) and for the other trial stopped working at 35^{th} min (did not restart). Data for these two trials were either interpolated or extrapolated based on the trend of values before and/or after the failure.

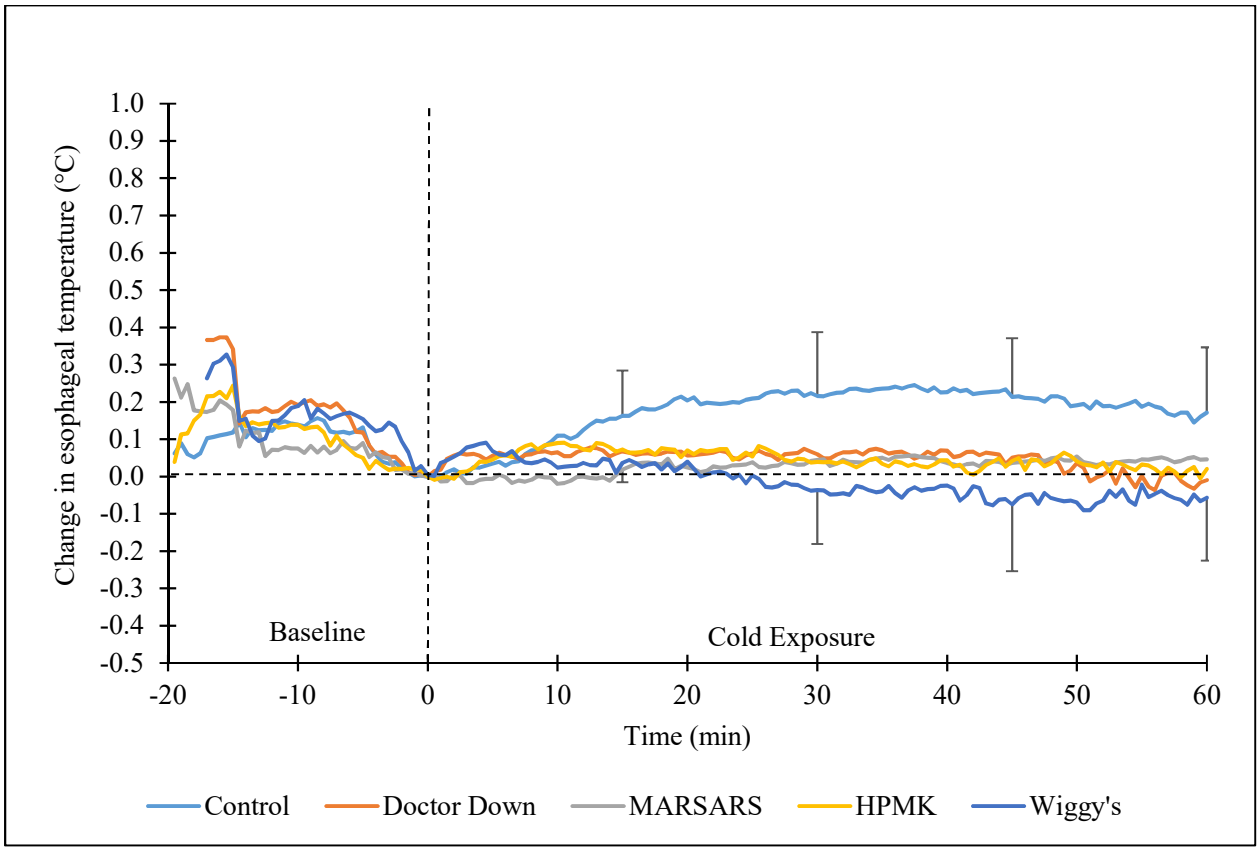
The mean core temperature (T_{co}) in all the systems during the baseline period was 37.2 ± 0.2°C. There were no significant differences between all the systems in any core temperature during baseline, at every 15 minutes, and mean change in core temperature (0-60 min) between all the systems (see Table 3; Figure 10).

Table 3. Mean core temperature (T_{co}) (°C) during baseline, at every 15 min of the cold exposure and Mean change in core temperature (T_{co}) (0-60 min) for the five hypothermia enclosure systems (HES) [mean (SD)].

	Control	Doctor Down	MARSARS	HPMK	Wiggy's
Baseline T_{es} (°C)	37.2 (0.3)	37.0 (0.3)	37.2 (0.2)	37.1 (0.2)	37.0 (0.1)
T_{es} (°C) at 15 min	37.2 (0.3)	37.1 (0.3)	37.1 (0.2)	37.0 (0.3)	37.1 (0.2)
T_{es} (°C) at 30 min	37.2 (0.3)	37.1 (0.3)	37.1 (0.2)	37.0 (0.4)	37.1 (0.2)
T_{es} (°C) at 45 min	37.2 (0.3)	37.1 (0.3)	37.1 (0.3)	37.0 (0.3)	37.0 (0.2)
T_{es} (°C) at 60 min	37.2 (0.3)	37.0 (0.3)	37.1 (0.3)	37.0 (0.4)	37.0 (0.2)
Change in T_{es} (0-60)	0.03 (0.2)	-0.15 (0.2)	-0.05 (0.1)	-0.11 (0.3)	-0.22 (0.2)

T_{es} = Esophageal temperature

Figure 10. Mean change in esophageal temperature (T_{es}) (°C) during baseline, and at every 15 min of the cold exposure in the five hypothermia enclosure systems (HES). Time 0 minutes and temperature 0°C indicate entrance of the subjects inside the climatic chamber (bars, SD). For clarity, SD bars are only included for top and bottom lines. Time (min) = -20 to 0 include baseline plus transition period of the subjects from the baseline to the cold exposure.



AVERAGE SKIN TEMPERATURE

There were no significant differences between baseline (32.6 ± 0.7°C) and 60 min of cold exposure (33.0 ± 1.6°C) for the average total skin temperature for the same systems.

There were no significant differences between the five systems for total body skin temperature ($T_{skTotal}$) during the baseline period (see Table 4). The average $T_{skTotal}$ was significantly higher during 0-15 minutes of the cold exposure in the Control (34.3 ± 0.8°C) and Doctor Down

(34.4 ± 0.7°C) systems than the HPMK (32.6 ± 0.9°C) system ($p<0.05$) (see Figure 11). There were no other significant differences between all systems during 0-15 min of the cold exposure.

During 15-30 minutes of the cold exposure, the average $T_{skTotal}$ was significantly higher in the Control (34.1 ± 0.9°C) system than the HPMK (31.3 ± 1.3°C) system ($p<0.01$). The higher average $T_{skTotal}$ was also found during this period of cold exposure in the Doctor Down (34.5 ± 0.6°C) system compared to the HPMK and the Wiggy's (32.5 ± 1.3°C) systems ($p<0.05$). There were no other significant differences between all systems during 15-30 min of the cold exposure.

During 30-45 minutes of the cold exposure, the average $T_{skTotal}$ was significantly higher in the Control (33.9 ± 0.9°C), the MARSARS (32.8 ± 1.3°C), and the Doctor Down (34.4 ± 0.7°C) systems than the HPMK (30.6 ± 1.6°C) system ($p<0.05$). The average $T_{skTotal}$ for Doctor Down system was also significantly higher than the Wiggy's (32.2 ± 1.4°C) system ($p<0.05$). There were no other significant differences among all systems.

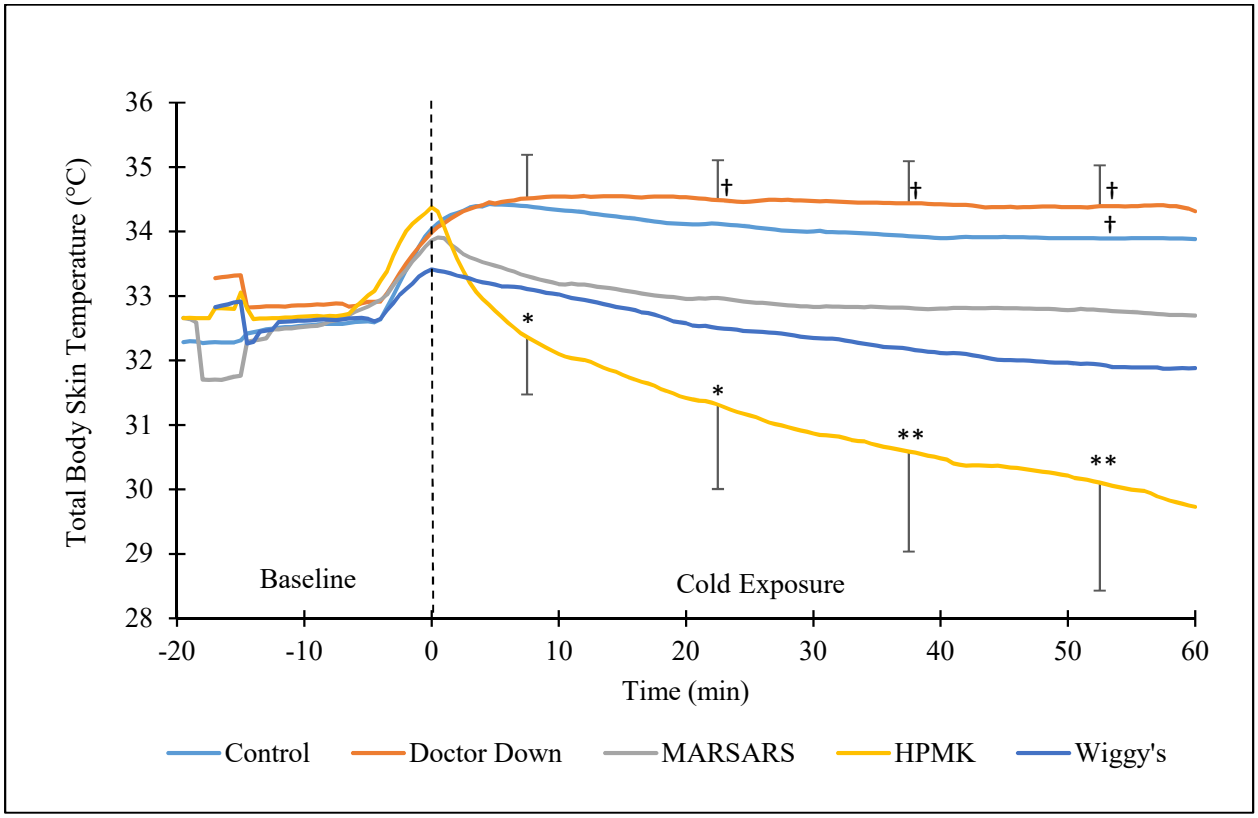
During 45-60 minutes of the cold chamber, the average $T_{skTotal}$ was significantly higher in the Control (33.9 ± 1.0°C), the MARSARS (32.8 ± 1.3°C), and the Doctor Down (34.4 ± 0.6°C) systems than the HPMK (30.1 ± 1.7°C) system ($p<0.01$). The average $T_{skTotal}$ for the Doctor Down and the Control systems was also significantly higher when compared with the Wiggy's (31.9 ± 1.4°C) system ($p<0.05$) with no other significant differences between all systems during 15-30 min of the cold exposure.

Table 4. The average total body skin temperature (°C) during baseline, and 60 min of cold exposure in the five hypothermia enclosure systems (HES) (mean ± standard deviation).

Time	Control (°C)	Doctor Down (°C)	MARSARS (°C)	HPMK (°C)	Wiggy's (°C)
Baseline	32.5 ± 0.9	32.9 ± 0.5	32.5 ± 0.9	32.6 ± 0.7	32.6 ± 0.5
0-15 min	34.3 ± 0.8†	34.4 ± 0.7†	33.4 ± 1.0	32.6 ± 0.9	33.1 ± 0.9
15-30 min	34.1 ± 0.9†	34.5 ± 0.6†*	32.9 ± 1.2	31.3 ± 1.3	32.5 ± 1.3
30-45 min	33.9 ± 0.9†	34.4 ± 0.7†*	32.8 ± 1.3†	30.6 ± 1.6	32.2 ± 1.4
45-60 min	33.9 ± 1.0†*	34.4 ± 0.6†*	32.8 ± 1.3†	30.1 ± 1.7	31.9 ± 1.4
0-60 min	34.1 ± 0.9†	34.4 ± 0.6†*	33.0 ± 1.2†	31.2 ± 1.4	32.4 ± 1.2

†Significantly higher than the HPMK system ($p<0.05$). *Significantly higher than the Wiggy's system ($p<0.05$).

Figure 11. Total body skin temperature (°C) during baseline, and during 60 min of the cold exposure in the five hypothermia enclosure systems (HES). Time 0 minutes indicate entrance of the subjects inside the climatic chamber (bars, SD). For clarity, SD bars are only included for top and bottom lines. Time (min) = -20 to 0 include baseline plus transition period of the subjects from the baseline to the cold exposure. *Significantly lower than the Control and Doctor Down systems ($p<0.05$). †Significantly higher than the Wiggy's system ($p<0.05$). **Significantly lower than the Control, Doctor Down and MARSARS systems ($p<0.05$). Note: Skin temperature increase in transition when subject enters HES.



There were no significant differences between the five systems for $T_{skTorso}$ during the baseline period (see Table 5). The average $T_{skTorso}$ significantly increased to 37.0 ± 0.6°C during 60 min of the cold exposure from baseline value (33.4 ± 1.0°C). During 0-15 minutes of the cold exposure, the average $T_{skTorso}$ was significantly higher in the Control (37.4 ± 0.7°C), and the Doctor Down (36.8 ± 0.9°C) and the HPMK (37.2 ± 0.5°C) systems than the Wiggy's (35.5 ± 0.5°C) system ($p<0.05$) (see Figure 12). There were no other significant differences between all systems during 0-15 min of the cold exposure.

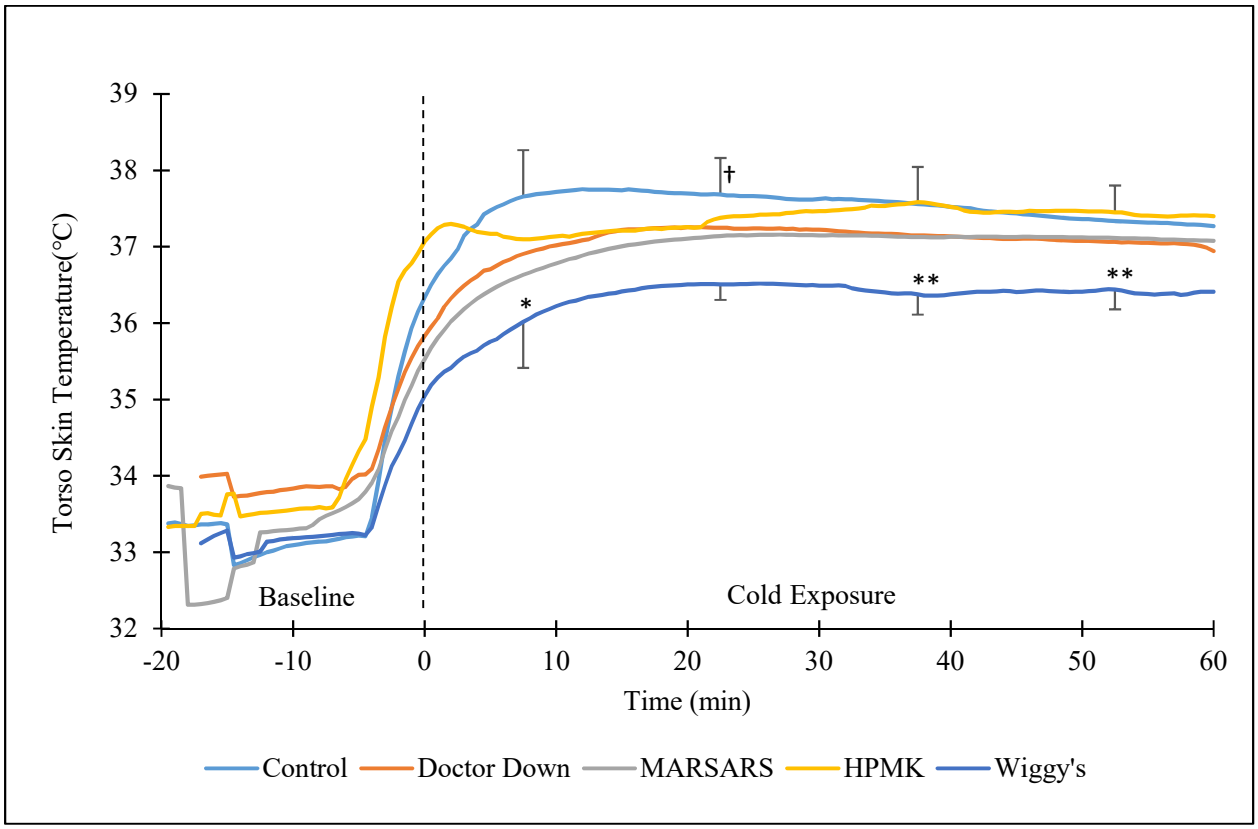
During 15-30 minutes of the cold exposure, the average $T_{skTorso}$ was significantly higher in the Control (37.7 ± 0.5°C) system compared to the Wiggy's (36.5 ± 0.2°C) system ($p<0.05$) but no other significant differences between all systems. The average $T_{skTorso}$ during 30-45 min and 45-60 min of cold exposure was higher in the Control (37.6 ± 0.4°C and 37.3 ± 0.4°C respectively) and the HPMK (37.5 ± 0.4°C and 37.4 ± 0.3°C respectively) systems than the Wiggy's (36.4 ± 0.2°C and 36.4 ± 0.3°C respectively) system ($p<0.05$). There were no other significant differences between all systems during 45-60 min and 45-60 min of the cold exposure.

Table 5. The average torso skin temperature (°C) during baseline, and 60 min of cold exposure in the five hypothermia enclosure systems (HES) (mean ± standard deviation).

Time	Control (°C)	Doctor Down (°C)	MARSARS (°C)	HPMK (°C)	Wiggy's (°C)
Baseline	33.0 ± 1.2	33.8 ± 0.9	33.3 ± 1.5	33.5 ± 0.9	33.2 ± 0.6
0-15 min	37.4 ± 0.7*	36.8 ± 0.9*	36.5 ± 0.5	37.2 ± 0.5*	35.5 ± 0.5
15-30 min	37.7 ± 0.5*	37.2 ± 0.8	37.1 ± 0.4	37.3 ± 0.5	36.5 ± 0.2
30-45 min	37.6 ± 0.4*	37.2 ± 0.8	37.1 ± 0.4	37.5 ± 0.4*	36.4 ± 0.2
45-60 min	37.3 ± 0.4*	37.1 ± 0.7	37.1 ± 0.4	37.4 ± 0.3*	36.4 ± 0.3
0-60 min	37.5 ± 0.4*	37.1 ± 0.8	37.0 ± 0.4	37.4 ± 0.4*	36.3 ± 0.2

*Significantly higher than the Wiggy's system ($p<0.05$).

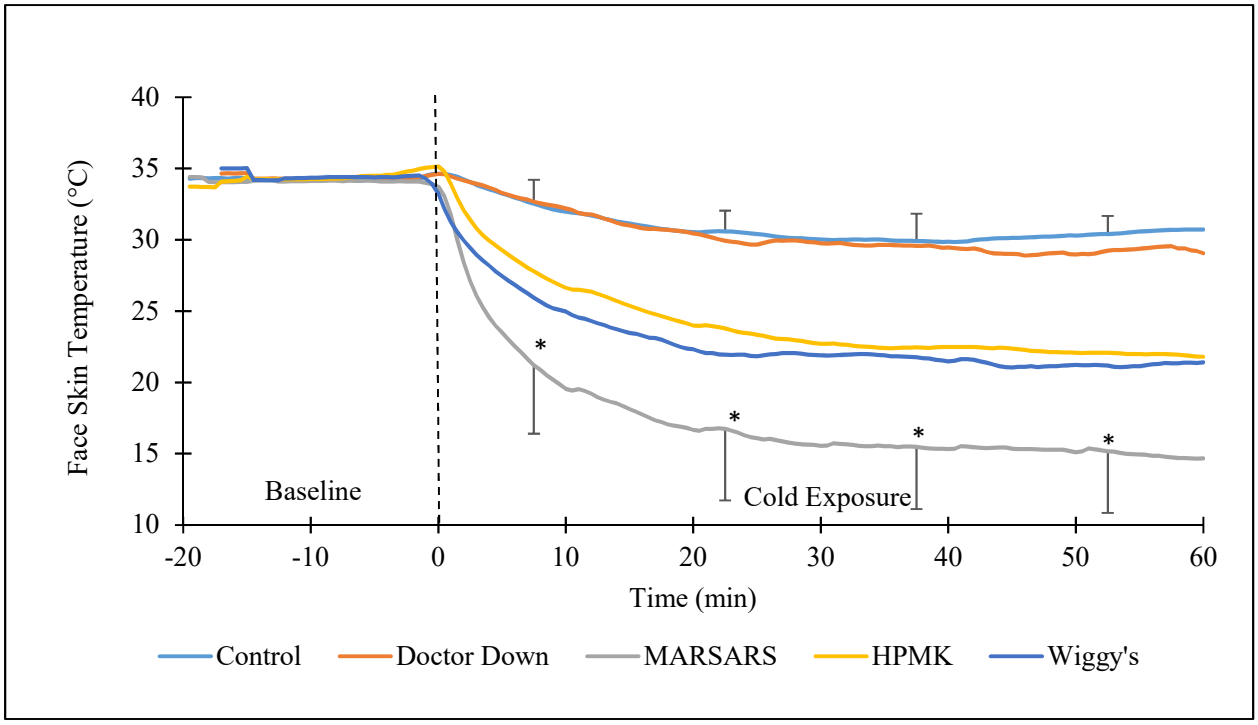
Figure 12. Torso skin temperature (°C) during baseline, and during 60 min of the cold exposure in the five hypothermia enclosure systems (HES). Time 0 minutes indicate entrance of the subjects inside the climatic chamber (bars, SD). For clarity, SD bars are only included for top and bottom lines. Time (min) = -20 to 0 include baseline plus transition period of the subjects from the baseline to the cold exposure. *Significantly lower than the Control, HPMK, and Doctor Down systems ($p<0.05$). †Significantly higher than the Wiggy's system ($p<0.05$). **Significantly lower than the Control and Doctor Down systems ($p<0.05$). Note: Skin temperature increase in transition when subject enters HES.



The average of every 15-min data of the cold exposure for the face skin temperature was analyzed. There were no significant differences in all the systems for the face skin temperature during baseline (34.2 ± 0.5°C). During 0-15 min, 15-30 min, 30-45 min and 45-60 min of the cold exposure, there was higher face skin temperature for the Control (32.7 ± 0.5°C, 30.5 ± 1.4°C, 30.0 ± 1.9°C and 30.4 ± 1.4°C respectively) and the Doctor Down (32.8 ± 1.4°C, 30.2 ± 2.2°C, 29.5 ± 2.2°C and 29.2 ± 2.4°C respectively) systems compared to the MARSARS (22.0 ± 5.2°C, 16.6 ±

5.0°C, 15.5 ± 4.4°C and 15.1 ± 4.3°C respectively) systems ($p<0.01$) (see Figure 13). There were no other significant differences during the entire period of the cold exposure.

Figure 13. Face skin temperature (°C) during baseline, and during 60 min of the cold exposure in the five hypothermia enclosure systems (HES). Time 0 minutes indicate entrance of the subjects inside the climatic chamber (bars, SD). For clarity, SD bars are only included for top and bottom lines. Time (min) = -20 to 0 include baseline plus transition period of the subjects from the baseline to the cold exposure. *Significantly lower than the Control, and Doctor Down systems ($p<0.05$).



METABOLIC HEAT PRODUCTION

Data for two trials in which the climatic chamber failed to function at the 30th min (restarted at 45th min) and at 35th min (did not restart) were interpolated and/or extrapolated based on the trend of values before and after the failure. The metabolic heat production data were analyzed at four data points- 7.5 min, 22.5 min, 37.5 min, and 52.5 minutes. Each data point represents the average of 15 minutes.

There were no significant differences for metabolic heat production between the five systems during the baseline period and the first 30 min of the cold exposure (see Table 6). The values of average metabolic heat production decreased from a baseline of 103.1 ± 17.1 W to 80.7 ± 17.9 W during 60 min of the cold exposure.

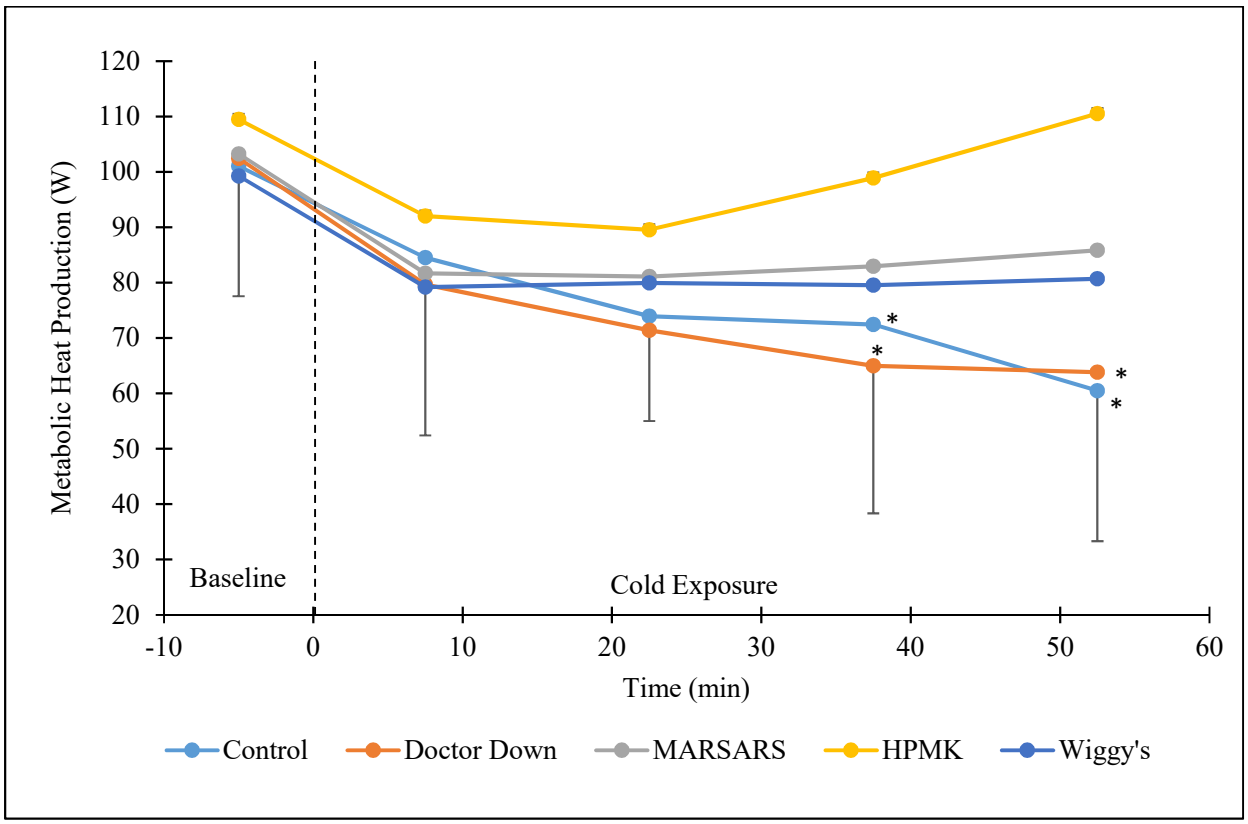
The metabolic heat production was significantly higher during 30-45 minutes and 45-60 minutes of cold exposure in the HPMK (97.3 ± 14.4 W and 110.6 ± 25.6 W respectively) system than the Control (72.5 ± 20.9 W and 60.5 ± 34.2 W respectively) and Doctor Down (65.0 ± 19.3 W and 63.8 ± 17.0 W respectively) systems ($p<0.05$) (see Figure 14). There were no other significant differences between all systems during 45-60 min and 45-60 min of the cold exposure.

Table 6. The average metabolic heat production (W) during baseline, and 60 min of cold exposure in the five hypothermia enclosure systems (HES) (mean ± standard deviation).

Time	Control (W)	Doctor Down (W)	MARSARS (W)	HPMK (W)	Wiggy's (W)
Baseline	101.1 ± 11.3	102.4 ± 15.1	103.3 ± 22.6	109.5 ± 19.2	99.3 ± 21.2
0-15 min	84.5 ± 17.2	79.7 ± 15.2	81.7 ± 19.7	92.0 ± 22.6	79.2 ± 18.8
15-30 min	73.9 ± 22.8	71.4 ± 11.6	81.1 ± 18.7	89.6 ± 13.7	80.0 ± 14.4
30-45 min	72.5 ± 20.9	65.0 ± 19.3	83.0 ± 18.1	97.3 ± 14.4*	79.6 ± 11.8
45-60 min	60.5 ± 34.2	63.8 ± 17.0	85.9 ± 20.5	110.6 ± 25.6*	80.7 ± 13.6
0-60 min	72.8 ± 22.7	70.0 ± 12.7	82.9 ± 18.3	97.9 ± 11.8*†	79.9 ± 13.6

*Significantly higher than the Control and Doctor Down systems ($p<0.05$). †Significant higher than the Wiggy's system ($p<0.05$).

Figure 14. Metabolic heat production (W) during baseline, and during 60 min of the cold exposure in the five hypothermia enclosure systems (HES). Time 0 minutes indicate entrance of the subjects inside the climatic chamber (bars, SD). For clarity, SD bars are only included for top and bottom lines. *Significantly lower than the HPMK system ($p<0.05$).



HEAT FLUX

There were no significant differences between baseline (84.8 ± 11.5 W) and 60 min of cold exposure (101.3 ± 56.0 W) for the average total body skin flux (HF_{Total}) for the same systems.

There were no significant differences for HF_{Total} between the five systems during the baseline period (see Table 7). During 0-15, 15-30, 30-45 and 45-60 min, there was significantly higher heat loss in the HPMK (123.8 ± 48.2 W, 139.4 ± 54.8 W, 137.7 ± 57.8 W, and 144.7 ± 48.7 W respectively), the MARSARS (115.5 ± 48.8 W, 137.0 ± 52.7 W, 139.0 ± 49.0 W, and 144.6 ±

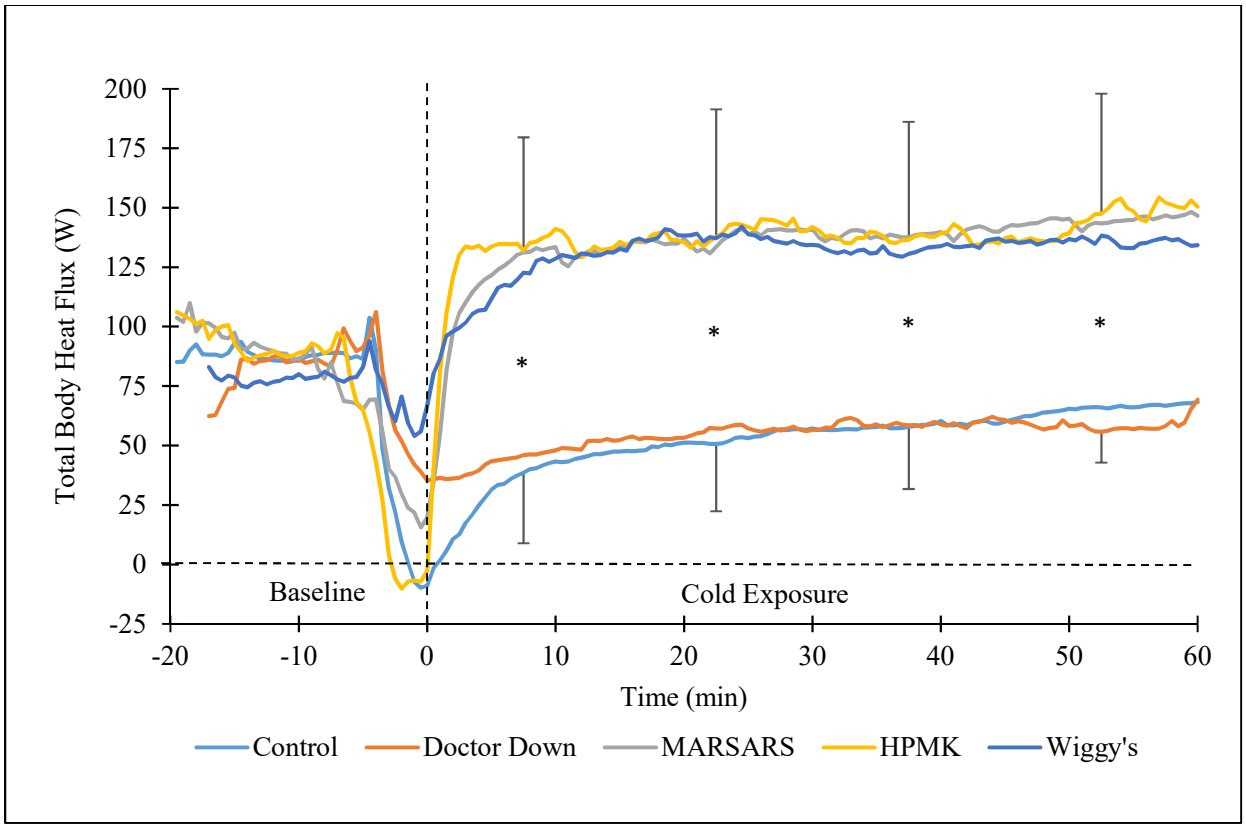
51.3 W respectively) and the Wiggy's (115.9 ± 43.7 W, 137.1 ± 59.2 W, 132.9 ± 57.7 W, and 135.7 ± 59.5 W respectively) systems than the Control (31.8 ± 29.1 W, 52.1 ± 27.6 W, 58.2 ± 27.1 W and 65.3 ± 29.6 respectively) and the Doctor Down (44.6 ± 12.2 W, 55.4 ± 16.1 W, 59.1 ± 16.9 W and 58.6 ± 13.9 W respectively) systems ($p<0.05$) (see Figure 15). There were no other significant differences between all systems during the entire period of an experiment for total heat flux.

Table 7. The average total body heat flux (W) during baseline, and 60 min of cold exposure in the five hypothermia enclosure systems (HES) (mean ± standard deviation).

Time	Control (W)	Doctor Down (W)	MARSARS (W)	HPMK (W)	Wiggy's (W)
Baseline	89.4 ± 4.0	85.8 ± 16.5	86.5 ± 11.6	86.6 ± 14.1	75.5 ± 5.3
0-15 min	31.8 ± 29.1	44.6 ± 12.2	115.5 ± 48.8*	123.8 ± 48.2*	115.9 ± 43.7*
15-30 min	52.1 ± 27.6	55.4 ± 16.1	137.0 ± 52.7*	139.4 ± 54.8*	137.1 ± 59.2*
30-45 min	58.2 ± 27.1	59.1 ± 16.9	139.0 ± 49.0*	137.7 ± 57.8*	132.9 ± 57.7*
45-60 min	65.3 ± 29.6	58.6 ± 13.9	144.6 ± 51.3*	144.7 ± 48.7*	135.7 ± 59.5*
0-60 min	51.8 ± 26.8	54.4 ± 14.5	133.9 ± 50.3*	136.3 ± 51.8*	130.3 ± 54.3*

*Significantly higher than the Control and Doctor Down systems ($p<0.05$).

Figure 15. Total body heat flux (W) during baseline, and during 60 min of the cold exposure in the five hypothermia enclosure systems (HES). Time 0 minutes indicate entrance of the subjects inside the climatic chamber (bars, SD). For clarity, SD bars are only included for top and bottom lines. Time (min) = -20 to 0 include baseline plus transition period of the subjects from the baseline to the cold exposure. *Significant difference between (the HPMK, MARSARS and Wiggy's systems) and (the Control, and the Doctor Down systems) ($p<0.05$). Note: Heat flux (loss) decrease in transition when subject enters HES.



There were no significant differences between the five systems for the heat loss from the torso (HF_{Torso}) during the baseline (23.8 ± 4.7 W) (see Table 8). The average HF_{Torso} significantly decreased from baseline values to -9.9 ± 15.5 during 60 min of the cold exposure. During 0-15 and 15-30 min, there was significantly higher heat gain from the torso in the Control (-33.9 ± 18.2 W and -27.1 ± 14.0 W respectively) and the HPMK (-28.2 ± 18.8 W and -22.9 ± 18.9 W respectively) systems than the Doctor Down (0.1 ± 6.3 Wand -1.2 ± 5.7 W respectively), and the Wiggy's (6.8

± 3.4 W and 4.5 ± 3.2 W respectively) systems ($p<0.05$) (see Figure 16). There were no other significant differences between all systems during these periods.

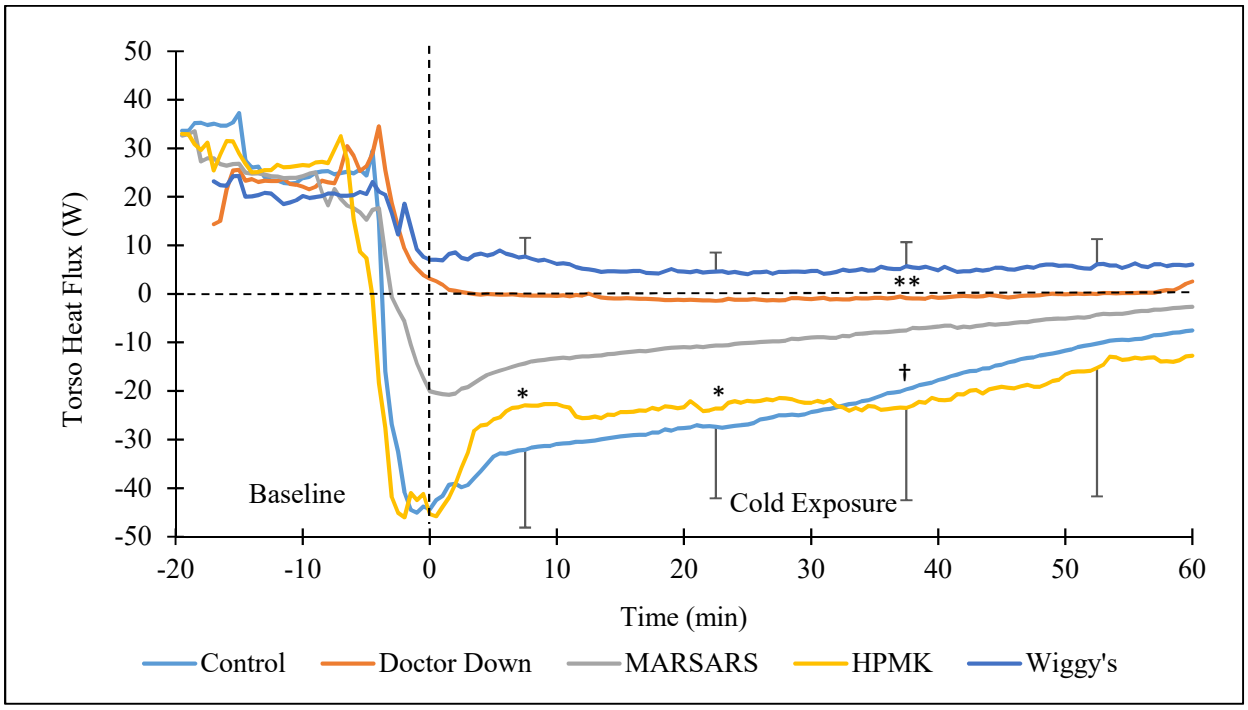
During 30-45 min, there was significantly higher heat gain in the Control (-19.6 ± 11.3 W; $p<0.05$) system compared to the Wiggy's (5.0 ± 4.2 W) system. Similarly, there was significantly higher heat gain in the HPMK (-22.1 ± 19.4 W) system compared to the Wiggy;s and the Doctor Down (-0.8 ± 5.8 W) systems ($p<0.05$). There were no significant differences in all systems for torso heat flux during 45-60 min.

Table 8. The average torso heat flux (W) during baseline, and 60 min of cold exposure in the five hypothermia enclosure systems (HES) (mean ± standard deviation).

Time	Control (W)	Doctor Down (W)	MARSARS (W)	HPMK (W)	Wiggy's (W)
Baseline	25.8 ± 5.1	23.1 ± 5.4	24.0 ± 5.1	26.3 ± 3.1	19.9 ± 3.4
0-15 min	-33.9 ± 18.2	0.1 ± 6.3*†	-15.5 ± 7.6	-28.2 ± 18.8	6.8 ± 3.4*†
15-30 min	-27.1 ± 14.0	-1.2 ± 5.7	-10.6 ± 5.1	-22.9 ± 18.9	4.5 ± 3.2
30-45 min	-19.6 ± 11.3	-0.8 ± 5.8†	-7.5 ± 4.7	-22.1 ± 19.4	5.0 ± 4.2*†
45-60 min	-10.6 ± 8.8	0.2 ± 5.3	-4.4 ± 4.1	-15.7 ± 24.8	5.7 ± 4.7
0-60 min	-22.8 ± 12.3	-0.4 ± 5.7*†	-9.5 ± 4.8	-22.2 ± 20.4	5.5 ± 3.1*†

*Significantly higher than the Control system ($p<0.05$). †Significantly higher than the HPMK system ($p<0.05$).

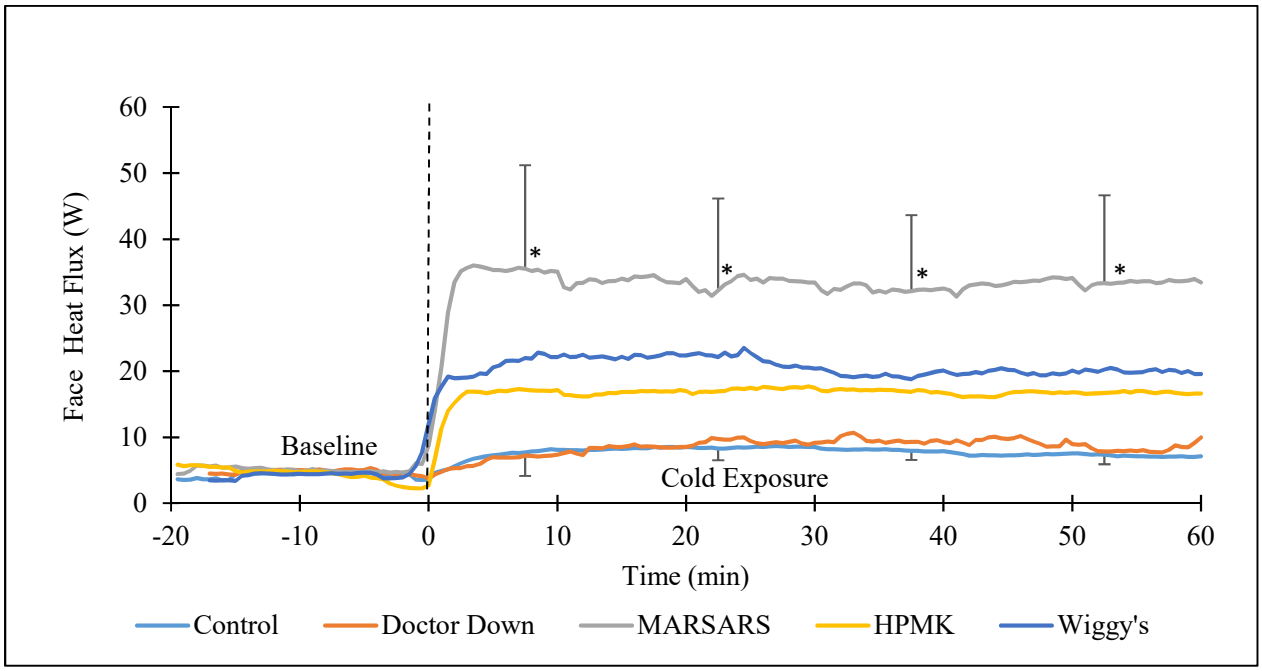
Figure 16. Torso heat flux (W) during baseline, and during 60 min of the cold chamber in the five hypothermia enclosure systems (HES). Time 0 minutes indicate entrance of the subjects inside the climatic chamber (bars, SD). For clarity, SD bars are only included for top and bottom lines. Time (min) = -20 to 0 include baseline plus transition period of the subjects from the baseline to the cold exposure. *Significant difference between (the Doctor Down and the Wiggy's systems) and (the Control bag and the HPMK systems) ($p<0.05$). †Significant difference between (the Control and the HPMK systems) and the Wiggy's system ($p<0.05$). **Significantly higher than the HPMK system ($p<0.05$). Note: Heat flux (loss) decrease in transition when subject enters HES.



The average of every 15-min data of the cold exposure for the face heat flux were analyzed. There were no significant differences between all the systems for the face heat flux during baseline (79.7 ± 10.9 W). During 0-15, 15-30, 30-45 and 45-60 min, there was significantly higher heat loss from face in the MARSARS (528.8 ± 194.3 W, 551.0 ± 192.2 W, 536.5 ± 165.6 W, and 553.2 ± 183.7 W respectively) system compared to the Control (121.4 ± 35.3 W, 143.9 ± 30.5 W, 134.1 ± 29.0 W, and 123.0 ± 20.3 W respectively), the Doctor Down (113.0 ± 35.6 W, 150.7 ± 68.2 W,

158.5 ± 78.8 W, and 144.2 ± 49.8 W respectively) and the HPMK (263.6 ± 80.8 W, 288.6 ± 86.6 W, 282.9 ± 98.3 W and 282.5 ± 91.0 W respectively) systems ($p<0.05$) (see Figure 17).

Figure 17. Face heat flux (W) during baseline, and during 60 min of the cold chamber in the five hypothermia enclosure systems (HES). Time 0 minutes indicate entrance of the subjects inside the climatic chamber (bars, SD). For clarity, SD bars are only included for top and bottom lines. Time (min) = -20 to 0 include baseline plus transition period of the subjects from the baseline to the cold exposure. *Significantly higher than the Control, the Doctor Down and the HPMK systems ($p<0.05$).



NET HEAT GAIN

There were no significant differences between baseline and first 15 min of cold exposure for the net heat gain for the same systems. However, the net heat gain significantly decreased from the baseline values (8.2 ± 12.3 W) to -33.9 ± 49.4 W during last 45 minutes of the cold exposure.

There were no significant differences between the five systems during the baseline (see Table 9). During 0-15 and 15-30 min of the cold exposure, there was significantly higher net heat

gain in the Control (45.1 ± 22.1 W and 15.1 ± 9.6 W respectively) and the Doctor Down (27.9 ± 11.1 W and 9.6 ± 15.1 W respectively) systems compared to the MARSARS (-41.2 ± 40.1 W and -63.2 ± 42.8 W respectively), the HPMK (-40.0 ± 35.7 W and -57.9 ± 43.9 W respectively) and the Wiggy's (-43.8 ± 49.2 W and -64.3 ± 53.1 W respectively) systems ($p<0.05$) (see Figure 18). There were no other significant differences for torso heat flux during these periods.

During 30-45 min of the cold exposure, the net heat gain was significantly higher in the Control (7.8 ± 11.4 W) system than the MARSARS (-63.5 ± 36.6 W) system ($p<0.05$). The net heat gain was significantly higher in the Doctor Down (0.0 ± 24.6 W) system during 45-60 min than the MARSARS system ($p<0.05$). There were no other significant differences for torso heat flux during 30-45 min and 45-60 min of the cold exposure.

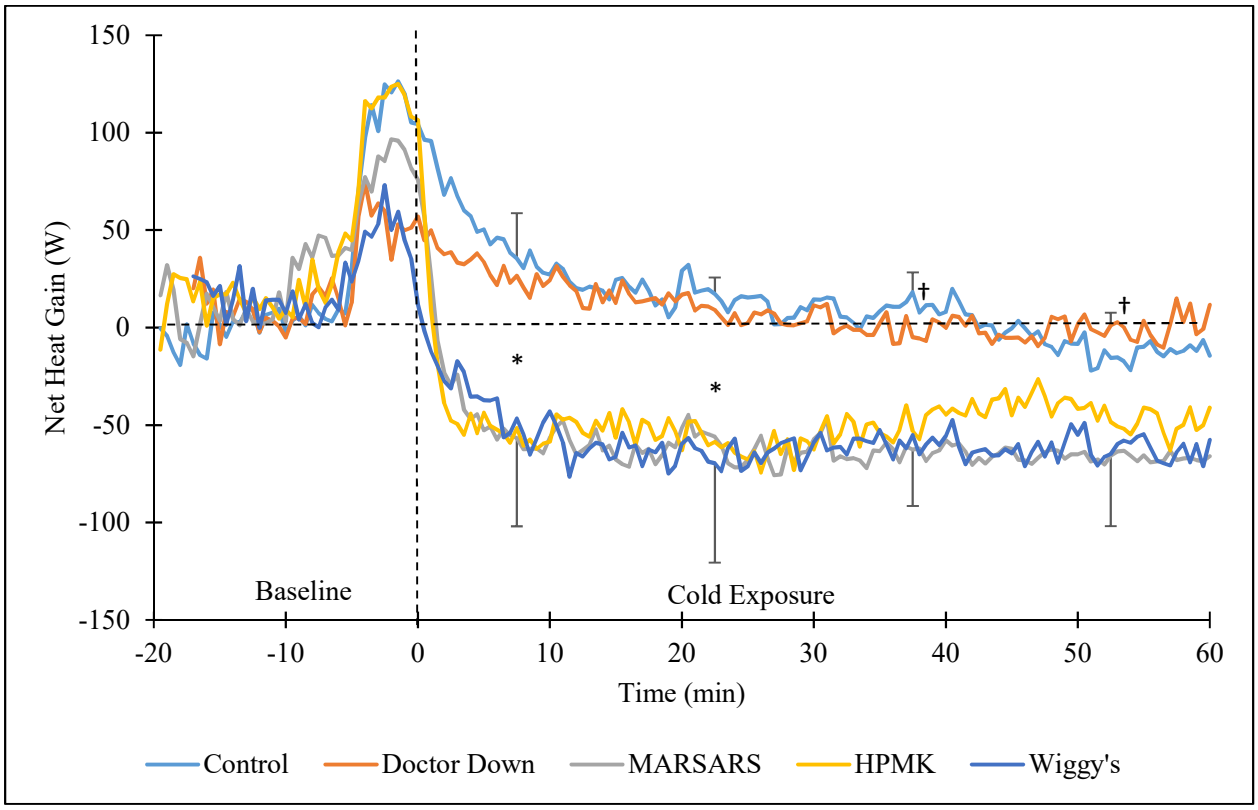
The total net heat gain in 60 min (cold exposure) for the Control and Doctor Down systems was 867.5 W and 558.7 W respectively whereas the total net heat loss in 60 min for the MARSARS, HPMK and Wiggy's systems was 3509.5 W, 2834.7 W and 3454.4 W respectively.

Table 9. The average net heat gain (W) during baseline, and 60 min of cold exposure in the five hypothermia enclosure systems (HES) (mean ± standard deviation).

Time	Control (W)	Doctor Down (W)	MARSARS (W)	HPMK (W)	Wiggy's (W)
Baseline	2.9 ± 9.0	7.7 ± 13.0	7.9 ± 15.5	10.2 ± 9.8	12.3 ± 16.0
0-15 min	45.1 ± 22.1	27.9 ± 11.1	-41.2 ± 40.1 *†	-40.0 ± 35.7 *†	-43.8 ± 49.2 *†
15-30 min	15.1 ± 9.6	9.6 ± 15.1	-63.2 ± 42.8 *†	-57.9 ± 43.9 *†	-64.3 ± 53.1 *†
30-45 min	7.8 ± 11.4	0.0 ± 24.6	-63.5 ± 36.6 *	-47.7 ± 65.7	-60.4 ± 58.0
45-60 min	-10.3 ± 16.0	-0.6 ± 13.2	-66.4 ± 35.6 †	-44.1 ± 61.2	-62.3 ± 65.5
0-60 min	14.5 ± 10.2	9.3 ± 12.5	-58.5 ± 38.4*†	-47.2 ± 50.6	-57.6 ± 55.3*†

*Significantly lower than the Control system ($p<0.05$). †Significantly lower than the Doctor Down system ($p<0.05$)

Figure 18. Net heat gain (W) during baseline, and during 60 min of the cold exposure in the five hypothermia enclosure systems (HES). Time 0 minutes indicate entrance of the subjects inside the climatic chamber (bars, SD). For clarity, SD bars are only included for top and bottom lines. Time (min) = -20 to 0 include baseline plus transition period of the subjects from the baseline to the cold exposure. *Significantly difference between three systems (the MARSARS, the HPMK and the Wiggy's) and other two systems (the Control, and the Doctor Down) ($p<0.05$). †Significantly higher than the MARSARS system ($p<0.05$). Note: Net heat gain increase in transition when subject enters HES.



SUBJECTIVE EVALUATION

The subjects were asked about their whole body cold discomfort by providing values at an interval of 10 minutes during cold exposure in a climatic chamber [25].

The cold discomfort data were analyzed at every 10 minutes of cold exposure (see Table 10). The cold discomfort was significantly higher in the HPMK system than the Control, the

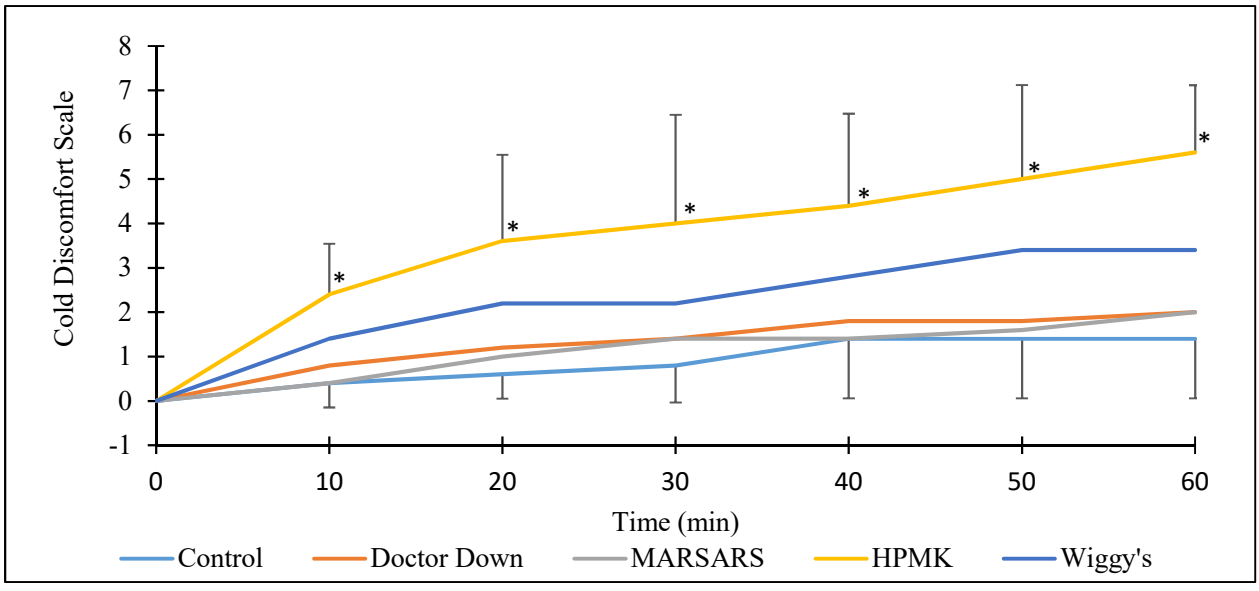
MARSARS and the Doctor Down system at every 10 minutes of the cold exposure (see Figure 19). There were no other significant differences between all systems for the whole body cold discomfort during the entire period of the cold exposure.

Table 10. The whole body cold discomfort at every 10 minutes of cold exposure in the five hypothermia enclosure systems (HES).

Time	Control	Doctor Down	MARSARS	HPMK	Wiggy's	P value
At 10 min	0.4 ± 0.5	0.8 ± 0.4	0.4 ± 0.5	2.4 ± 1.1*	1.4 ± 0.9	P<0.05
At 20 min	0.6 ± 0.5	1.2 ± 1.1	1.0 ± 0.7	3.6 ± 1.9*	2.2 ± 1.6	P<0.05
At 30 min	0.8 ± 0.8	1.4 ± 1.1	1.4 ± 0.9	4.0 ± 2.4*	2.2 ± 1.6	P<0.05
At 40 min	1.4 ± 1.3	1.8 ± 1.5	1.4 ± 0.9	4.4 ± 2.1*	2.8 ± 1.9	P<0.05
At 50 min	1.4 ± 1.3	1.8 ± 1.5	1.6 ± 1.1	5.0 ± 2.1*	3.4 ± 2.4	P<0.05
At 60 min	1.4 ± 1.3	2.0 ± 1.6	2.0 ± 1.4	5.6 ± 1.5*	3.4 ± 2.4	P<0.05

*Significantly higher than the Control, MARSARS and Doctor Down systems.

Figure 19. The whole body cold discomfort at every 10 minutes of the cold exposure (bars, SD). For clarity, SD bars are only included for top and bottom lines. *Significantly higher than the MARSARS, Doctor Down and Wiggy's systems (p<0.05).



The overall subject's preferences in the systems were asked at the end of each trial and the preferred systems were the Control, Doctor Down and MARSARS; the overall preference for the Wiggy's system was neutral and the HPMK system was least preferred (see Table 11). One subject terminated the trial at 44.5 min with the MARSARS system because of claustrophobia. Three subjects reported about tightness of the MARSARS system during their trial with this system.

Table 11. Overall preferences for the five hypothermia enclosure systems (HES) indicated by each subject following completion of each trial.

Overall Preferences					
Subjects	Control	Doctor Down	MARSARS	HPMK	Wiggy's
1	Most Preferred	Neutral	Most Preferred	Less Preferred	Preferred
2	Neutral	Most Preferred	Preferred	Least Preferred	Less Preferred
3	Preferred	Neutral	Most Preferred	Less Preferred	Least Preferred
4	Most Preferred	Neutral	Preferred	Least Preferred	Less Preferred
5	Neutral	Most Preferred	Less Preferred	Least Preferred	Preferred

The overall shivering responses were taken at the end of each trial and there was no shivering in the Control, Doctor Down and MARSARS systems during cold exposure whereas there was low shivering during cold exposure with the Wiggy's and the HPMK systems (see Table 12).

Table 12. Overall shivering responses for the five hypothermia enclosure systems (HES) indicated by each subject following completion of each trial.

Shivering Responses					
Subjects	Control	Doctor Down	MARSARS	HPMK	Wiggy's
1	No	Low	No	Low	No
2	No	No	No	High	Low
3	No	No	No	Low	Low
4	No	No	No	High	Low
5	No	No	No	Low	No

The overall cold rating in the systems were taken at the end of each trial and the Control system was very warm bag; the Doctor Down and MARSARS systems were warm system; and the overall response for the Wiggy's system was neutral and the HPMK systemwas very cold system (see Table 13). Three subjects reported about cold face during their trial with the MARSARS system.

Table 13. Overall cold rating for the five hypothermia enclosure systems (HES) indicated by each subject following completion of each trial.

Overall Cold Rating at the end of experiment					
Subjects	Control	Doctor Down	MARSARS	HPMK	Wiggy's
1	Very Warm	Cold	Warm	Very Cold	Neutral
2	Warm	Very Warm	Very Warm	Very Cold	Cold
3	Very Warm	Very Warm	Warm	Cold	Very Cold
4	Very Warm	Warm	Warm	Very Cold	Cold
5	Very Warm	Very Warm	Very Warm	Very Cold	Very Warm

DISCUSSION

This was the first study to compare physiological and subjective responses of subjects to five hypothermia enclosure systems in which four systems (MARSARS, Doctor Down, HPMK and Wiggy's with their built-in or separate internal vapor barrier and chemical heat sources) were commercial and one user assembled (3-season sleeping bag with separate internal vapor barrier and gel chemical heat packs) was the Control. This study compared the combined effect of active warming sources (gel chemical heat packs, dry chemical heating blanket, and dry chemical heating pads) which generates heat and applied directly on the subjects and passive insulation which prevents heat loss from the skin to the outside cold environment. These systems also included vapor barrier (separate internal or built-in internal) which prevents evaporative heat loss. Evaporative heat loss occurs with sweating or with wet clothing. This study, however, did not include any wet clothing. One subject in this study reported sweating in one of the trials with the Control system.

Four subjects (1 female) were exposed to -22°C cold environment (cold climatic chamber) and one subject exposed to -20°C on five different occasions, each with one of the hypothermia enclosure systems, for a period of 60 min or until they reached to their T_{es} of 36°C (or a drop of 0.5°C which ever came first).

This study found that all systems provided insulation and heat. However, the Control and Doctor Down systems were most effective compared to other three systems (MARSARS, HPMK, and Wiggy's). The user-assembled (Control system) demonstrated significantly less heat loss (total heat flux and torso heat flux), low metabolic heat production, higher skin temperature (total and torso) and higher net heat gain during 60 min of cold exposure. The subjects in the Control system

felt very warm, with no shivering and less cold discomfort. The Control system was the preferred HES amongst the other systems. The Doctor Down system demonstrated similar results with significantly less heat loss (total), low metabolic heat production, higher skin temperature(total) and higher net heat gain during 60 min of cold exposure. Total heat loss was significantly higher with the HPMK (136.3 ± 51.8 W), Wiggy's (130.3 ± 54.3 W) and MARSARS (133.9 ± 50.3 W) systems compared to the Control (51.8 ± 26.8W) and Doctor Down (54.4 ± 14.5 W) systems ($p<0.05$) during 60 min of cold exposure. Net heat gain was higher with the Control (14.5 ± 10.2 W) and Doctor Down (9.3 ± 12.5 W) systems compared to the Wiggy's (-57.6 ± 55.3 W), and MARSARS (-58.5 ± 38.4 W) systems ($p<0.05$) during 60 min of cold exposure. The Doctor Down system showed significantly higher heat loss from torso compared to the Control system (during 0-30 min of the cold exposure) and the HPMK systems (0-45 min of the cold exposure). This Doctor Down system also showed significantly higher torso skin temperature during first 15 min of the cold exposure than the Wiggy's system. The overall response of the subjects for the Doctor Down system was preferred and warm system with no shivering and less cold discomfort.

We hypothesized that the MARSARS system would result in greater net heat gain, less heat loss, and higher core temperature because of its high insulation thickness and the heating pads covered more high heat transfer areas (chest, both axilla and upper back). However, our results did not support this hypothesis. The MARSARS system showed lower net heat gain, higher heat loss compared to the Control and the Doctor Down systems, although subjects felt warm in this system and this system was the preferred HES, with no shivering and less cold discomfort. The MARSARS system also showed higher face heat loss and lower face skin temperature compared to the Control and the Doctor Down systems. Three subjects felt that the MARSARS system was very tight. One subject terminated the experiment at 44.5 min with the MARSARS system because

of claustrophobia. We also hypothesized that the HPMK system would be least effective. Our study supports this hypothesis as the HPMK and the Wiggy's systems demonstrated significantly higher heat loss (total heat flux), lower skin temperature (total) and lower net heat gain. The HPMK system, however, showed significantly lower torso heat loss than the Doctor Down and the Wiggy,s systems during 0-45 min of the cold exposure. The HPMK system also showed higher metabolic heat production than the Control and the Doctor Down systems during 30-60 min. The subjects felt very cold in the HPMK system with low shivering. The HPMK system was the least preferred system. The Wiggy's system, however, showed higher heat loss from the torso and lower torso skin temperature compared to the Control and the HPMK systems. The overall subjective response for the Wiggy's system was low shivering and neutral for cold rating and preference for the systems.

RELATION TO PREVIOUS LITERATURE

This study compared five hypothermia enclosure systems which include vapor barrier to prevent evaporative heat loss, active warming sources to actively warm the subjects, and insulation shell to prevent heat loss from the body.

Several studies indicated that evaporative heat loss would be reduced by either removing wet clothes or by adding vapor barrier in cold austere environment [21, 30]. Though this study did not include any wet clothing, however, it is expected that vapor barrier with these systems would reduce evaporative heat loss in wet condition. Thomassen et al compared three different insulation systems (bubble wrap, ambulance blanket and Hibler's method– a combination of a tight layer of vapor barrier and dry insulating layer). The subjects participated in this study dressed in moistened clothes and then walked into a cold climatic chamber at 5°C and 3m/s and wrapped in one of the

insulation systems. This study indicated that Hibler's method was an effective method to prevent heat loss and a combination of vapor barrier and dry insulating layer would be an effective method to insulate the patients in a cold environment [24].

Several studies reported the effectiveness of various insulation systems including rescue bags, blankets with a number of layers/thickness, bubble wrap, mountain casualty bags, military survival bags [23-25, 90, 91]. The data from these studies supported the result of our study that the thicker the insulation, the greater the effect of the insulation system to prevent heat loss (the Doctor Down system in our study). Press et al compared six passive insulation methods using thermal manikin. Passive insulations were Wiggy's bag, a vacuum mattress/Pertex fibrepile blanket system, mountain equipment casualty bag, blizzard bag, a light weight foil bag and an orange plastic survival bag. The author concluded that the vacuum mattress/Pertex/fibrepile blanket system, either alone or in combination with the Wiggy's bag was the most effective in comparison to other passive insulations. The water temperature of thermal manikin in the combined system of vacuum mattress/Pertex/fibrepile blanket system and the Wiggy's bag decreased by 3.2°C over 130 min which was the lowest decline in the water temperature compared to the Control, the Wiggy's bag alone, mountain casualty bag, blizzard bag and plastic orange survival bag . This study also indicated that the higher thickness increases the insulation value of the system [90].

Several studies were performed to compare different active warming devices as these active warming devices decrease the cold stress and effective in rewarming hypothermic patients [13, 17]. Lundgren et al compared the four active torso warming devices using severe hypothermic human model. This study compared spontaneous rewarming, a charcoal heater, two hot water bags and two chemical heating pads. The study found that hot water bags (1.6°C) and chemical heating

pads (1.5°C) reduced the post-cooling afterdrop. The rate of rewarming was higher for the hot water bags (0.7°C /h) and the charcoal heater (0.6°C /h) [35]. Watts et al compared six groups using trauma patients during prehospital transport. The six groups were: 1) no intervention 2) cotton sheet or blanket 3) reflective blanket with cotton blanket 4) hot pack with cotton blanket 5) warm IV fluid with cotton blanket and 6) warm IV with reflective blanket and cotton blanket. This study indicated that hot pack with cotton blanket increased the mean core temeprature (+ 1.36°F) during transport compared to other groups [decrease in core temperature (-0.34 to -0.61°F)] [92]. Our study indicated that higher heat gain from torso in the Control and HPMK systems compared to the Doctor Down and the Wiggy's systems which is consistant with the previous studies which indicated that external heat application to the upper torso – axilla, chest and upper back (high heat transfer areas) was more effective [15, 93].

Our study compared the combined effect of active and passive devices. Allen et al compared active and passive hypothermia prevention devices and with a control group using 5 l dialysate fluid bag as a model, which was wrapped in different hypothermia prevention devices and placed in an ambient temperature. This study indicated that the combination of active and passive hypothermia prevention devices (HPMK) was most effective and maintained highest core temperature compared to all other methods. However, other active devices and some passive devices (Hot Pocket and Blizzard) performed similarly at 120 min exposure [75]. This study was performed at room temperature and does not represent the prehospital cold environment. Lungren et al failed to find out the advantage of combined effect of active and passive warming devices over passive warming only [72].

It is difficult to compare our study with the data from previous insulation studies because they have either compared different passive insulation only or compared active warming devices with passive warming devices. However, our study compared the five systems consisting insulation, vapor barrier and heat sources.

POSSIBLE MECHANISMS FOR THE RESULTS

There were no significant differences in all the hypothermia enclosure systems for core temprature (T_{co}). The thermo regulatory centre maintains T_{co} either by increasing the heat production and/or reducing the heat loss. The core temprature (T_{co}) in all the systems in our study was maintained during the cold exposure by a compensatory increase in the metabolic heat production. This can be supported by the results from total skin temperature and metabolic heat production. The results show the lower total skin temperature of subjects in the HPMK system with higher metabolic heat production and higher total skin temperature in the Control and the Doctor Down systems with lower metabolic heat production.

The effectiveness of the systems is affected by two properties of the systems: 1) insulation to decrease heat loss, 2) external heat to increase the heat gain by the body. The Control and the Doctor Down systems were the most effective compared to other three systems. This can be explained by the thickness of these bags and areas covered by the gel chemical heat packs. The Control bag has a moderate thickness and gel chemical heat packs cover all the high heat transfer areas (chest, axilla, and upper back). These two properties explain the reason behind the effectiveness of this system comparison to the HPMK and the Wiggy's systems. The control system showed higher net heat gain, low metabolic heat production, and less heat loss. The subjects reported less cold discomfort, very warm system and with no shivering in this system.

Although the MARSARS system provided insulation and heat, it was not more effective than the Control and the Doctor Down systems, though it contains the same properties- high thickness and gel chemical heat packs cover all high heat transfer areas (chest, axilla, and upper back). This system was uncomfortable and the three subjects complained about tightness of the bag. One subject terminated the trial with the MARSARS system because of claustrophobia. Because of the tightness of this bag, insulation was compressed which led to higher total heat loss compared to the Control and the Doctor Down systems. The average total heat loss in the MARSARS system for three subjects, who complained about the tightness of the bag, was 133.2 ± 9.5 W, 158.8 ± 16.9 W and 198.4 ± 12.4 W compared to other two subjects (62.8 ± 10.0 W and 117.0 ± 16.1 W). The subjects in this system also reported having a cold face. The head in the MARSARS system was not closely fitted and could have a large volume of cold air. The face skin temperature in the MARSARS system was significantly lower compared to the Control and the Doctor Down systems. The MARSARS system also showed higher face heat flux compared to the Control and the Doctor Down systems.

The Doctor Down bag has a higher thickness and gel chemical heat packs cover the chest and the abdomen. The higher insulation property explains the effectiveness of this system compared to the HPMK and the Wiggy's systems. The Doctor Down system showed lower total heat loss, higher net heat gain, higher total skin temperature, and lower metabolic heat production because of high thickness compared to other systems. However, the torso heat flux was higher in this system compared to the Control and the HPMK systems which can be explained by the fewer areas covered by the gel chemical heat sources in the Doctor Down system compared to the Control and the HPMK systems. The subjects also felt warm in this system.

The Wiggy's bag has a moderate thickness and two dry chemical heating pads cover chest and abdomen areas. This system showed low (torso and total) skin temperature, high (torso and total) heat flux. There were no significant differences in the Doctor Down and the Wiggy's systems for torso heat flux which can be explained by the fewer areas covered by the chemical heat sources. The net heat gain was lower in the Wiggy's system compared to the Doctor Down and the Control systems.

The HPMK has a very low thickness and dry chemical heating blanket covers chest, axilla, and abdomen. The HPMK and the Wiggy's systems also provided the insulation and heat. However, these systems were least effective compared to the Control, the Doctor Down, and the MARSARS systems. The higher total heat flux, higher net heat loss, higher metabolic heat production and lower total skin temperature in the HPMK system explain its relative ineffectiveness in a cold environment compared the Control and the Doctor Down systems. However, the torso skin temperature in this system was comparable to the Control system and was significantly higher than Wiggy's system. Similarly, torso heat flux was significantly lower in this system than the Doctor Down and the Wiggy's system. This can be explained by the areas covered by the dry chemical heating blanket which were more than the Doctor Down and the Wiggy's systems.

PRACTICAL IMPLICATIONS

The pre-hospital management of the cold exposed patients are to insulate the patients from the ground, remove wet clothing if possible, and use a vapor barrier to prevent evaporative heat loss and provide waterproof and the windproof insulation to prevent convective heat loss and active warming if needed.

According to this study on the coldly exposed subjects, all systems would provide insulation and heat. However, the Control, and the Doctor Down systems would be most effective systems to prevent heat loss in a cold environment. An additional heat gain through active warming from the gel chemical heat packs in both the systems might be of considerable clinical importance in scenarios with impaired shivering responses. Though this study was performed on young healthy individuals, however, benefits of these systems can be extrapolated to the mild or severe hypothermic patients. The low weight (2.3 kg) and low cost of the 3-season sleeping bag (Control) is an additional advantage of this system over the Doctor Down system. The low cold discomfort and no shivering in this system will be beneficial to decrease cardiac work, to increase physical and psychological comfort during pre-hospital care.

The HPMK system showed higher total body heat loss and higher net heat loss compared to the Control and Doctor Down systems. However, advantages of the HPMK system over other systems are low weight (1.58 kg) and low cost. The HPMK is waterproof and windproof. Therefore, the HPMK system could be used during transportation in prehospital evacuation in cold, windy and rainy conditons.

LIMITATIONS

Because of some technical problems, the climatic chamber failed to work in the two trials at the 30^{th} min (the chamber restarted at 40^{th} min) and at 35^{th} min (did not restart) of the cold exposure. Data for these trials were either interpolated or extrapolated based on the trend of values before and after the failure.

Our study did not include wet or windy conditions. Studies showed a reduction of insulation value if the patient is wet (cold water immersion) or insulations are exposed to rain

water. Wind also decreases the thermal resistance of insulation. The wet and windy condition may have influenced our results.

DELIMITATIONS

This study was limited to:

1) Young, healthy and normothermic population.
2) Sample size - five subjects (four male and one female).
3) -22°C temperature and dry condition inside of the cold climatic chamber.

CONCLUSION

The results of the present study indicate that all systems provide insulation and heat, however, the Control and the Doctor Down systems were most effective compared to other three systems (the MARSARS, the HPMK, and the Wiggy's). The high thickness and heat applied to all the areas of high surface heat transfer (chest, axilla, and upper back) would be important properties of these two systems (the Control and the Doctor Down). These two systems might be of great importance in prehospital rescue scenarios in cold austere environment. We recommend that user-assembled (Control) and the Doctor Down systems could be used for patients exposed to cold during the prehospital evacuation. Though this study was performed on young healthy normothermic individuals, the results could be extrapolated to hypothermic patients. The advantages of the 3-season sleeping bag over the Doctor Down bag are low weight and low cost which could be a reason to choose the Control system during search and rescue operations by rescue teams.

REFERENCES:

1. Gasparrini, A., et al., Mortality risk attributable to high and low ambient temperature: a multicountry observational study. The Lancet, 2015. 386(9991): p. 369-375.
2. Mercer, J.B., Cold—an underrated risk factor for health. Environmental Research, 2003. 92(1): p. 8-13.
3. Näyhä, S., Environmental temperature and mortality. International Journal of Circumpolar Health, 2005. 64(5).
4. Mäkinen, T.M. and J. Hassi, Health problems in cold work. Industrial health, 2009. 47(3): p. 207-220.
5. JURKOVICH, G.J., et al., Hypothermia in trauma victims: an ominous predictor of survival. Journal of Trauma and Acute Care Surgery, 1987. 27(9): p. 1019-1024.
6. LUNA, G.K., et al., Incidence and effect of hypothermia in seriously injured patients. Journal of Trauma and Acute Care Surgery, 1987. 27(9): p. 1014-1018.
7. Husum, H., et al., Preventing post-injury hypothermia during prolonged prehospital evacuation. Prehospital and disaster medicine, 2002. 17(01): p. 23-26.
8. Aléx, J., S. Karlsson, and B.-I. Saveman, Patients' experiences of cold exposure during ambulance care. Scand J Trauma Resusc Emerg Med, 2013. 21(1): p. 44.
9. Kempainen, R.R. and D.D. Brunette, The evaluation and management of accidental hypothermia. Respiratory Care, 2004. 49(2): p. 192-205.
10. Kurz, A., Physiology of thermoregulation. Best Practice & Research Clinical Anaesthesiology, 2008. 22(4): p. 627-644.
11. Boulant, J.A. Hypothalamic mechanisms in thermoregulation. in Federation proceedings. 1981.

12. Stocks, J.M., et al., Human physiological responses to cold exposure. Aviation, space, and environmental medicine, 2004. 75(5): p. 444-457.
13. Giesbrecht, G.G., Cold stress, near drowning and accidental hypothermia: a review. Aviation, space, and environmental medicine, 2000. 71(7): p. 733-752.
14. Faulkner, J.A., E. Zerba, and S.V. Brooks, Muscle temperature of mammals: cooling impairs most functional properties. American Journal of Physiology-Regulatory, Integrative and Comparative Physiology, 1990. 259(2): p. R259-R265.
15. Zafren, K., et al., Wilderness Medical Society practice guidelines for the out-of-hospital evaluation and treatment of accidental hypothermia. Wilderness & environmental medicine, 2014. 25(4): p. 425-445.
16. Auerbach, P.S., Field guide to wilderness medicine. 2013: Elsevier Health Sciences.
17. Mills, W., Field care of the hypothermic patient. International journal of sports medicine, 1992. 13: p. S199-202.
18. Lundgren, P., et al., Insulated spine boards for prehospital trauma care in a cold environment. International Journal of Disaster Medicine, 2004. 2(1-2): p. 33-37.
19. Vanggaard, L., Physiological reactions to wet-cold. Aviation, space, and environmental medicine, 1975. 46(1): p. 33-36.
20. Pugh, L., Cold stress and muscular exercise, with special reference to accidental hypothermia. British medical journal, 1967. 2(5548): p. 333.
21. Henriksson, O., et al., Protection against cold in prehospital care: wet clothing removal or addition of a vapor barrier. Wilderness & environmental medicine, 2015. 26(1): p. 11-20.
22. Giesbrecht, G.G., et al., Effectiveness of three field treatments for induced mild (33.0 degrees C) hypothermia. Journal of Applied Physiology, 1987. 63(6): p. 2375-2379.

23. Henriksson, O., et al., Protection against cold in prehospital care—thermal insulation properties of blankets and rescue bags in different wind conditions. Prehospital and disaster medicine, 2009. 24(05): p. 408-415.
24. Thomassen, O., et al., Comparison of three different prehospital wrapping methods for preventing hypothermia-a crossover study in humans. Scand J Trauma Resusc Emerg Med, 2011. 19(41): p. 1-7.
25. Grant, S.J., et al., A comparison of mountain rescue casualty bags in a cold, windy environment. Wilderness & environmental medicine, 2002. 13(1): p. 36-44.
26. Chadwick, S. and A. Gibson, Hypothermia and the use of space blankets: a literature review. Accident and emergency nursing, 1997. 5(3): p. 122-125.
27. Giesbrecht, G.G. and J.A. Wilkerson, Hypothermia, Frostbite and Other Cold Injuries: Prevention, Survival, Rescue, and Treatment. 2006: The Mountaineers Books.
28. Petrone, P., E. Kuncir, and J.A. Asensio, Surgical management and strategies in the treatment of hypothermia and cold injury. Emergency Medicine Clinics, 2003. 21(4): p. 1165-1178.
29. Petrone, P., J.A. Asensio, and C.P. Marini, Management of accidental hypothermia and cold injury. Current problems in surgery, 2014. 51(10): p. 417-431.
30. Henriksson, O., et al., Protection against cold in prehospital care: evaporative heat loss reduction by wet clothing removal or the addition of a vapor barrier—a thermal manikin study. Prehospital and disaster medicine, 2012. 27(01): p. 53-58.
31. Plowman, S.A. and D.L. Smith, Exercise physiology for health fitness and performance. 2013: Lippincott Williams & Wilkins.

32. McArdle, W.D., F.I. Katch, and V.L. Katch, Exercise physiology: nutrition, energy, and human performance. 2010: Lippincott Williams & Wilkins.

33. Kang, J., Nutrition and metabolism in sports, exercise and health. 2013: Routledge.

34. Gleeson, M., Temperature regulation during exercise. International Journal of Sports Medicine, 1998. 19: p. S96-9.

35. Bristow, G., et al., FIELD TORSO-WARMING MODALITIES. PREHOSPITAL EMERGENCY CARE, 2009. 13(3): p. 371-378.

36. Giesbrecht, G., M. Schroeder, and G.K. Bristow, Treatment of mild immersion hypothermia by forced-air warming. Aviation, space, and environmental medicine, 1994. 65(9): p. 803-808.

37. Steele, M.T., et al., Forced air speeds rewarming in accidental hypothermia. Annals of emergency medicine, 1996. 27(4): p. 479-484.

38. Casa, D.J., et al., Cold water immersion: the gold standard for exertional heatstroke treatment. Exercise and sport sciences reviews, 2007. 35(3): p. 141-149.

39. Havenith, G., Heat balance when wearing protective clothing. Annals of Occupational Hygiene, 1999. 43(5): p. 289-296.

40. Nadel, E., Energy exchanges in water. Undersea biomedical research, 1984. 11(2): p. 149-158.

41. Hamilton, R.S. and B.C. Paton, The diagnosis and treatment of hypothermia by mountain rescue teams: a survey. Wilderness & Environmental Medicine, 1996. 7(1): p. 28-37.

42. Hayward, J., The physiology of immersion hypothermia. The nature and treatment of hypothermia, 1986: p. 3-19.

43. Hayes, P., P. Sowood, and R. Cracknell, Reactions to cold water immersion with and without waves. Farnborough, UK: RAF Institute of Aviation Medicine, 1985.

44. Giesbrecht, G. and A.M. Steinman, Immersion in cold water. Wilderness medicine. Edited by PS Auerbach. Mosby, Philadelphia, Pa, 2007: p. 160-188.

45. Brandt, S., J. Mühlsteff, and M. Imhoff, Diagnosis, prevention and treatment of accidental and perioperative hypothermia. Biomedizinische Technik/Biomedical Engineering, 2012. 57(5): p. 307-322.

46. Corneli, H.M., Accidental hypothermia. Pediatric emergency care, 2012. 28(5): p. 475-480.

47. Keatinge, W., The effects of subcutaneous fat and of previous exposure to cold on the body temperature, peripheral blood flow and metabolic rate of men in cold water. The Journal of physiology, 1960. 153(1): p. 166.

48. LeBlanc, J., Subcutaneous fat and skin temperature. Canadian journal of biochemistry and physiology, 1954. 32(4): p. 354-358.

49. Doubt, T.J., Physiology of exercise in the cold. Sports Medicine, 1991. 11(6): p. 367-381.

50. Pretorius, T., et al., Shivering heat production and core cooling during head-in and head-out immersion in 17 C water. Aviation, space, and environmental medicine, 2008. 79(5): p. 495-499.

51. Bristow, G.K. and G. Giesbrecht, Contribution of exercise and shivering to recovery from induced hypothermia (31.2 degrees C) in one subject. Aviation, space, and environmental medicine, 1988. 59(6): p. 549-552.

52. Steinman, A.M., et al., Immersion hypothermia: comparative protection of anti-exposure garments in calm versus rough seas. Aviation, space, and environmental medicine, 1987. 58(6): p. 550-558.

53. Fox, G., J. Hayward, and G. Hobson, Effect of alcohol on thermal balance of man in cold water. Canadian journal of physiology and pharmacology, 1979. 57(8): p. 860-865.

54. Johnston, C.E., et al., Alcohol lowers the vasoconstriction threshold in humans without affecting core cooling rate during mild cold exposure. European journal of applied physiology and occupational physiology, 1996. 74(3): p. 293-295.

55. Martin, S. and K. Cooper, Alcohol and respiratory and body temperature changes during tepid water immersion. Journal of Applied Physiology, 1978. 44(5): p. 683-689.

56. Mekjavic, I.B., C.J. Sundberg, and D. Linnarsson, Core temperature" null zone". Journal of Applied Physiology, 1991. 71(4): p. 1289-1295.

57. Webb, P., The physiology of heat regulation. American Journal of Physiology-Regulatory, Integrative and Comparative Physiology, 1995. 268(4): p. R838-R850.

58. Sessler, D.I., Temperature monitoring and perioperative thermoregulation. The Journal of the American Society of Anesthesiologists, 2008. 109(2): p. 318-338.

59. Xu, X., et al., Thermoregulatory model for prediction of long-term cold exposure. Computers in biology and medicine, 2005. 35(4): p. 287-298.

60. Giesbrecht, G.G., Human thermoregulatory inhibition by regional anesthesia. Anesthesiology, 1994. 81(2): p. 277.

61. Mekjavic, I.B. and O. Eiken, Contribution of thermal and nonthermal factors to the regulation of body temperature in humans. Journal of Applied Physiology, 2006. 100(6): p. 2065-2072.

62. Neil, H., J. Dawson, and J. Baker, Risk of hypothermia in elderly patients with diabetes. Br Med J (Clin Res Ed), 1986. 293(6544): p. 416-418.

63. Henriksson, O., Protection against cold in prehospital trauma care. 2012.

64. DuCharme, M., A. Steinman, and G. Giesbrecht, Pre-hospital management of immersion hypothermia, in Drowning. 2014, Springer. p. 875-880.

65. Golden FS, Hervey GR, and T. MJ, Circum-rescue collapse: collapse, sometimes fatal, associated with rescue of immersion victims. JR Nav Med Serv, 1991. 77: p. 139-149.

66. Hoek, T.L.V., et al., Part 12: cardiac arrest in special situations 2010 American Heart Association Guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. Circulation, 2010. 122(18 suppl 3): p. S829-S861.

67. Giesbrecht, G.G., Prehospital treatment of hypothermia. Wilderness & environmental medicine, 2001. 12(1): p. 24-31.

68. Holmér, I., Protection against cold. Textiles in sport, 2005: p. 262-286.

69. Havenith, G. and H.O. Nilsson, Correction of clothing insulation for movement and wind effects, a meta-analysis. European journal of applied physiology, 2004. 92(6): p. 636-640.

70. Havenith, G., et al., Apparent latent heat of evaporation from clothing: attenuation and "heat pipe" effects. Journal of Applied Physiology, 2008. 104(1): p. 142-149.

71. Sookram, S.M., et al., Can body temperature be maintained during aeromedical transport? CJEM, 2002. 4(03): p. 172-177.

72. Lundgren, P., et al., The effect of active warming in prehospital trauma care during road and air ambulance transportation-a clinical randomized trial. Scand J Trauma Resusc Emerg Med, 2011. 19: p. 59.

73. Greif, R., et al., Resistive heating is more effective than metallic-foil insulation in an experimental model of accidental hypothermia: a randomized controlled trial. Annals of emergency medicine, 2000. 35(4): p. 337-345.

74. Oliver, S.J., et al., Portable prehospital methods to treat near-hypothermic shivering cold casualties. Wilderness & environmental medicine, 2016. 27(1): p. 125-130.

75. Allen, P.B., et al., Preventing hypothermia: comparison of current devices used by the US Army in an in vitro warmed fluid model. Journal of Trauma and Acute Care Surgery, 2010. 69(1): p. S154-S161.

76. Auerbach, P.S., Wilderness Medicine: Expert Consult Premium Edition-Enhanced Online Features. 2011: Elsevier Health Sciences.

77. Jussila, K., et al., Evaluating cold, wind, and moisture protection of different coverings for prehospital maritime transportation--a thermal manikin and human study. Prehospital and disaster medicine, 2014. 29(6): p. 580-588.

78. Schmelz, J.O., et al., Comparison of three strategies for preventing hypothermia in critically injured casualties during aeromedical evacuation. Military medicine, 2007. 172(3): p. 322-326.

79. Hassard, T.H., Understanding biostatistics. 1991: Mosby year book.

80. Sessler, D.I. and M. Schroeder, Heat loss in humans covered with cotton hospital blankets. Anesthesia & Analgesia, 1993. 77(1): p. 73-77.

81. Du Bois, D. and E. Du Bois, A formula to estimate the approximate surface area if height and weight be known. 1916. Nutrition (Burbank, Los Angeles County, Calif.), 1989. 5(5): p. 303.

82. Durnin, J. and J. Womersley, Body fat assessed from total body density and its estimation from skinfold thickness: measurements on 481 men and women aged from 16 to 72 years. British journal of nutrition, 1974. 32(01): p. 77-97.

83. Cooper, K. and J. Kenyon, A comparison of temperatures measured in the rectum, oesophagus, and on the surface of the aorta during hypothermia in man. British Journal of Surgery, 1957. 44(188): p. 616-619.

84. Hayward, J., J. Eckerson, and D. Kemna, Thermal and cardiovascular changes during three methods of resuscitation from mild hypothermia. Resuscitation, 1984. 11(1): p. 21-33.

85. Layton, R., et al., Calorimetry with heat flux transducers: comparison with a suit calorimeter. Journal of Applied Physiology, 1983. 54(5): p. 1361-1367.

86. Vanggaard, L., et al., Immersion of distal arms and legs in warm water (AVA rewarming) effectively rewarms mildly hypothermic humans. Aviation Space and Environmental Medicine, 1999. 70: p. 1081-1088.

87. Matthews, D.K. and E. Fox, The physiological basis of physical education and athletics. WB Saunders, Philadelphia, 1976.

88. Fanger, P.O., Thermal comfort. Analysis and applications in environmental engineering. Thermal comfort. Analysis and applications in environmental engineering., 1970.

89. Lundgren, P., et al., Validity and reliability of the Cold Discomfort Scale: a subjective judgement scale for the assessment of patient thermal state in a cold environment. Journal of clinical monitoring and computing, 2014. 28(3): p. 287-291.

90. Press, C., et al., Measurements of rates of cooling of a manikin insulated with different mountain rescue casualty bags. Extreme physiology & medicine, 2017. 6(1): p. 1.

91. Zasa, M., et al., A torso model comparison of temperature preservation devices for use in the prehospital environment. Emerg Med J, 2016. 33(6): p. 418-422.

92. Watts, D.D., et al., The utility of traditional prehospital interventions in maintaining thermostasis. Prehospital Emergency Care, 1999. 3(2): p. 115-122.

93. Hayward, J., M. Collis, and J. Eckerson, Thermographic evaluation of relative heat loss areas of man during cold water immersion. Aerospace medicine, 1973. 44(7): p. 708.

APPENDIX A

UNIVERSITY OF MANITOBA

Research Ethics and Compliance
Office of the Vice-President (Research and International)

Human Ethics
208-194 Dafoe Road
Winnipeg, MB
Canada R3T 2N2
Phone +204-474-7122
Fax +204-269-7173

APPROVAL CERTIFICATE

April 25, 2016

TO: **Gordon Giesbrecht**
Principal Investigator [redacted]

FROM: **Zana Lutfiyya, Chair**
Education/Nursing Research Ethics Board (ENREB)

Re: **Protocol #E2016:037 (HS19549)**
"A comparison of five hypothermic enclosure system in cold environment"

Please be advised that your above-referenced protocol has received human ethics approval by the **Education/Nursing Research Ethics Board**, which is organized and operates according to the Tri-Council Policy Statement (2). **This approval is valid for one year only and will expire on April 25, 2017.**

Any significant changes of the protocol and/or informed consent form should be reported to the Human Ethics Secretariat in advance of implementation of such changes.

Please note:

- **If you have funds pending human ethics approval, please mail/e-mail/fax (261-0325) a copy of this Approval (identifying the related UM Project Number) to the Research Grants Officer in ORS in order to initiate fund setup. (How to find your UM Project Number: http://umanitoba.ca/research/ors/mrt-faq.html#pr0)**

- **if you have received multi-year funding for this research, responsibility lies with you to apply for and obtain Renewal Approval at the expiry of the initial one-year approval; otherwise the account will be locked.**

The Research Quality Management Office may request to review research documentation from this project to demonstrate compliance with this approved protocol and the University of Manitoba *Ethics of Research Involving Humans*.

The Research Ethics Board requests a final report for your study (available at: http://umanitoba.ca/research/orec/ethics/human_ethics_REB_forms_guidelines.html) **in order to be in compliance with Tri-Council Guidelines.**

UNIVERSITY OF MANITOBA Research Ethics and Compliance

Human Ethics
208-194 Dafoe Road
Winnipeg, MB
Canada R3T 2N2
Phone +204-474-7122
Email: humanethics@umanitoba.ca

RENEWAL APPROVAL

Date: April 18, 2017 **New Expiry:** April 25, 2018

TO: **Gordon Giesbrecht**
Principal Investigator

FROM: **Zana Lutfiyya, Chair** [redacted]
Education/Nursing Research Ethics Board (ENREB)

Re: **Protocol #E2016:037 (HS19549)**
"A Comparison of Five Hypothermic Enclosure System in Cold Environment"

Education/Nursing Research Ethics Board (ENREB) has reviewed and renewed the above research. ENREB is constituted and operates in accordance with the current *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.*

This approval is subject to the following conditions:

1. Any modification to the research must be submitted to ENREB for approval before implementation.
2. Any deviations to the research or adverse events must be submitted to ENREB as soon as possible.
3. This renewal is valid for one year only and a Renewal Request must be submitted and approved by the above expiry date.
4. A Study Closure form must be submitted to ENREB when the research is complete or terminated.

Funded Protocols:
- **Please mail/e-mail a copy of this Renewal Approval, identifying the related UM Project Number, to the Research Grants Officer in ORS.**

APPENDIX B

Physical Activity Readiness Questionnaire - PAR-Q (revised 2002)

PAR-Q & YOU

(A Questionnaire for People Aged 15 to 69)

Regular physical activity is fun and healthy, and increasingly more people are starting to become more active every day. Being more active is very safe for most people. However, some people should check with their doctor before they start becoming much more physically active.

If you are planning to become much more physically active than you are now, start by answering the seven questions in the box below. If you are between the ages of 15 and 69, the PAR-Q will tell you if you should check with your doctor before you start. If you are over 69 years of age, and you are not used to being very active, check with your doctor.

Common sense is your best guide when you answer these questions. Please read the questions carefully and answer each one honestly: check YES or NO.

YES	NO		
☐	☐	1.	**Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?**
☐	☐	2.	**Do you feel pain in your chest when you do physical activity?**
☐	☐	3.	**In the past month, have you had chest pain when you were not doing physical activity?**
☐	☐	4.	**Do you lose your balance because of dizziness or do you ever lose consciousness?**
☐	☐	5.	**Do you have a bone or joint problem (for example, back, knee or hip) that could be made worse by a change in your physical activity?**
☐	☐	6.	**Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?**
☐	☐	7.	**Do you know of any other reason why you should not do physical activity?**

If you answered

YES to one or more questions

Talk with your doctor by phone or in person BEFORE you start becoming much more physically active or BEFORE you have a fitness appraisal. Tell your doctor about the PAR-Q and which questions you answered YES.

- You may be able to do any activity you want — as long as you start slowly and build up gradually. Or, you may need to restrict your activities to those which are safe for you. Talk with your doctor about the kinds of activities you wish to participate in and follow his/her advice.
- Find out which community programs are safe and helpful for you.

NO to all questions

If you answered NO honestly to all PAR-Q questions, you can be reasonably sure that you can:

- start becoming much more physically active – begin slowly and build up gradually. This is the safest and easiest way to go.
- take part in a fitness appraisal – this is an excellent way to determine your basic fitness so that you can plan the best way for you to live actively. It is also highly recommended that you have your blood pressure evaluated. If your reading is over 144/94, talk with your doctor before you start becoming much more physically active.

DELAY BECOMING MUCH MORE ACTIVE:

- if you are not feeling well because of a temporary illness such as a cold or a fever – wait until you feel better; or
- if you are or may be pregnant – talk to your doctor before you start becoming more active.

PLEASE NOTE: If your health changes so that you then answer YES to any of the above questions, tell your fitness or health professional. Ask whether you should change your physical activity plan.

Informed Use of the PAR-Q: The Canadian Society for Exercise Physiology, Health Canada, and their agents assume no liability for persons who undertake physical activity, and if in doubt after completing this questionnaire, consult your doctor prior to physical activity.

No changes permitted. You are encouraged to photocopy the PAR-Q but only if you use the entire form.

NOTE: If the PAR-Q is being given to a person before he or she participates in a physical activity program or a fitness appraisal, this section may be used for legal or administrative purposes.

"I have read, understood and completed this questionnaire. Any questions I had were answered to my full satisfaction."

NAME _____

SIGNATURE _____ DATE _____

SIGNATURE OF PARENT or GUARDIAN (for participants under the age of majority) _____ WITNESS _____

Note: This physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if your condition changes so that you would answer YES to any of the seven questions.

APPENDIX C

Medical Screening Questionnaire for Hypothermia Enclosure Systems Study

Please circle answer for each question below.

1. Do you have any history of cardiac disease (e.g., heart murmur or palpitations, chest pain on exertion)?

   Yes / No

2. Do you have any history of respiratory disease (e.g., asthma, chronic bronchitis)?

   Yes / No

3. Do you have diabetes or thyroid disease?

   Yes / No

4. Do you have any negative reactions caused by cold exposure (e.g., Raynaud's Phenomenon, hives, rashes, trouble breathing)?

   Yes / No

5. Do you have epilepsy?

   Yes / No

6. Do you have any other neurological diseases such as multiple sclerosis.

   Yes / No

7. Do you have any history of kidney disease?

   Yes / No

8. Do you have any history of liver disease?

   Yes / No

APPENDIX D

UNIVERSITY OF MANITOBA | Faculty of Kinesiology and Recreation Management

102 Frank Kennedy Centre
Winnipeg, Manitoba
Canada R3T 2N2

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: **A Comparison of five different hypothermic enclosure systems in a cold environment.**

Protocol number:	NSERC Discovery Grant (2010-17)
Principal Investigator:	Gordon Giesbrecht
	211 Max Bell Centre, University of Manitoba,
	Winnipeg, MB - R3T 2N2
	Phone: 474-8646
Co-Investigator:	None
Sponsor:	NSERC

350 Albert Street,

Ottawa, ON – K1A 1H5

This consent form, a copy of which will be left with you for your records and reference, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

1. Purpose of the study

The purpose of this study is to compare and determine the effectiveness of five hypothermic enclosure systems in preventing heat loss in cold environment (-20°C).

2. Study procedures

You are being asked to take part in this study because you have fulfilled the criteria of being a healthy adult between the ages of 18-45 years with no adverse responses to cold exposure nor any cardiorespiratory disease. A total of six to eight participants will participate in this study.

The order of experiments will follow a randomized balanced design. The order of the five hypothermic enclosure systems will be randomly assigned to each participant so that all participants have a different order of treatments.

Neither you nor the study staff will be blinded to the treatment groups.

If you take part in this study, you will have the following tests and procedures:

The study will require 5 trials for each participant each lasting approximately 2-3 hours in total. Each session will involve lying still in a room at -20˚C for one hour of cold exposure, each time with one of the following hypothermic enclosure systems:

a) Regular 3-season sleeping bag with chemical heat pac (Control)
b) NAR Hypothermia Prevention and Management Kit (HPMK) and chemical heat pacs
c) MARSARS bag and chemical heat pacs
d) Wiggy's bag and chemical heat pacs
e) Dr. Down bag and chemical heat pacs

Experimental data will be recorded directly to a computer at 30 second intervals.

You will be asked at 10-minute intervals throughout the studies about how cold you feel and if you would like to stop. The cooling portion of the trial will be terminated when one of the following criteria met: a time period of 60 minutes elapses, you wish to stop, the experimenter advises stopping, your core temperature decreases by 0.5˚C or to 36˚C (whichever comes first). A core temperature of below 32˚C is necessary to produce dangerous effects. Following that, you will be actively rewarmed by entering a warm water bath of 40-42˚C.
Participation in the study will be for a period of up to 3-4 months, until you have visited the laboratory 5 times.

3. <u>Research Instrumentation</u>

1. You will be asked to complete a "PAR-Q-Activity questionnaire" and "Medical Screening Questionnaire for Hypothermia Enclosure System Study" prior to participating (both

forms attached). You will not be able to participate if you answer yes to any of the questions in these forms.

2. You will be instructed to abstain from alcohol, medications or vigorous physical activity for a 24 hour period prior to the study.
3. You will be instructed to have a small breakfast and no other food 2-3 hours prior to the beginning of test.
4. Anthropometric data will be collected and recorded including: Age; weight; height; and skin fold thicknesses
5. Core temperature will be measured with a sterile disposable esophageal thermocouple. A thin, flexible tube will be inserted through the nose, to midway down the esophagus at the level of the heart. The esophageal probe will be inserted by Dr. Giesbrecht. You will have your own thermocouple which will not be used by anyone else.
6. Metabolic rate will be continuously monitored; you will be asked to wear a face mask which will collect the expired breath, during the entire experimental period.
7. 10 to 15 heat flux discs (2 cm in diameter) will be taped to my skin to measure heat transfer from or to the skin.
8. Electrocardiogram leads will also be affixed to the skin.

The researcher may decide to take you off this study if you are not able to cope with the cold stress, any of the procedures causes unexpected negative reactions or adverse events, or there are any problems with data acquisition or protocol adherence are detected which nullifies the value of collected data.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to inform the study staff first.

4. Benefits

By participating in this study, you will be providing information to the study investigators that will compare the effectiveness of five hypothermic enclosure systems in cold environment. There may or may not be direct medical benefit to you from participating in this study. We hope the information learned from this study will benefit accidental victims of cold exposure in the future.

5. Risks and Discomforts

While on the study, you are at risk for certain side effects.

1) Cold stress – The study in which you have been asked to participate involves lowering of body core (esophageal) temperature by a maximum of 0.5ºC (to a minimum of 36.0ºC). The cooling stress will be minimal and will pose no risk to you.
2) Core temperature measurement – You will have your own sterilized disposable esophageal thermocouple probe. The insertion of the esophageal probe may invoke some gag reflexes but for our technique has been well tolerated for 26 years. There is a slight risk of minor nose bleed. If it occurs, direct pressure will be applied to the nostrils until bleeding stops. Rarely, it is also possible that the probe could enter the wind pipe (trachea). This will not cause any damage but would be uncomfortable. This can be identified by difficulty in talking. If this occurs the probe will be removed.

6. Anonymity and Confidentiality

Participant's identity will remain confidential and will not be disclosed without their permission. Participants will not be identified in any written reports or publications. Data will be

coded and names will not be revealed at any time. Only group data or coded individual data will be presented or exposed.

Hard copies of forms with personal data will be kept in a locked file cabinet in Dr. Gordon Giesbrecht's Laboratory (Laboratory for Exercise and Environmental Medicine, 211 Max Bell Centre). Any personal information in digital form will be in password protected files. All data that includes subject's identity or personal information will be destroyed (paper copies will be shredded and digital copies will be erased) by June 30th 2021, unless subjects indicate willingness to be contacted for future studies.

Only Dr. Giesbrecht and his graduate students working on the study will have access to the identity of the participants and their data. Study results will not be identified with individual participants and will be kept on file digitally and/or in paper form indefinitely. All graduate students who participate in this research study will sign a "Confidentiality Oath".

7. Honorarium

Subjects will be paid a $50 for each trial as an honorarium for time, effort and discomfort. They will be paid in full for any trial in which they start, whether they complete that trial or not.

Payment will be in the form of a cheque mailed after the last experiment with delay of 3 to 6 weeks.

8. Voluntary Participation/Withdrawal From the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect your other care at this site. If anyone from the investigation team feels that it is in your best interest to withdraw you from the study, they will remove you without your consent.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

9. Feedback/Debriefing.

I would like to receive a summary report of this study once it is completed.

Yes ☐ No ☐

If yes, please provide your e-mail address:_____

10. Dissemination.

Results will be submitted for publication in a scientific journal. No personal or identifying information will be included in any manuscript or presentation without written permission.

11. Future Studies Recruitment.

I am willing to be contacted regarding possible participation in future studies of this type.

Yes ☐ No ☐

If yes, please provide your e-mail address and phone no.

E-mail address: _____

Phone no: _____

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the researchers, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time, and /or refrain from answering any questions you prefer to omit, without prejudice or consequence. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation.

The University of Manitoba may look at your research records to see that the research is being done in a safe and proper way.

This research has been approved by the Education/Nursing Research Ethics Board. If you have any concerns or complaints about this project you may contact any of the above-named persons or the Human Ethics Coordinator at 204-474-7122. A copy of this consent form has been given to you to keep for your records and reference.

Participant signature_____ Date _____

(day/month/year)

Primary Investigator: Dr. Gordon Giesbrecht Date _____

(day/month/year)

Signature: _____

APPENDIX E

Equations for calculating body density given by Durnin and Womersley.

Equations for different age groups in Males:

Age (yrs)	Density, Db (kg/l) = c-m x log sum of four skinfolds
17-19	Db (kg/l) = 1.1620 – 0.0630 x log sum of four skinfolds
20-29	Db (kg/l) = 1.1631 – 0.0632 x log sum of four skinfolds
30-39	Db (kg/l) = 1.1422 – 0.0544 x log sum of four skinfolds
40-49	Db (kg/l) = 1.1620 – 0.0700 x log sum of four skinfolds
50+	Db (kg/l) = 1.1715 – 0.0779 x log sum of four skinfolds
17-72	Db (kg/l) = 1.1765 – 0.0744 x log sum of four skinfolds

Equations for different age groups in Females:

Age (yrs)	Db (kg/l) = c-m x log sum of four skinfolds
16-19	Db (kg/l) = 1.1549 – 0.0678 x log sum of four skinfolds
20-29	Db (kg/l) = 1.1599 – 0.0717 x log sum of four skinfolds
30-39	Db (kg/l) = 1.1423 – 0.0632 x log sum of four skinfolds
40-49	Db (kg/l) = 1.1333 – 0.0612 x log sum of four skinfolds
50+	Db (kg/l) = 1.1339 – 0.0645 x log sum of four skinfolds
16-68	Db (kg/l) = 1.1567 – 0.0717 x log sum of four skinfolds

APPENDIX F

Subjective Response Scales

1) Whole-body cold discomfort

    0. No Sensation of Cold

    1.

    2. Slightly Cold

    3.

    4. Fairly Cold

    5.

    6. Moderately Cold

    7.

    8. Very Cold

    9.

    10. Unbearable

2) The Overall Preference Rating

    1 = Most Preferred

    2 = Preferred

    3 = Neutral

    4 = Less Preferred

    5 = Least Preferred

3) Shivering Rating

1 = No Shivering

2 = Low Shivering

3 = High Shivering

4) Overall Cold Rating

1 = Very Warm

2 = Warm

3 = Neutral

4 = Cold

4 = Very Cold