Hypothermia Rewarming Effectiveness of Distal Limb Warming with Either Fluidotherapy® or Warm Water Immersion

by

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ABSTRACT

Rewarming mildly hypothermic subjects with distal extremity rewarming has been associated with significantly greater rewarming rate compared to shivering-only as it increases heat flow to the core by opening up of arteriovenous anastomoses in the extremities. This study compared distal extremity rewarming with Fluidotherapy® or warm water, or shivering-only. Seven healthy individuals were cooled in 8°C water to either a core temperature of 35°C or a maximum of one hour. The subjects were then rewarmed with one of the three rewarming methods (distal extremity rewarming with 44°C water or 46°C Fluidotherapy® or shivering-only) on three different occasions. There was no significant difference in the afterdrop length and duration between the three conditions. Fluidotherapy® provided rewarming rates similar to the shivering-only condition. Warm water rewarming provided higher heat donation to distal extremities and lead to a threefold higher rewarming rate compared to the other two treatments.

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DEDICATION

This thesis is entirely dedicated to my wife for her constant love and support in every aspect of my life.

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INTRODUCTION

Canada is one of the coldest countries in the world and has very low winter temperatures. It is a challenge for the human body to maintain normal core temperature (T_{co}) in the winter during outside exposure. Heat loss may occur because of chilling weather or accidental cold water immersion. This gives a great challenge to human thermoregulation. At times, the human body is not able to compensate for disproportionate heat loss resulting from extreme cold and/or insufficient heat production in the body. This uncompensated heat loss can lead to hypothermia, the lowering of the T_{co} from approximately 37°C to below 35°C.[1]

In the United States, more than fifteen thousand (estimated) patients were admitted to emergency departments with hypothermia or other cold related conditions between 1995 and 2004.[2] Most of the accidental hypothermia cases occur in winter months.[3, 4] Older individuals,[2, 5] malnourished people,[5] people with thermoregulatory, skin, nervous system or endocrinal disorders,[6] and homeless individuals[4] are more prone to hypothermia. Another high risk group includes hill climbers,[7] sailors, yachtsmen, campers,[3] and other outdoor adventurers. Factors which may contribute to the development of hypothermia include physical exhaustion, insufficient or wet clothing, and no training or experience in dealing with cold weather extremes.[3] Hypothermia can be classified based on T_{co} into three levels: mild hypothermia (35°-32°C), moderate hypothermia (32°-28°C), and severe hypothermia (<28°C).[1]

After being removed from a cold environment, the T_{co} of a hypothermic person may continue to fall further, which is known as afterdrop,[8, 9] and this should be kept in mind

during any hypothermia treatment.[9] Giesbrecht and Bristow mentioned that the hypothermia treatment should provide a rapid and safe rewarming and try to minimize the T_{co} afterdrop. The treatment should also concentrate to keep the cardiovascular system stable and treat any metabolic imbalance.[9] Rewarming can be done either through endogenous heat production (heat produced within the body) or exogenous heat application (heat applied from outside the body).[10] Endogenous heat production includes heat produced through shivering and exercise.[9] Rewarming with shivering heat production in dry conditions is a good rewarming method.[11] Shivering is no longer active in moderate-to-severe hypothermia.[10] In a non-shivering victim some form of exogenous heat must be applied to raise the $T_{co.}$[11] Exogenous heat application can be divided into invasive and non-invasive methods. Invasive methods include warmed intravenous fluid administration, gastric, peritoneal or thoracic lavage or cardiopulmonary bypass.[6, 9] Non-invasive heating modalities provide heat to the body externally or internally and include heating pads,[12] warm water bottles,[13] warm water immersion,[9] body-to-body rewarming,[14] forced air rewarming[15] and inhalation of heated air.[16] Studies on exogenous heating modalities have shown that exogenous heat application increases skin temperature (T_{skin}) and reduces shivering heat production. Exogenous heat application thus provides overall similar rewarming rate, utilizes less energy, requires less cardiac work and is associated with feeling of comfort.[9, 12, 14, 15, 17]

Normally warm water immersion is not used as a rewarming method because warm water immersion causes peripheral vasodilation,[9, 18] which decreases the blood pressure, and can further lead to cardiovascular collapse of the patient.[19] However, Vanggaard and Gjerloff proposed that if the warm water (45°C) is applied only to the distal arms and

legs and hands and feet, it opens the arteriovenous anastomosis (AVA) of the hands and feet and causes only local vasodilation without any significant blood pressure change,[20] Warm water which has high thermal conductivity,[21] efficiently provides heat to the distal extremities, and rewarms the local blood which returns to the heart via venous circulation. This warmed blood returning to the heart increases heat content of the body's core.[20] Daanen and Linde did a similar study and rewarmed hypothermic subjects by hands and feet immersion in 42°C water and found it to be less effective than whole body immersion.[22] Cahill et al. rewarmed both the hands and forearms of hypothermic subjects in 42°C water and also concluded it to be less effective than whole body immersion.[23] But neither of these two studies[22, 23] immersed all the recommended body surface area (both arms and legs) nor did they use the recommended temperature of water (45°C). Vanggaard et al. rewarmed mild hypothermic subjects by immersing all four distal extremities in 45°C water and found very good results. The rewarming rate for distal extremities immersion in 45°C and 42°C water were significantly greater (9.9 and 6.1°C/hour respectively) compared to the shivering protocol (3.4°C/hour).[24] This AVA rewarming method is associated with water spillage and requires specialized equipment to maintain water at the desired level and temperature.

Another potential way to apply heat to extremities is through Fluidotherapy®, which is a convection-based heating modality used in rehabilitation departments. The Fluidotherapy® chamber has minute cellulose particles with low thermal conductance, which are heated as hot air is blown from the bottom of the chamber. There are portals in the equipment for introducing distal arms or legs into the heating chamber, and once the desired extremity is inserted into the chamber, these portals are sealed with the attached

sleeves to prevent cellulose particles from coming out of the chamber.[25] When the pressure of air blowing from the bottom of the chamber in upward direction equals the weight of cellulose particles in the chamber, the cellulose particles spread out.[26] These cellulose particles are referred as a Fluidized bed and this process is called Fluidization.[25, 26] This Fluidized bed has heat transfer characteristics similar to a low viscosity fluid and allows body parts to be submerged.[25] This high velocity cellulose particle arrangement evenly distributes the temperature inside the chamber and gives Fluidotherapy® a very good thermal conductance.[26] Fluidotherapy® causes no thermal irritation even at high temperatures because the heat provided is dry.[25]

Higher treatment temperatures can be tolerated with Fluidotherapy® compared with warm water or a paraffin wax bath.[25, 27] Repeated bombardment of the cellulose particles on the skin causes repeated stimulation of the thermoreceptors and mechanoreceptors in the skin. This overstimulation of the thermoreceptors and mechanoreceptors decreases the pain sensitivity and this process is called counter irritation. This decreased pain sensitivity aids in higher temperature tolerance by decreasing painful heat sensations.[25] The temperature of Fluidotherapy® application in rehabilitation settings varies from 43°C to 50°C based on the body part to be treated.[25] Fluidotherapy® is very easy to apply and body parts can be moved during the treatment.[28]

Borrell et al. compared Fluidotherapy® with warm water and paraffin wax bath (applied at different temperatures) and found that low thermal conductance of cellulose allows high temperature tolerance, and this overall combination allows Fluidotherapy® to provide three times greater heat transfer than Paraffin wax bath and warm water application.[26] In another similar study on heat absorption by hands and feet of

normothermic subjects, Borrell et al. concluded that the amount of heat absorbed from Fluidotherapy® (47.8°C) was more than that from warm water application (40°C) and paraffin wax bath application.[27] In the same study, Fluidotherapy® provided a maximum rise in tissue temperature at the levels of thumb joint capsule and inside the flexor hallucis brevis muscle (9.0°C and 5.3°C respectively) compared to hydrotherapy (6.0°C and 4.3°C respectively) and paraffin wax bath (7.5°C and 4.5°C respectively). Fluidotherapy® was also found to be very comfortable to the subjects.[27] Given the high heat transfer of Fluidotherapy®, this method might be beneficial for the treatment of hypothermic victims.

As already mentioned, rewarming distal extremities using warm water immersion at 45°C has been proved to be a very effective rewarming method for hypothermic patients,[24] but has sometimes been associated with thermal discomfort.[23] Also, it has been observed that Fluidotherapy® is better tolerated than warm water application in normothermic human subjects.[25, 27] To our knowledge, no study has ever used Fluidotherapy® administration to rewarm hypothermic subjects.

The purpose of this study was to determine if Fluidotherapy® application to distal extremities is more effective in rewarming mildly hypothermic human subjects in terms of afterdrop, rewarming rate (RR), shivering heat production, and heat delivery compared to distal extremities immersion in warm water, and a shivering-only protocol.

HYPOTHESIS 1: That rewarming of distal extremities with Fluidotherapy® (at 50°C) would provide more heat compared to rewarming of distal extremities in warm water (at 45°C) and shivering only.

RATIONALE: Previous studies have used Fluidotherapy® at a temperature 8-9°C higher than warm water (48 vs. 39-40°C).[26, 27] In these conditions Fluidotherapy® led to approximately 47% higher tissue temperatures in hands and feet[27] and approximately three times higher heat absorption by copper bars, which represented human hands in the study.[26] Therefore, even though in the present study, Fluidotherapy® with a proposed temperature 5°C higher than warm water (compared to 8-9°C in previous studies), more heat absorption was still expected; Fluidotherapy® temperature would only be 5°C higher than warm water because we want to use warm water at its maximum potential (i.e., subjects can tolerate 45°C water temperature).

HYPOTHESIS 2: That rewarming of distal extremities with Fluidotherapy® (at 50°C) would be associated with less shivering heat production compared to rewarming of distal extremities in warm water (at 45°C) and shivering only.

RATIONALE: Exogenous heat application has been shown to decrease shivering heat production.[14, 15] Based on the fact that Fluidotherapy® is an exogenous heating modality and provides more heat (applied at 9°C higher temperature than warm water) in normothermic individuals, reduction in shivering heat production was hypothesized in hypothermic individuals (applied at 5°C higher temperature than warm water).

HYPOTHESIS 3: That rewarming of distal extremities with Fluidotherapy® (at 50°C) would have less T_{co} afterdrop compared to rewarming of distal extremities in warm water (in 45°C water) and shivering only.

RATIONALE: In a previous study on normothermic individuals,[26] Fluidotherapy® (applied at 49°C) provided more heat to copper bars (representing hands) compared to

warm water immersion (applied at 40.5°C). Similar results were expected in hypothermic individuals. One factor contributing to T_{co} afterdrop is higher post-cooling perfusion of cold peripheral tissue (e.g. arms and legs). Because Fluidotherapy® was expected to warm these peripheral tissues more than warm water, this cooling effect should be diminished.

HYPOTHESIS 4: That rewarming of distal extremities with Fluidotherapy® (at 50°C) would provide a higher rewarming rate compared to rewarming of distal extremities in warm water (at 45°C) and shivering only.

RATIONALE: Fluidotherapy® provided higher soft tissue warming rates in hands and feet (where AVAs are abundant) in normothermic individuals compared to warm water immersion.[27] This factor might play a role to increase rewarming rates in hypothermic individuals as well.

LITERATURE REVIEW

ACCIDENTAL HYPOTHERMIA

Accidental hypothermia occurs when the human body is unable to compensate for the heat loss due to cold exposure[29] and the T_{co} of human body decreases to below 35°C.[30, 31] Accidental hypothermia can occur outdoors as well as indoors[30] and is common in both summer and winter months.[32] Giesbrecht mentioned that significant cold water exposure duration of at least half an hour is required for a body to become hypothermic.[10] Based on the reductions in T_{co}, hypothermia can be classified into mild (32°C-35°C), moderate (28°C-32°C), and severe (<28°C).[34] The diagnosis of hypothermia is an important factor in determining the mortality rates of the victims. White studied 102 hypothermia patients who came to a medical center in 1978 and found hypothermia diagnosis to be significantly correlated to mortality rate.[33]

CONTRIBUTING FACTORS TO HYPOTHERMIA

Accidental hypothermia can be acute (occurring rapidly from severe cold exposure), exhaustion (occurs from a combination of cold exposure, inadequate insulation, and lack of nutrition leading to inability to generate adequate heat), or chronic (that occurs over a period of time and is more prevalent in the older population).[35] Heat loss and rate of body core cooling during cold exposure depends on various factors such as water temperature and sea state, thermal protection, body morphology, surface area of the body exposed to cold water, body posture and other non-thermal factors.[1]

Water temperature and sea state

During cold water immersion, T_{water} plays a critical role in the rate of core cooling. The T_{water} is inversely proportional to core cooling rate.[1, 36] Since the thermal conductivity of water is 25 times greater and also specific heat is 4000 times greater than that of air at the same temperature, heat loss during cold water immersion is much higher than cold air exposure.[1, 37]

Thermal protection

Clothing is another factor that affects cooling rate during cold exposure. Various studies conducted in calm water showed that insulation provided by dry insulated garments is much better than wet insulated garments.[38, 39] However, rough water leads to flushing of cold water through wet suits or leakage into dry suits, leading to a higher cooling rate. The core cooling rate in rough water may also be influenced by the victim's efforts to swim or waves causing passive body movements. Therefore, wet protective garments showed even faster cooling rates in turbulent water compared to calm water.[1, 40]

Body morphology (size and composition)

Cooling rate is also affected by the size or composition of the body. A greater surface area-to-mass ratio leads to faster cooling.[1] Thus, smaller adults as well as children have been found to cool faster than larger adults.[29, 30] Cooling rate is also inversely proportional to the body's skinfold thickness as subcutaneous fat acts as an insulator against heat loss.[1, 41]

Surface area exposed

Heat loss further depends on the surface area exposed to cold water. As thermal conductivity of water is much higher than that of air, it becomes important for an immersed victim to expose the least surface area to cold water and to attempt to keep as much of their body area out of water as possible.[1]

Behavior and body posture

Behavioral variables such as body postures during cold immersion also influence the cooling rate.[1] In a study by Hayward et al., it was shown that heat losses are high in the groin, lateral and central thorax, and neck due to relatively superficial large blood vessels in the groin and neck regions and less subcutaneous fat and muscle in lateral and central thorax regions.[42] To decrease these heat losses, they developed cold water survival techniques including the heat escape lessening posture (HELP) and the group huddle.[43]

Non-thermal factors

Other non-thermal factors such as hypercapnia (such as in an avalanche) and hypoxia decrease the shivering threshold (i.e. the temperature at which shivering starts), and increase core cooling.[44, 45] Deterioration of mental and physical function because of alcohol consumption is also related to accidental hypothermia.[1] Moderate alcohol consumption (blood alcohol levels of 50 to 100 mg/dl) has been associated with lowering of the vasoconstriction threshold during moderate cold stress (28°C water immersion) and reduction in shivering thermogenesis in colder water (less than 28°C water immersion) by approximately 10-20%.[46] Cooling rate, however, was not significantly

increased in any of these conditions.[46] When intoxicated with high doses of alcohol (blood alcohol level greater than 200 mg/dl), there is deterioration in body functions including thermoregulatory responses, and if exposed to cold the victim may become hypothermic.[1, 47]

MECHANISMS OF HEAT LOSS

The human body loses heat through various physical mechanisms and several factors influence these mechanisms. Conduction is a major source of heat loss when the human body is in direct contact with a solid or liquid.[30] Conductive heat loss depends on the temperature gradient and the conductance between the body and that solid or liquid.[48] Heat loss can also occur through the mechanism of convection which refers to the loss of heat from the body to air or water currents.[5] When a fluid (liquid or gas) at a temperature lower than T_{skin} flows over the contacted skin, heat is lost from the skin to that colder liquid or gaseous layer. Because of flowing current, the warmed liquid or gaseous layer moves away and a new colder layer comes in contact with the skin that must be warmed again. Convective heat losses occur during windy cold air exposure, also known as wind chill effect.[48] Another mechanism of heat loss is the evaporation which is the conversion of liquid into vapor form. Evaporative heat loss from the body includes evaporation of sweat, insensible water loss from the skin, water in clothing, and respiratory heat loss. Normally, sweating accounts for maximum evaporative heat loss from skin surface.[48] At room temperature, respiratory heat loss accounts for only nine percent of total metabolic heat production.[49] The fourth mechanism of heat loss to the environment is through radiation as the body emits infrared rays from the skin.[6] According to Hardy and DuBois, radiation accounts for 70% of total heat loss at about 22 to 23°C. The amount of

heat loss through radiation reduces as the environmental temperature increases, approaching zero at approximately 35°C.[50]

THERMOREGULATION

The human body tries to maintain its T_{co} at 37 $\pm$ 0.5°C in a set range called the thermoneutral zone.[51] The thermoreceptors present in the core and periphery of the body sense the temperature and send signals to the thermoregulatory center in the hypothalamus of the brain.[52] These signals are collectively referred to as the integrated thermal signal (ITS).[53] This ITS is compared with the thresholds in the hypothalamus for different efferent responses. The range of ITS between the thresholds for warm (vasodilation and sweating) and cold (vasoconstriction and shivering) responses, where there is no thermoregulatory response, is known as inter-threshold range or null zone.[48]

If the ITS rises, the body responds by behavioral changes, followed by peripheral vasodilation, and lastly by sweating. Behavioral changes such as removing extra layers of clothing and turning on an air conditioner are the first responses to occur. If the behavioral changes are not enough to maintain the ITS within the interthreshold range, peripheral vasodilation occurs leading to increased heat loss from the skin. Further increase in ITS leads to sweating response associated with evaporative heat loss from the skin surface.[48, 51, 53-55]

However, if the ITS decreases, the body responds by behavioral changes (wearing warm clothes, taking shelter etc.) followed by peripheral vasoconstriction and shivering heat production.[51, 53-55] During severe cold, behavioral changes are the most important responses in preventing hypothermia compared to the body's physiological responses

including shivering and vasoconstriction.[7, 48] Peripheral vasoconstriction is the first thermoregulatory response to occur after behavioral changes.[48] The decreased peripheral blood flow from vasoconstriction reduces the heat loss from the skin surface.[56] With further reduction in ITS, shivering thermogenesis occurs (i.e. increased metabolic heat production).[48] The intensity of each thermoregulatory response (warm as well as cold responses) is directly proportional to the deviation of ITS away from the interthreshold range (gain) and finally reaches a plateau of maximum response.[48]

Some researchers believe that the above mentioned thresholds for heat production mechanisms and heat loss mechanisms coincide at a single point called a set point and the body tries to maintain T_{co} at that particular set point[52, 57] while others believe that the target temperature is not a single set point but a range which is called as thermoneutral zone.[48, 51]

SHIVERING

The primary responses of the body to cold exposure include reductions in metabolism, neural activities, mean arterial pressure (MAP), heart rate (HR), and cardiac output (CO).[1, 11, 34, 58] The Q_{10} is a factor that represents the decrease in metabolism for every 10°C decrease in tissue temperature. The Q_{10} value for the whole body is approximately 2, which means that deceasing the T_{co} from 37°C to 27°C will approximately decrease the metabolism by 50%.[1] The secondary responses to cold exposure include shivering thermogenesis and increased metabolic rate, MAP, HR, CO, and ventilation. These secondary responses predominate over the primary responses if the victim is mildly to moderately hypothermic.[1, 9, 34]

Shivering is a major heat production mechanism of human body against hypothermia and is prominent in mild hypothermia.[30] During shivering, the body's metabolic rate can reach nearly five times the resting metabolic rate.[59] As the T_{co} lowers from mild hypothermia into moderate hypothermia (28°-32°C), shivering thermogenesis deteriorates along with the depressed heat control mechanism, respiratory depression, peripheral vasodilatation, cardiac insufficiency, and affected mental functions.[30] Absence of shivering also leads to reduction in the rewarming rate. Giesbrecht et al. pharmaceutically inhibited shivering by administering Meperidine in mildly hypothermic subjects which resulted in 3.2 times increase in T_{co} afterdrop and decreased rewarming rate.[60]

FOUR PHASES OF COLD WATER IMMERSION

Several researchers have described four phases of cold water immersion.[1, 34, 61] The first phase is the cold shock response. In this phase, rapid cooling of the skin leads to peripheral vasoconstriction, gasping, hyperventilation, and inability to control breathing. These problems may restrict a victim from performing survival strategies including swimming or calling for help and if not controlled they may lead to fainting and drowning. This cold shock response normally diminishes within a few seconds to one minute. The cold exposure victim should first control his/her hyperventilation and gasping in this initial phase to better control their physical movements and to plan and execute survival procedures.[1, 10, 34, 62, 63] Those victims who survive the first phase go into the second phase which is called cold incapacitation. Progressive cooling of peripheral muscle and nerve tissues decreases physical strength and coordination especially within the initial 15 minutes. Poor muscle control makes survival procedures difficult to

perform. The cooling causes decrease in blood supply and neuromuscular activity and these lead to finger stiffness and inability to perform fine and gross movements.[1, 34, 64, 65] The third phase of cold water immersion is hypothermia. The continuous body cooling (at least 30 minutes) in cold water may lead to significant decrease in T_{co} leading to hypothermia. Though drowning is the leading cause of death in the first two phases of immersion, deaths in the third phase would likely be due to cardiac arrest if victim has self-righting personal floatation device (PFD).[1, 10, 34] Also, for victims immersed without a self-righting PFD, the most common cause of death is to lose consciousness which leads to drowning. The last phase of cold water immersion is circum-rescue collapse when the victim may collapse before, during or after being rescued. This collapse may occur because of cardiac failure. These may occur as a result of T_{co} afterdrop, decreased MAP, or fibrillation.[1, 34, 61]

CORE TEMPERATURE AFTERDROP

After a victim is removed from cold exposure, his T_{co} continues to drop as much as 3-6°C before reversing its direction. This decrease in T_{co} is referred to as afterdrop.[8, 9, 66] There are two mechanisms for explaining the T_{co} afterdrop. The first is the convection or tissue perfusion mechanism which has two different forms.[67] The first form explains the T_{co} afterdrop as a result of core cooling occurring because of the cold blood returning from the extremities,[68] this theory has been discontinued because blood is not sequestrated in the periphery by vasoconstriction. The second form states that during cold exposure, the limbs are vasoconstricted with very little blood in the cold periphery. Rewarming initiates peripheral vasodilation, and blood flow is increased to the extremities. This blood gets cooled as it flows through the cold tissues, and returns to the

core and thereby cools the core.[66, 67] The second explanation is the conduction or temperature gradient mechanism. Cold application to superficial tissue creates a temperature gradient. Different layers of the body tissues thus have different temperatures, in such a way that deeper layers are warmer than the adjacent peripheral layers. When the skin is rewarmed, the temperature gradient starts reversing, and the superficial layers now start becoming warmer than the adjacent deeper layers. The deeper layers continue to cool until the surrounding layers are warmer. This continued cooling of the core layers cause the T_{co} afterdrop.[8, 67]

HYPOTHERMIA TREATMENT

The immediate objectives of treatment of a victim removed from cold exposure are to stop further heat loss and to provide rewarming. In addition to maximizing insulation, stabilizing cardiorespiratory system, and minimizing T_{co} afterdrop are the primary requirements.[1, 10] Conscious shivering victims are usually not considered emergencies as shivering can produce heat as much as five to six times of resting metabolic rate[69] and rewarming rates as high as 3-4°C/hr.[1, 12, 14, 34] External rewarming can however provide similar rewarming rates and also reduces the body's energy consumption and work of heart. External rewarming is also associated with feeling of comfort.[1] A non-shivering victim should be provided with some form of exogenous rewarming modality[10, 70] because passive rewarming is not effective in severe hypothermia.[31]

REWARMING METHODS

Rewarming methods can be divided into endogenous and exogenous (further divided into invasive and non-invasive methods) as discussed in the Introduction.[10] Endogenous rewarming occurs from the heat produced through shivering or exercise.[9]

Exogenous rewarming refers to rewarming through external sources of heat such as charcoal heatpac.[9] Giesbrecht et al. compared rewarming from exercise, shivering, and an exogenous heating modality in hypothermic subjects and found that exercise was associated with more T_{co} afterdrop (both amount and duration) and had a higher rewarming rate. Exercise increases the flow of warm blood from the core to the exercising muscles, thus cooling the blood before it returns to the core. Once the afterdrop period is complete the additional energy produced by exercising muscles provides higher rewarming rate compared to shivering and external heat.[12] In a similar experiment Giesbrecht and Bristow found 58% more T_{co} afterdrop with exercise rewarming compared to a shivering-only protocol.[67] Shivering as discussed earlier is one of the most important rewarming methods and has been studied extensively in many studies.[12, 24, 60, 71, 72] Shivering studies have shown that shivering provides a rewarming rate of approximately 3.5°C/hour.[12, 24] Shivering is usually performed with some kind of insulation like a sleeping bag or blanket. Sessler and Schroeder studied the effect of passive insulation by applying blankets and found that the application of a single layer of blanket reduces heat loss from the human body by 33% compared to no blanket. Adding two more layers of blankets further reduced heat loss by 18%. Blankets preheated in a 50°C oven, had no significant beneficial effect over blankets kept at room temperature.[73]

Exogenous rewarming can be performed with various methods. Warm water immersion has been studied by various researchers.[18, 67] Hoskin et al. compared whole body (below the neck) immersion with trunk only immersion (without arms and legs) in 40°C water as a rewarming method for experimentally induced hypothermia and found them to be equally effective in terms of increasing rewarming rate.[18] However, whole

body warm water immersion is not a recommended method of rewarming as it is associated with distal vasodilation further leading to T_{co} afterdrop,[9, 18] and reduction in blood pressure which can further lead to collapse.[19] Another rewarming method is a charcoal heatpac. Giesbrecht et al. found these heatpacs to be equally effective as shivering in rewarming hypothermic subjects.[12] Body-to-body rewarming is another rewarming method as studied by Giesbrecht et al. where hypothermic subjects (heat recipients) were rewarmed by normothermic individuals (heat donors) through physical contact in a sleeping bag. This study found that body-to-body rewarming blunts shivering heat production and thus, has no rewarming advantage over spontaneous shivering for treating hypothermia. Body-to-body rewarming can be administered to rewarm a non-shivering subject who is not being evacuated.[14] Forced air rewarming has been studied several times and proved to be an effective method in rewarming hypothermic subjects.[15, 74-77] Giesbrecht et al. found that forced air rewarming provides a similar rewarming rate and 30 percent less T_{co} afterdrop compared to shivering. The metabolic stress which occurs from shivering was also reduced because of external heat.[15]

AVA REWARMING

Arteriovenous anastomoses (AVAs) are the shunts between arteries and veins which are present in human digits and forearms as well as lower legs. AVAs are most abundant in fingers and toes.[21] These shunts are dependent on the environmental temperature. They remain open in warm and thermoneutral environment in order to increase superficial venous return thereby increasing heat loss, and constrict in a colder temperature thereby preventing heat loss. However, in colder temperature, applying heat

to these areas may open the AVAs transporting warmed venous blood to the core. The blood flow through the fingers and toes can change one hundredfold from 0.5-1 cc/min/100 cc tissue while AVAs are vasoconstricted to 80-90 cc/min/100 cc tissue while AVAs are vasodilated.[1, 21]

Vanggaard and Gjerloff used plethysmography to measure venous blood flow in the hands and forearms. In their first experiments, they applied cold stress by reducing the room temperature to 15° to 18°C and then, rewarmed hands and forearms through warm water immersion (ranging from 46 to 37°C). Immersion of forearms in 46°C water led to heat uptake of 1.5 kcal/min which is equivalent to normal basal heat production. In other experiments, cold stress was applied by immersing the subject up to neck level in 15°C stirred water bath and rewarmed using perfused fracture splints around hands and forearms. In the latter experiments, the fall in rectal and ear temperature was almost stopped. The authors also stated that heat influx of around 5 kcal/min could occur by rewarming distal extremities in a hypothermic subject. The study concluded that this heat uptake was due to opening of AVAs in hands and forearms.[20]

Daanen and Linde compared four rewarming treatments including body immersion, hand and feet immersion and body except all four extremities immersion in 42°C water and shivering rewarming. This study showed that extremities rewarming was less effective than whole body rewarming and body except the extremities rewarming.[22] This study was not able to show better results with the AVA rewarming method compared to the other two methods as they used only 42°c water and not 45°C water, and also they rewarmed only the hands and feet and not the forearm and legs.[24] Cahill et al. compared bilateral hand and forearm immersion (42°C), below neck immersion (40°C), and

shivering for rewarming experimentally induced hypothermia subjects and found hand and forearm rewarming was less effective than the other two protocols.[23] These latter two studies rewarmed less surface areas and with water at lower temperature than those recommended by Vanggaard and Gjerloff.[23] Vanggaard et al. studied this AVA rewarming for rewarming experimentally induced mild hypothermia subjects. The subjects were monitored for their T_{co}, T_{skin} at different sites, and oxygen consumption. This study compared rewarming rate and T_{co} afterdrop between rewarming from shivering and from distal extremities immersion in 42°C and 45°C water. The rate of rewarming by immersion in both 45°C and 42°C water provided significantly better rewarming rate (9.9°C/h and 6.1°C respectively) than shivering-only (3.4°C/h). The T_{co} afterdrop was also reduced in AVA rewarming in 45°C water as well as 42°C water (0.4°C) compared to shivering-only (0.6°C). The subjects also felt extremities rewarming as more comfortable than shivering.[24]

FLUIDOTHERAPY®

Fluidotherapy® is a rewarming modality used in rehabilitation departments. Fluidotherapy® is based on convection of heat through fine cellulose particles. These particles have kinetic energy which is transferred, along with heat, to the body part in contact leading to counter irritation and pain relief. Fluidotherapy® temperature application in rehabilitation settings ranges from 43°C to 50°C.[25] Fluidotherapy® is indicated in many medical conditions such as arthritis, injuries like ankle sprains, fractures, circulatory disorders as well as infections.[25]

The Fluidotherapy® equipment consists of a heater, an air blower, and a chamber containing cellulose particles. The heater heats the air which is blown in the chamber

from below, and once the air pressure is more than the weight of the cellulose, it lifts the cellulose up and the cellulose particles spread out inside the chamber. Portals in the top and end of the chamber allow the entry of limbs for heating and the limbs can be moved during the treatment. Treatment with Fluidotherapy® equipment allows the subject to tolerate higher temperatures compared to warm water application.[25, 27] This occurs due to a concept called counter irritation which refers to repeated stimulation of temperature and pressure receptors in the skin by the cellulose particles in Fluidotherapy®, thereby increasing temperature tolerance and decreasing pain sensation.[25] The higher temperature tolerance allows more heat to be delivered to the limbs compared to warm water application.[25, 78]

Kelly et al. studied the effects of 20 minutes of Fluidotherapy® application on the nerve conduction velocity of the radial nerve and the rise in local T_{skin} and found that Fluidotherapy® not only increases the T_{skin} but also causes increased nerve conduction velocity because of a higher temperature. Any localized pain in the treated area is also reduced as a result of pain gate control theory.[79] The pain gate control theory is based on the fact that repeated sensory stimulation of the skin stimulates high velocity large diameter sensory nerve fibers. Signals in these neurons have a faster conduction velocity than small diameter fibers that conduct pain signals from pain receptors. The faster signals block the slow pain signals at the level of the Substantia Gelatinosa in the spinal cord. Thus the persons feel only the sensation caused by repeated stimuli and not the pain.[80] In case of Fluidotherapy® this sensation is caused by repeated striking of cellulose particles against the skin.

Valenza et al. studied Fluidotherapy® treatment (20 minutes application) for several types of patients (total 365 treatment sessions) and measured blood pressure, oral temperatures, and edema and found minor changes in oral temperature (increased), blood pressure (reduced), and pulse rate (increased). This study found that Fluidotherapy® treatment was felt as relaxing, sedative, and pain relieving. This study also found that Fluidotherapy® increases local blood circulation and thus aids in infection treatment by draining effect.[78] Fluidotherapy® combined with exercise therapy has been used in another study to treat hospitalized children suffering from sickle cell anemia and was found to be effective in providing pain relief and help reduce the dose of analgesic medications.[81]

COMPARISON OF FLUIDOTHERAPY® WITH OTHER HEATING MODALITIES

Borrell et al. did a study to compare the Fluidotherapy® (48.89°C), whirlpool (tank with moving water at 40.6°C), and a paraffin wax bath (52.2°C) for the amount of heat delivered in 15 minutes. The researchers attached thermocouples to a copper bar and immersed the bar in three heating modalities separately to find their thermal conductance. The heat gained was estimated based on overall thermal conductance and was found to be three times more for Fluidotherapy® (17.2 BTU) compared to whirlpool (5.6 BTU) and paraffin wax bath (4.8 BTU).[26] Borrell et al. did another similar study with the same three modalities and compared temperatures at the levels of the thumb joint capsule and flexor hallucis brevis muscle. They inserted hypodermic needles (containing a thermistor for temperature measurement) at four different sites in hands and feet of four subjects. They found higher temperatures with Fluidotherapy® at the levels of thumb joint and flexor hallucis longus muscle throughout the 20 minutes of treatment. Interestingly, the

researchers had to apply cold water to the heated areas after the Fluidotherapy® treatments. The study concluded that Fluidotherapy® delivers more heat compared to warm water and a paraffin wax bath.[27]

Thus, there is evidence that Fluidotherapy® is better tolerated and provides more heat to the extremities than warm water application. Also, it has been seen that application of heat to distal extremities leads to opening up of AVAs providing higher rewarming rates in hypothermia victims compared to shivering-only. No study has ever compared the effects of Fluidotherapy® and warm water application to distal extremities in mildly hypothermic subjects. This study evaluated if Fluidotherapy® is advantageous over warm water to gain better rewarming rates.

METHODS

SUBJECTS

The study was approved from the Biomedical Research Ethics Board (Appendix A) at the University of Manitoba. Seven physically active and healthy subjects (based on power calculation) between 18 and 45 years of age and either gender were studied. Subjects' names will be kept confidential and will not be reported anywhere else. The subjects were screened based on Physical Activity Readiness - Questionnaire (PAR-Q) (Appendix B). Each subject was also screened for the presence of Raynaud's syndrome or any other condition that may be stimulated by cold exposure. The study was explained to the subjects and a signed consent (Appendix C) was obtained. The subjects were advised to abstain from the use of any drug, alcohol, and caffeine for 24 hours prior to each experiment and to bring a bathing suit or shorts for all three trials.

POWER CALCULATION

Power analysis was done to calculate the required number of subjects for this study. The following equation was used for this calculation:[82]

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

where:

n = required number of subjects

PI = power index, calculated from the desired power of the study

μ_d = true mean difference between two different treatment methods

σ = true standard deviation of the difference between two different treatment methods

PI was determined based on the assumptions of 5% chance of committing a Type I error (e.g. failure to detect a real difference) (alpha = 0.05) and 10% chance of committing a Type II error (e.g. detecting a difference when none exists) (beta = 0.10). Based on these values the power index for this study will be 3.24.[82] A previous study on post cooling afterdrop done in our lab demonstrated a significant difference of 0.24°C (mean) in T_{co} afterdrop between two protocols (shivering and exercise rewarming protocols) with a standard deviation of 0.12.[67] Based on this:

$n = (3.24 * 0.12/0.24)^2$

$n = (1.62)^2$

$n = 2.62$

This study required a sample size of at least three subjects; in keeping with standard procedures in this laboratory seven subjects were studied.

ANTHROPOMETRIC MEASUREMENTS

Once a subject was selected, the following variables were measured:

- Height (ht) in meters (m)
- Weight (wt) in kilograms (kg)
- Skinfold measurements using Harpenden skinfold caliper (Appendix D)
- Limb circumference (Appendix D)
- Age in years (yrs)

The following variables were calculated:

- Body mass index (BMI) was calculated according to the following equation:

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

- Body surface area (BSA) was calculated from height and weight based on the following equation[83]

Body surface area (m^2) = weight (kg)$^{0.425}$ x height$^{0.725}$ (m) x 0.007184

- Body density (BD) was calculated according to Durnin and Womersley, by using the age and gender specific equations (Appendix E)[84]

- Body fat percentage (fat%) was calculated based on the following equation[84]

fat% = ((4.95/BD) – 4.5) x 100

INSTRUMENTATION

Esophageal Temperature (T_{es}) was measured using disposable esophageal thermocouple which was inserted into the esophagus through the nose to the level of heart. This represented the T_{co}.

Heat flux (HF) and T_{skin} were measured at 12 different body sites using thermal flux transducers (Mon-a-therm General purpose temperature probe, Mallinckrodt Medical, St-Louis, MO). These 12 sites represented the corresponding BSA and this study assumed that HF and T_{skin} were same within every single body surface region. These 12 sites were derived from 14 sites studied by Layton et al. (1983).[85] This study assumed same T_{skin} and HF on left and right side of the body. These skin sites and their regional percentages were forehead (7%), anterior torso (17.5%), posterior torso (17.5%), left upper arm (7%), right forearm proximal (3.5%), right forearm distal (3.5%), left hand (5%), left anterior

thigh (9.5%), right posterior thigh (9.5%), left lower leg proximal (6.5%), right lower leg distal (6.5%), and left foot (7%). Regional HF for these 12 body areas were calculated based on the following equation.

HF_{actual} (W) = HFT (W/m^2) x BSA (m^2) x regional%/100

Oxygen consumption (VO_2), carbon dioxide production (VCO_2), and respiratory rate were measured using an open circuit metabolic cart (Sensormedics - Vmax 229 series, Yorba Linda, CA). A sterilized face mask was applied to the subject, and this face mask was connected to the metabolic cart for measurements.

Electrocardiogram (Kendall Meditrace conductive ECG adhesive electrodes-533, Fluxlow Company, Chicopee, MA, USA) was used to monitor subjects' HR throughout the experiment.

All these variables were measured throughout the trials and recorded every 30 seconds.

REWARMING CONDITIONS

Shivering Only (Control)

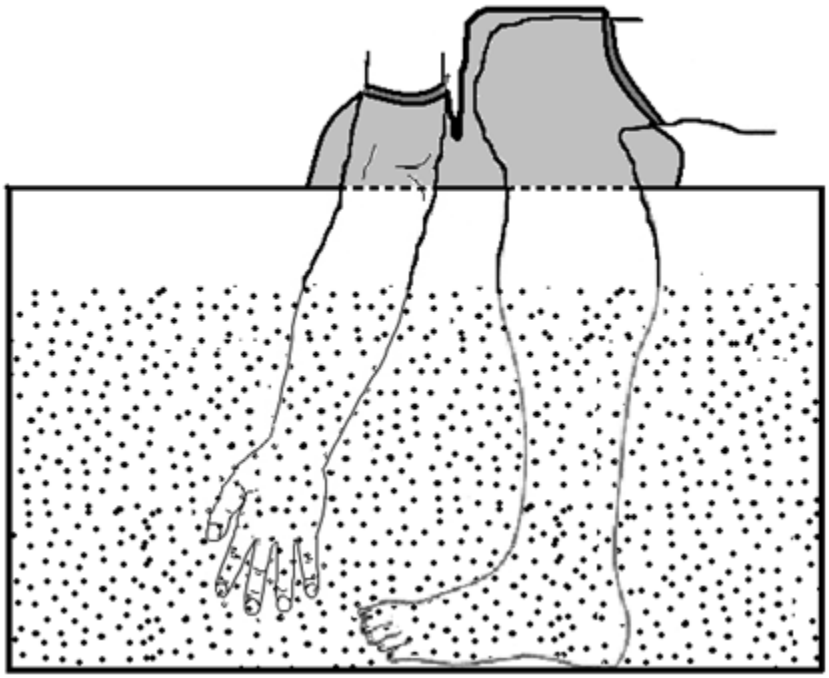
Both Fluidotherapy® and warm water immersion rewarming conditions involved subjects in a sitting position, although shivering is usually done in supine position.[12, 60, 67] We wanted to remove any possible effect of position from the comparison between the three conditions. For example compared to sitting, the supine position has been shown to increase shivering[86] and lower $T_{co.}$[87] Therefore, in this study, the subjects were in a sitting position in the shivering only condition as well. Also, the subjects leaned forward

in this condition as well because they were in this position in other two conditions. After towel drying the subjects sat on a chair and a sleeping bag was applied over the back and the shoulders. They leaned forward and rested on a head support.

Fluidotherapy® Rewarming

Chattanooga Fluidotherapy® model 115D, provided by DJO Canada, Inc (cuboid in shape, 86.4 cm long, 47 cm wide and 83.8 cm high) was used to rewarm the subjects. This equipment consists of a chamber which has four portals (two on the top and two on one of the ends) which allow distal extremities to be inserted into the chamber for the treatment (as shown in figure 1). Each portal has an attached sleeve that can be tightened to prevent the cellulose particles from coming out. Normally, the Fluidotherapy® equipment (model 115D) is used to treat either one or both the upper or lower extremities at a time. But since this study required treatment of all the four extremities together, new sleeves were created for the top portals of the chamber. The new sleeve had two openings and allowed two ipsilateral extremities to be inserted through different holes in the same sleeve attached to a top portal of the chamber and these holes could be tightened separately. The two news sleeves created for each of the two top portals allowed the warming of all the four extremities together. The Fluidotherapy® can be set at any temperature between 31°C and 51°C and the air speed can be controlled at different levels (0% to 100% of the maximum) at increments of 5%. The Fluidotherapy® equipment was preheated to 45°C at 35% air speed before application to the subjects.

Figure 1. Schematic representation of Fluidotherapy chamber®



After towel drying, the subject walked and sat on the chair for Fluidotherapy® rewarming. The equipment was turned off and the openings on the sleeves attached to the top portals were opened. The subject would then gradually insert his/her legs through the lower leg openings of the sleeves attached to each top portal and rested his/her feet at the bottom of chamber. The top of the leg sleeves were tightened at the knee level using attached Velcro straps. The subject then leaned forward to rest his/her head on the front support and gradually inserted both the forearms into the Fluidotherapy® chamber through arm openings of the sleeve on the same top portal (as shown in figure 2). The sleeves were then sealed just above elbow level using Velcro straps. The Fluidotherapy® equipment was then turned on at 100% air speed and 45°C. The back and shoulders were covered with a sleeping bag to prevent heat loss. The Fluidotherapy® temperature (T_F) was adjusted during the rewarming period on the basis of subjects' maximum

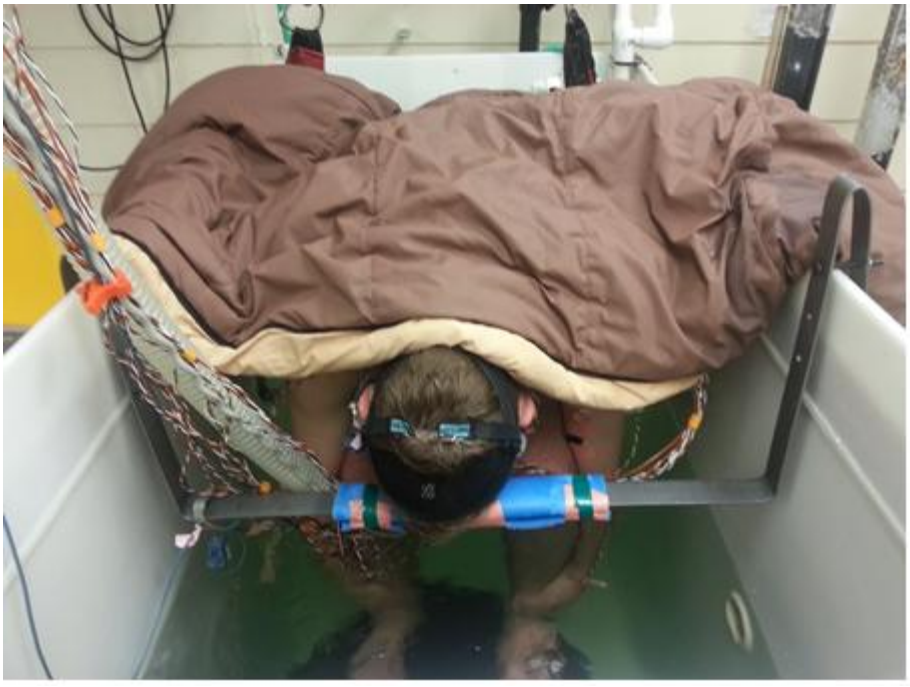
temperature tolerance. The Fluidotherapy® temperature was measured throughout the experiment and recorded every 2.5 minutes.

Figure 2. Fluidotherapy rewarming – without and with the sleeping bag

Warm Water Rewarming

The T_{water} of the heating tank was maintained at 45°C ($\pm$1°C). The tank was equipped with an adjustable foot and head supports to allow for precise positioning of the legs and arms in water. After towel drying, the subject was hoisted to a seat inside the warm water tank, via an electrically isolated hoist. The subject sat on the seat such that only lower legs were immersed in water to the level of the knee joints. The subject then leaned forward immersing his/her hands and forearms in the water up to the level of elbow, and rested his/her head on the anterior head support. The back and shoulders were covered with a sleeping bag (Figure 3).

Figure 3. Warm water rewarming



PROTOCOL

First Visit

After obtaining the informed consent, an individual subject number was allotted to every subject. All the anthropometric data (as mentioned above) were measured and recorded. Each subject underwent different rewarming experiments each in three subsequent visits. The order for these three rewarming methods for each subject followed a balanced design.

Experimental Visits

The three rewarming experiments were performed at the same time of the day, separated by at least 48 hours. Every subject was confirmed for not using any drug, alcohol, and caffeine in the last 24 hours as advised. A brief introduction about the upcoming experiment was provided to the subject. The subjects were advised to use the washroom if they required before commencing the experiment. The subjects were required to wear bathing suit/shorts and remove all the jewelry/wrist watch.

Instrumentation

The three adhesive ECG leads were applied (at right shoulder, left shoulder, and anterior chest) and connected to the ECG equipment. The heat flux discs were applied at the designated 12 skin areas and secured using skin tapes. The esophageal thermocouples were inserted to the level of heart. A sterilized facemask for oxygen consumption measurement was applied and connected to metabolic cart through a well supported flexible tube.

Experimentally induced hypothermia

This was the common initial part of all the three experiments. The subject sat relaxed and quiet on a chair and the baseline measures of VO_2, respiratory rate, HR, T_{skin}, HF and T_{co} were recorded for 10 minutes. An electrically isolated hoist was then used to hoist the subject into a water tank maintained at 20°C. The subject was immersed to the neck level in a sitting position. The T_{water} was decreased to 8°C within a few minutes by the addition of ice. The temperature was maintained at 8°C ± 1°C throughout the cooling phase. The subjects were then hoisted out once any of the following criteria was achieved:

i. T_{es} of 35°C
ii. Maximum of 60 minutes of immersion
iii. Subject wished to terminate the experiment
iv. Researcher's decision to terminate the experiment

After the cooling phase, the subjects were dried as much as possible using towels.

Rewarming phase

After towel drying, the subject underwent one of the three rewarming experiments as explained above. The rewarming was stopped once any of the following criteria was achieved:

i. T_{es} of 37°C
ii. Maximum of 60 minutes of rewarming
iii. Subject wishes to come out

iv. Researcher's decision to terminate rewarming

Immersion in 42°C water tank

This was the last phase for all the experiments. The subjects were hoisted to a water tank maintained at 42°C water and immersed to the neck level in a sitting position. This immersion phase was performed for the subjects to feel comfortable and is a standard procedure of our lab experiments.[24] The subjects were then hoisted out when either the subject felt hot and wanted to come out or the researcher decided to take him/her out.

End of trial

In the end, the face mask, esophageal thermocouple, ECG electrodes, and the skin thermocouples were removed. The subjects changed clothes, and were advised about the next experiment (if any).

DATA ANALYSIS

The HF from the whole body (HF_{total}) was calculated by adding all the 12 regional HF values. The HF through the extremities (HF_{ext}) was calculated by adding the six extremity HF values.

Metabolic heat production (M) was measured from VO_2 and RER based on the following equation.[24] Based on mixed diet, RER of 0.83 was assumed for calculating MHP.

$$M\ (W) = VO_2 \times 69.7\ [\ 4.686 + (\ RER - 0.707\ ) \times 1.232\ ]$$

Respiratory heat loss (RHL) was calculated from the following equation.[49]

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

Net Heat Gain (NHG) was calculated based on the following equation.

$$NHG\ (W) = MHP\ (W) - RHL - HF_{total}$$

Cooling rate (CR) was calculated from linear regression of T_{es} during the last 20 minutes of cold water immersion.

T_{es} afterdrop (AD) was calculated by subtracting T_{es} at exit from the cold water and its lowest value thereafter.

Length of afterdrop period (ADL) was calculated as the time duration between exit from the cooling tank and the time when T_{es} returned back to T_{es} at exit.

Rewarming rate (RR) was calculated from linear regression of T_{es} during the rewarming.

One way analysis of variance (ANOVA) test for repeated measures was used to compare heat flux and average skin temperature values for total body, arms, legs and distal extremities during the baseline, last 20 minutes of cooling and rewarming phases. ANOVA was also applied to compare MHP, RHL, AD, ADL, RR and NHG between the three rewarming conditions.

RESULTS

Total seven subjects (5 male, 2 female) were studied with age (mean ± standard deviation) 29.3 ± 3.1 years, height 174.6 ± 12.2 cm, weight 80.9 ± 16.0 kg, body surface area 1.96 ± 0.2 m^2, and fat percentage 23.61 ± 7.3% (Table 1).

Table 1: Descriptive data for the seven subjects

Subject	Age (yr)	Gender	Height (cm)	Weight (kg)	BSA (m^2)	SFSF (mm)	Body Fat%
1	25	M	176.0	74.5	1.90	48.0	18.4
2	26	F	164.0	86.0	1.92	88.2	35.1
3	31	M	184.0	75.0	1.97	23.6	13.7
4	32	M	181.0	98.5	2.19	55.5	22.6
5	32	M	174.0	88.0	2.03	104.5	29.5
6	32	M	189.5	93.5	2.21	40.2	19.2
7	27	F	154.0	50.7	1.47	49.6	26.7
Mean	**29.3**		**174.6**	**80.9**	**1.96**	**58.5**	**23.6**
S.D.	**3.1**		**12.2**	**16.0**	**0.2**	**28.1**	**7.3**

CORE TEMPERATURE

The mean core temperatures of all the seven subjects during the baseline period were 37.23 ± 0.3°C (for shivering-only), 37.11 ± 0.3°C (for Fluidotherapy®) and 37.20 ± 0.4°C (for warm water) with no difference between the three conditions. The rate of core cooling for the last 20 minutes of cooling was also statistically similar in all the three conditions. During cooling, the mean exit core temperature was similar in all the three

conditions (35.9 $\pm$ 1°C for shivering-only, 35.9 $\pm$ 1°C for Fluidotherapy® and 36.0 $\pm$ 1°C for warm water) (Table 3).

The core temperature afterdrop in all the three conditions were also similar (0.59°C for shivering-only, 0.69°C for Fluidotherapy® and 0.59°C for warm water) (Table 2). In three trials (two for one subject and one for another subject), the subjects did not return to their respective exit core temperatures during rewarming (Figure 5). These subjects were excluded for calculating the mean length of afterdrop duration. There was no significant difference in the duration of core temperature afterdrop periods among the three conditions.

The rewarming rate in the warm water condition (6.1 $\pm$ 2°C/h) was significantly higher ($p<0.01$) than the other two conditions (2.0 $\pm$ 1°C/h for shivering-only and 2.2 $\pm$ 1°C/h for Fluidotherapy®).

In order to see if there was an effect of higher BMI on the overall results, five subjects with BMI<30 were also analyzed separately. The relative results for these five subjects for T_{co} afterdrop, afterdrop duration and rewarming rate were similar to the overall results.

Table 2: Esophageal temperature data (afterdrop, afterdrop length and rewarming rate) for five subjects (with BMI<30) and all seven subjects.

† In three trials (two for one subject and one for another), the core temperature did not return to exit temperature and continued in the afterdrop period throughout the rewarming phase. Therefore, the overall means presented are for five subjects (instead of seven subjects) with all three afterdrop length values. Also mean for subjects with BMI<30 are for four subjects (instead of five subjects) with all three afterdrop length values.

*significantly different from shivering-only and Fluidotherapy® (P<0.05)

**significantly different from shivering-only and Fluidotherapy® (P<0.01)

Subject	Afterdrop (°C)			Afterdrop length (min)			Rewarming rate (°C/h)		
	SO	FL	WW	SO	FL	WW	SO	FL	WW
1	0.54	0.69	0.44	16	39.5	33	2.86	2.36	4.84
3	0.91	0.73	0.53	38	45.5	24	2.90	2.13	7.85
5	0.56	0.76	0.32	†	†	18†	0.30	1.58	3.33
6	1.16	1.40	1.21	46.5	59.5	28.5	2.97	3.74	8.87
7	0.04	0.26	0.06	6	16	5	3.34	3.80	4.12
Mean (SD) (n=5)	0.64 (0.4)	0.77 (0.4)	0.51 (0.4)	26.62 (18.8)	40.12 (18.1)	22.62 (12.3)	2.47 (1.2)	2.72 (1.0)	5.80 (2.4)*
2	0.42	0.92	1.04	26†	†	27.5†	0.96	1.68	7.86
4	0.46	0.04	0.52	18	6	28.5	0.61	0.06	6.00
Mean (SD) (n=7)	0.59 (0.4)	0.69 (0.4)	0.59 (0.4)	24.9 (16.8)	33.3 (21.9)	23.8 (11.0)	1.99 (1.3)	2.19 (1.3)	6.12 (2.1)**

SO, Shivering-only; FL, Fluidotherapy®; WW, Warm water

Figure 4. Mean change in esophageal temperature (°C) for all three conditions (bars, SD); time 0 and 0°C temperature indicate exit from the 8°C water. One subject (in all three trials) cooled to the target T_{es} of 35°C in less than 60 minutes (ranging from 38 to 46 minutes). To show how all the subjects responded to cold water immersion, the data for this subject is presented for the first 17.5 minutes and last 20 minutes so that the exit is lined up at the same time. As a result, n = 7 for baseline, the first 17.5 minutes and for the last 20 minutes of cooling and n ranges from 6 to 7 for the cooling period between 17.5 and 40 minutes.

* Significantly different rewarming rate from other conditions ($p<0.01$).

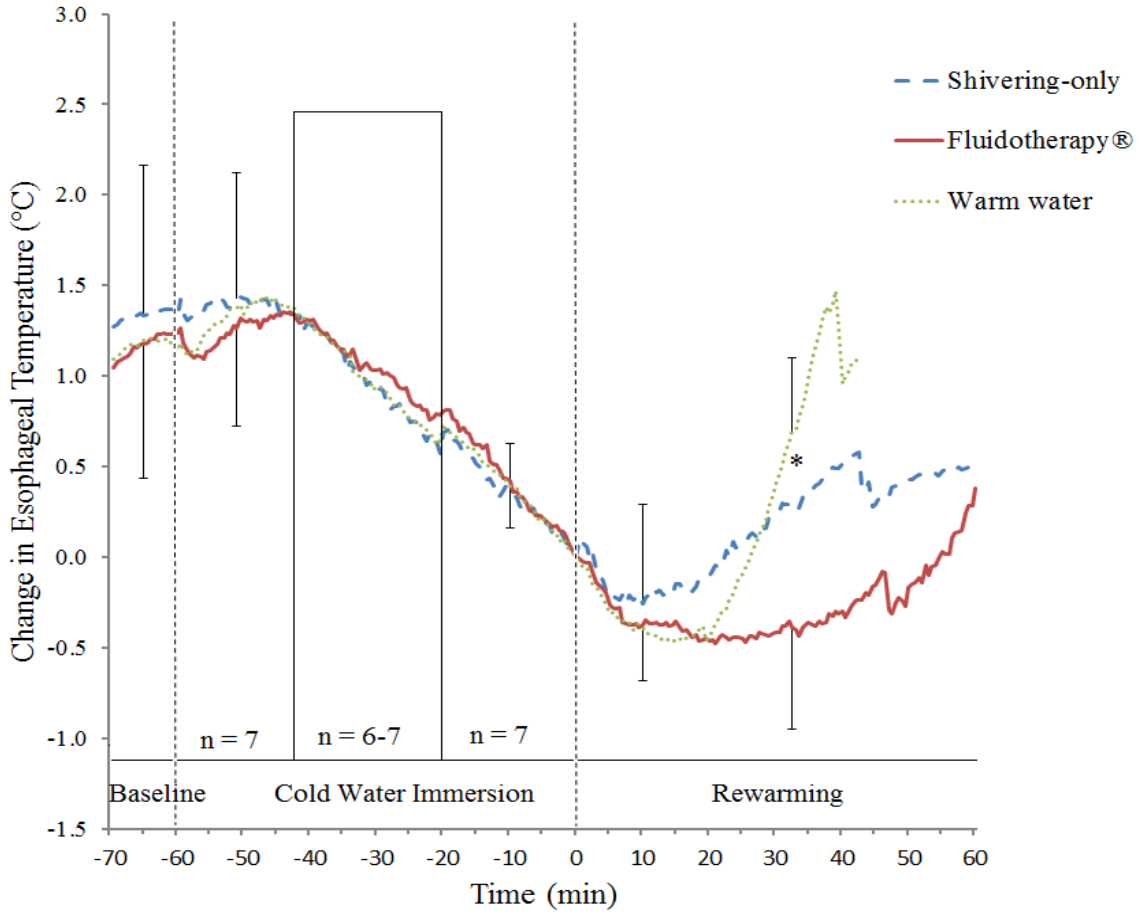


Figure 5. Change in esophageal temperature for the seven subjects during the rewarming period in the shivering-only, Fluidotherapy® and warm water conditions. Subjects with BMI > 30 are indicated with an asterisk (*)

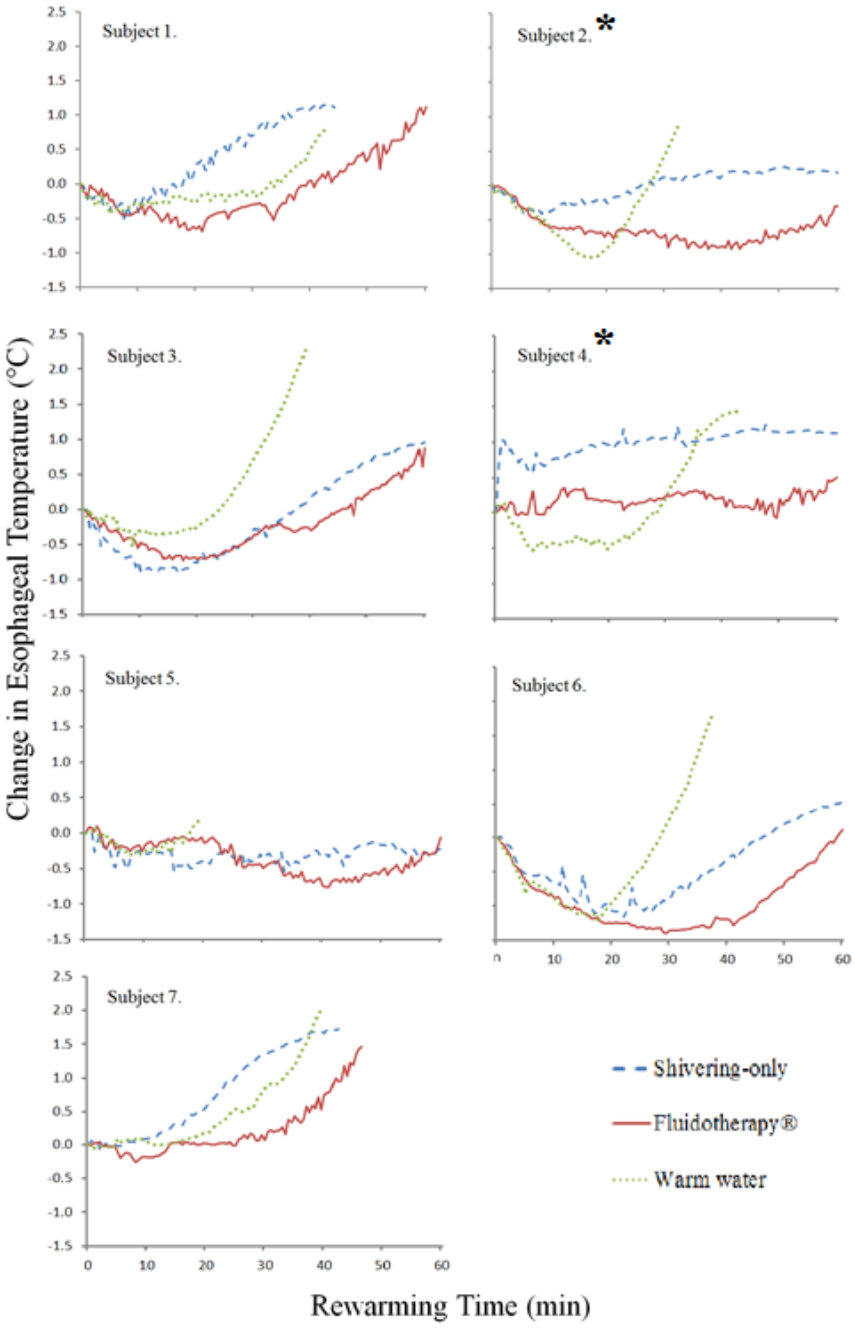


Table 3: Duration of cooling and the exit esophageal temperature for the seven subjects during the shivering-only, Fluidotherapy® and warm water conditions.

Subject	Duration of cooling (min)			Exit T_{es} (°C)		
	Shivering -only	Fluidotherapy®	Warm water	Shivering -only	Fluidotherapy®	Warm water
1	60.0	60.0	60.0	35.8	35.4	36.2
2	60.0	60.0	60.0	37.3	37.1	37.0
3	43.5	38.0	46.0	35.0	35.0	34.9
4	60.0	60.0	60.0	35.0	36.1	35.8
5	60.0	60.0	60.0	37.1	36.8	36.8
6	60.0	60.0	60.0	35.5	35.7	35.6
7	60.0	60.0	60.0	35.6	35.5	35.5
Mean	**57.6**	**56.9**	**58.0**	**35.9**	**35.9**	**36.0**
SD	**6**	**8**	**5**	**1**	**1**	**1**

The core temperature of all the seven subjects returned to 37°C in the warm water rewarming condition within 60 minutes (Table 4). However, only two subjects in the shivering-only and one subject in Fluidotherapy® returned to 37°C within the 60 minutes of rewarming.

Table 4. The rewarming durations (min) for seven subjects in the shivering-only, Fluidotherapy® and warm water conditions.

Subject#	Shivering-only	Fluidotherapy®	Warm water
1	44.0	60.0	42.5
2	60.0	60.0	32.5
3	60.0	60.0	39.0
4	60.0	60.0	42.5
5	60.0	60.0	19.0
6	60.0	60.0	37.5
7	42.5	46.5	39.5
Mean	**55.2**	**58.1**	**36.1**
SD	**8**	**5**	**8**

HEART RATE

There were no significant differences in heart rates between the three conditions during the baseline, cooling and rewarming phases. The mean heart rate was 76.2 ± 10 b/min during baseline, 75.7 ± 10 b/min during the final 20 minutes of cooling, and 84.0 ± 11 b/min over the 60 minutes of rewarming.

AVERAGE SKIN TEMPERATURE AND HEAT FLUX

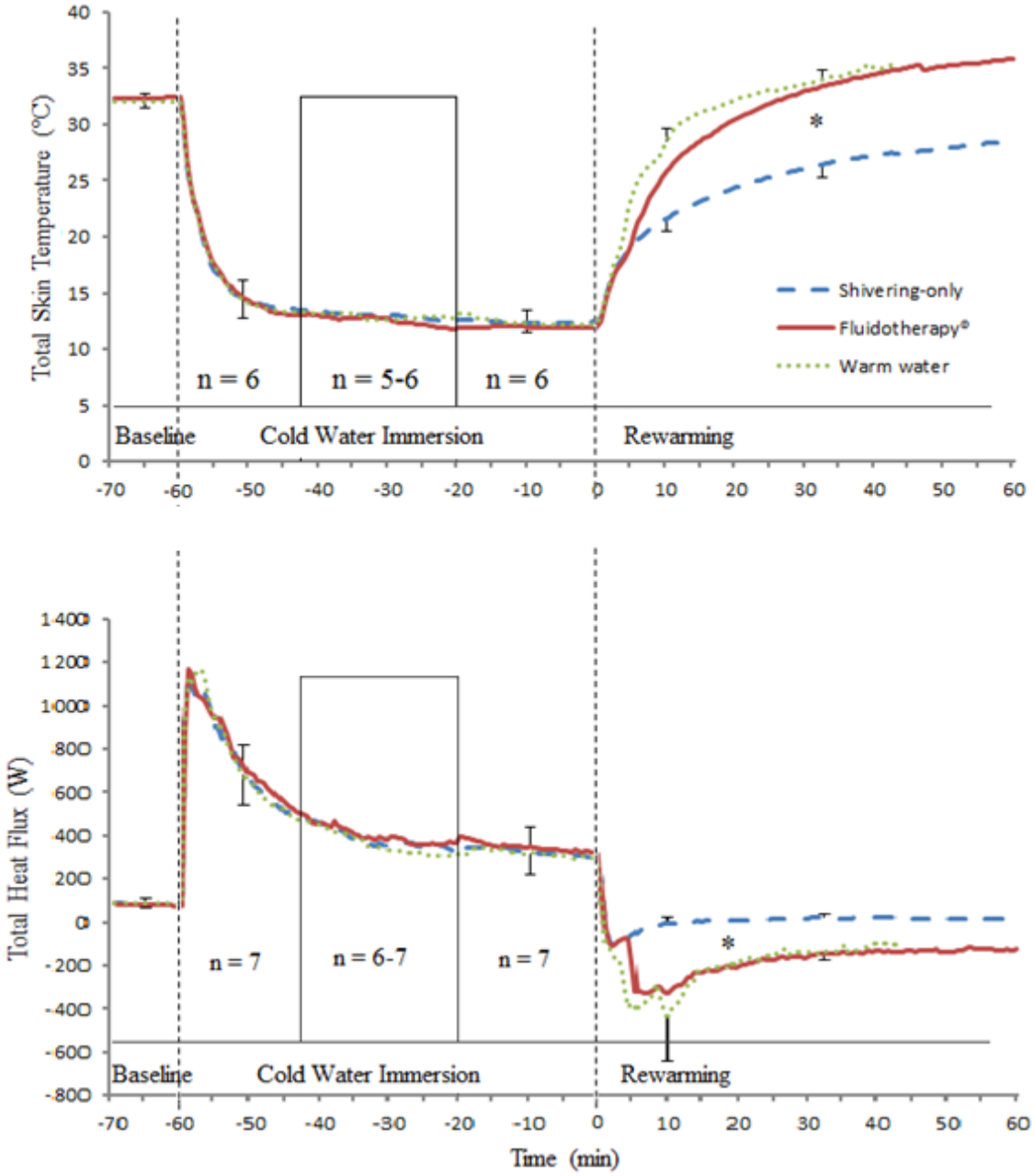
The anterior torso temperature for one subject was unexplainably 10°C lower in one trial compared to her other two trials and all the other subjects. Therefore, the chest and total skin temperatures for this subject were removed for all 3 conditions. There

were no significant differences in the average skin temperature between the three conditions (shivering-only, Fluidotherapy® and warm water) at baseline and in the cooling phase (n=6, Figure 6). During the rewarming, average skin temperature for shivering-only condition (24.6 ± 1°C) was significantly ($p<0.01$) lower than Fluidotherapy® (30.6 ± 1°C) and warm water conditions (29.5 ± 2°C). However, there were no skin temperature differences between the Fluidotherapy® and warm water conditions.

Similarly there were no significant differences in the heat flux between the three conditions (shivering-only, Fluidotherapy® and warm water) at baseline and in the cooling phase. The mean heat flux in the rewarming phase for shivering-only condition (5.1 ± 22 W) was significantly ($p<0.01$) lower than Fluidotherapy® (-169.0 ± 33 W) and warm water conditions (-222.1 ± 72 W). The mean heat flux was similar between the Fluidotherapy® and warm water conditions.

Figure 6. Mean values for total skin temperature and total heat flux for three conditions (bars, SD).

* Significant differences between conditions ($p<0.01$).

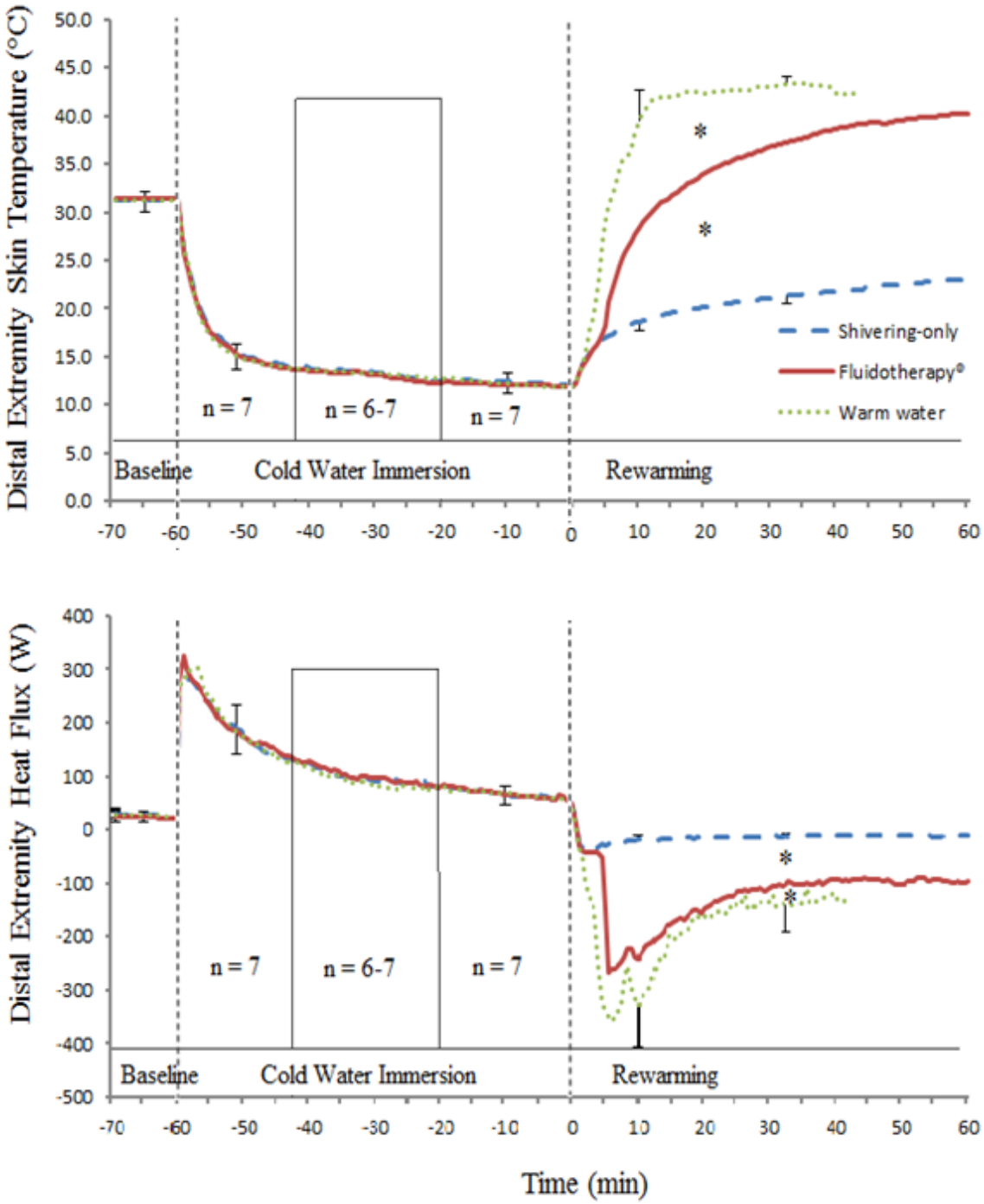


DISTAL EXTREMITIES SKIN TEMPERATURE AND HEAT FLUX

There were no significant differences in the distal extremities skin temperature and heat flux between the three conditions in the baseline and cooling phases (Figure 7). The mean values for distal extremities skin temperature and heat flux for the entire rewarming period were significantly different ($p<0.01$) in all the three conditions. The distal extremity skin temperature were lowest in the shivering-only condition (20.3 ± 1°C) followed by Fluidotherapy® (33.9 ± 2°C) and warm water (38.3 ± 1°C) conditions. The distal extremity heat flux was less in the shivering-only condition (-14.9 ± 6 W) followed by Fluidotherapy® (-123.2 ± 19.2 W) and warm water conditions (-192.1 ± 45 W).

Figure 7. Mean distal extremities skin temperature and heat flux (bars, SD).

* Significantly different ($p<0.01$).

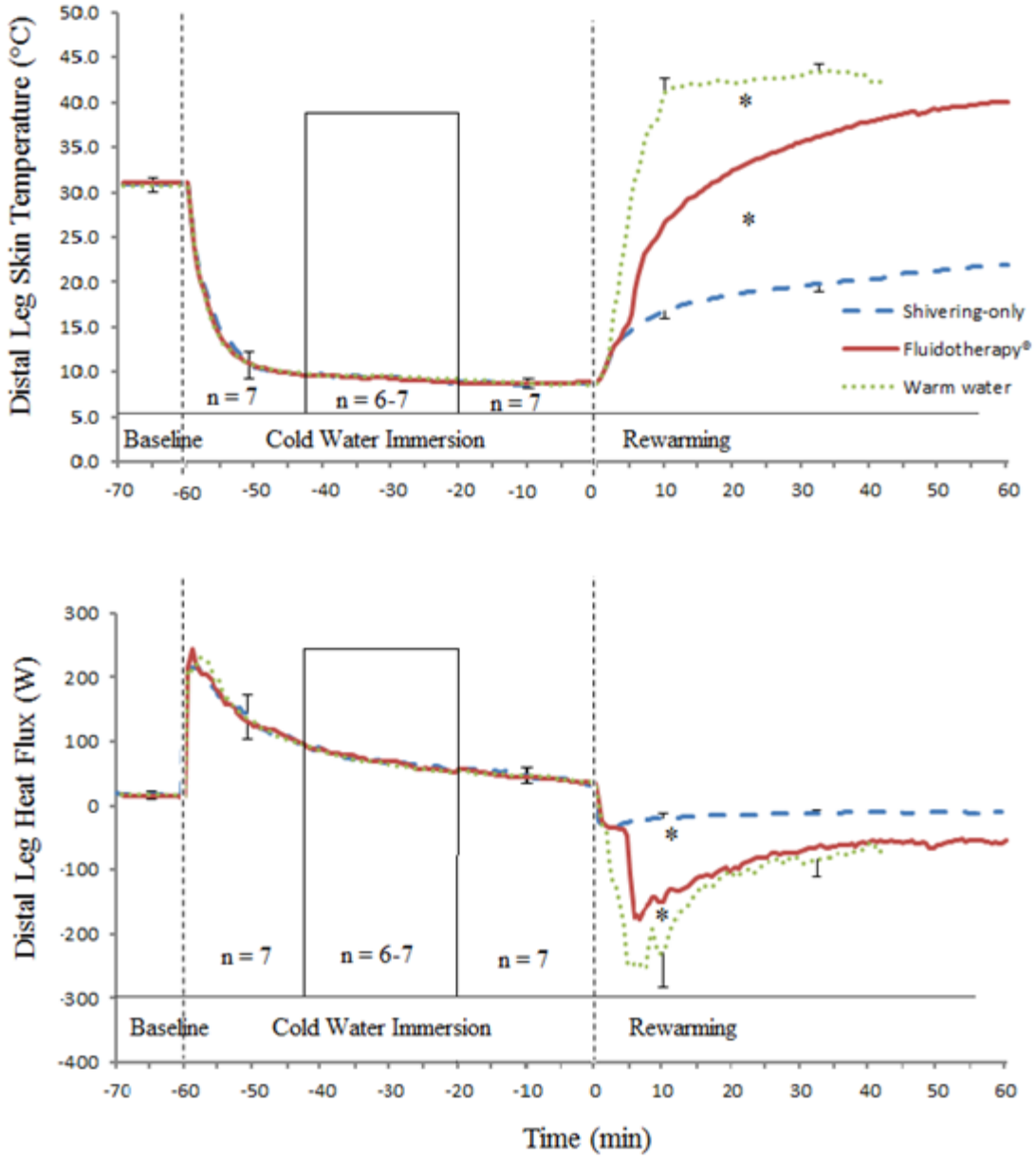


DISTAL LEG SKIN TEMPERATURE AND HEAT FLUX

There were no significant differences in the distal leg skin temperature and heat flux between the three conditions in the baseline and cooling phases (Figure 8). The mean values for distal leg skin temperature and heat flux for the entire rewarming period were significantly different ($p<0.01$) in all the three conditions. The distal leg skin temperature and heat flux were lowest in the shivering-only condition followed by Fluidotherapy® and warm water conditions.

Figure 8. Mean distal leg skin temperature and heat flux (bars, SD).

* Significantly different from other conditions ($p<0.01$).

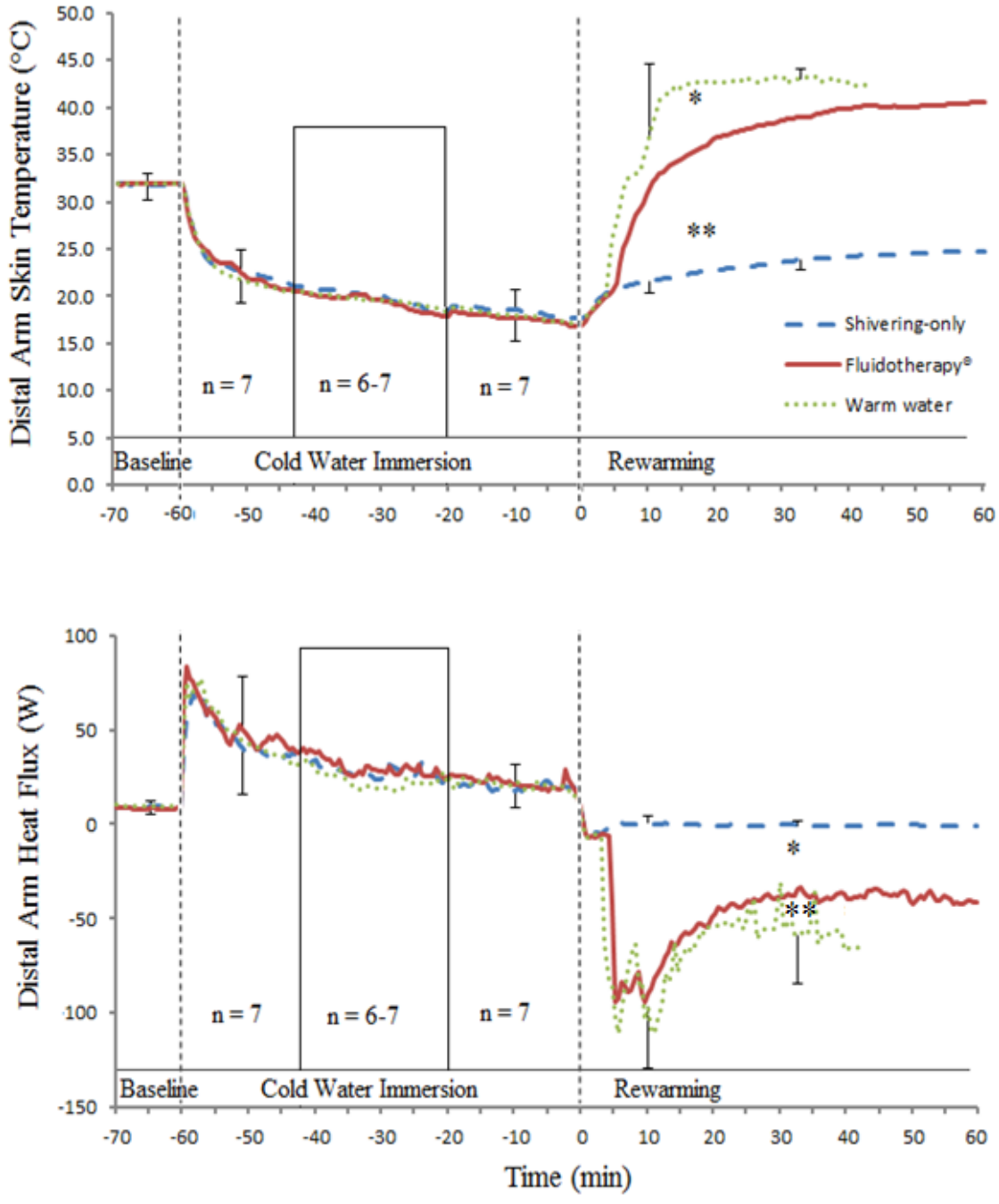


DISTAL ARM SKIN TEMPERATURE AND HEAT FLUX

There were no significant differences in the distal arm skin temperature and heat flux between the three conditions in the baseline and cooling phases (Figure 9). The mean values for distal arm skin temperature and heat flux for the entire rewarming period were significantly different ($p<0.01$ between shivering-only and other conditions; $p<0.05$ between Fluidotherapy® and warm water conditions) in all the three conditions. The distal arm skin temperature and heat flux was lowest in the shivering-only condition followed by Fluidotherapy® and warm water conditions.

Figure 9. Mean distal arm skin temperature and heat flux (bars, SD).

* Significantly different ($p<0.01$). ** Significantly different ($p<0.05$).

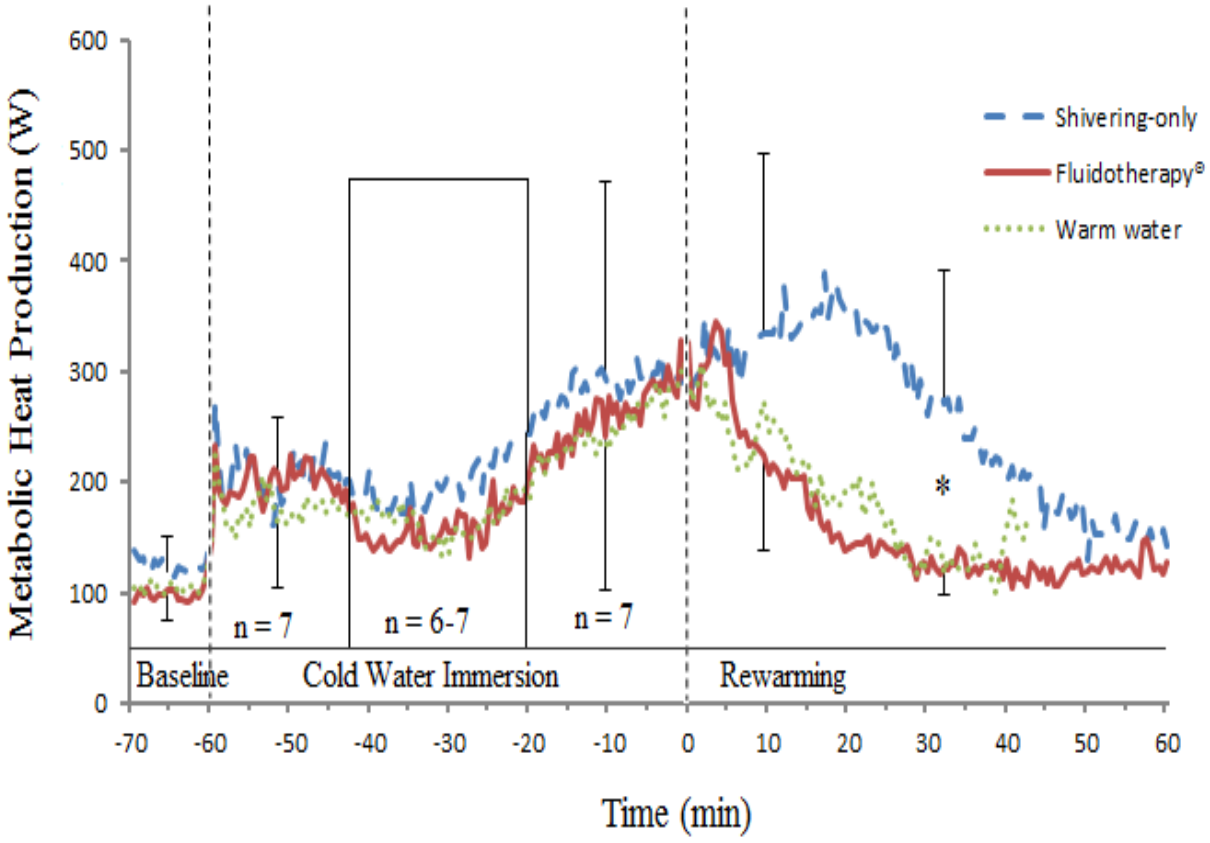


METABOLIC HEAT PRODUCTION

There were no significant differences in metabolic heat production between the three conditions in the baseline and cooling phases (Figure 10). During rewarming, the average metabolic heat production was significantly higher in the shivering-only condition (279.9 ± 122 W) compared to the Fluidotherapy® (162.4 ± 34 W) and warm water (188.1 ± 41 W) conditions ($p<0.05$). There were no significant differences in the metabolic heat production between the Fluidotherapy® and warm water conditions.

Figure 10. Mean metabolic heat production (bars, SD).

* Significantly different metabolic heat production ($p<0.05$).



NET HEAT GAIN

There were no significant differences in net heat gain between the three conditions in the baseline and cooling phases (Figure 11). During rewarming phase, the average net heat gain was significantly higher in the warm water condition (393.2 ± 45 W) compared to the shivering-only (249.6 ± 101 W) condition ($p<0.05$). There were no significant differences in the net heat gain between the Fluidotherapy® (162.4 ± 34 W) and the other two conditions.

Figure 11. Mean net heat gain in the shivering-only, Fluidotherapy® and warm water conditions (bars, SD).

* Significantly different between the shivering-only and warm water conditions ($p<0.05$).

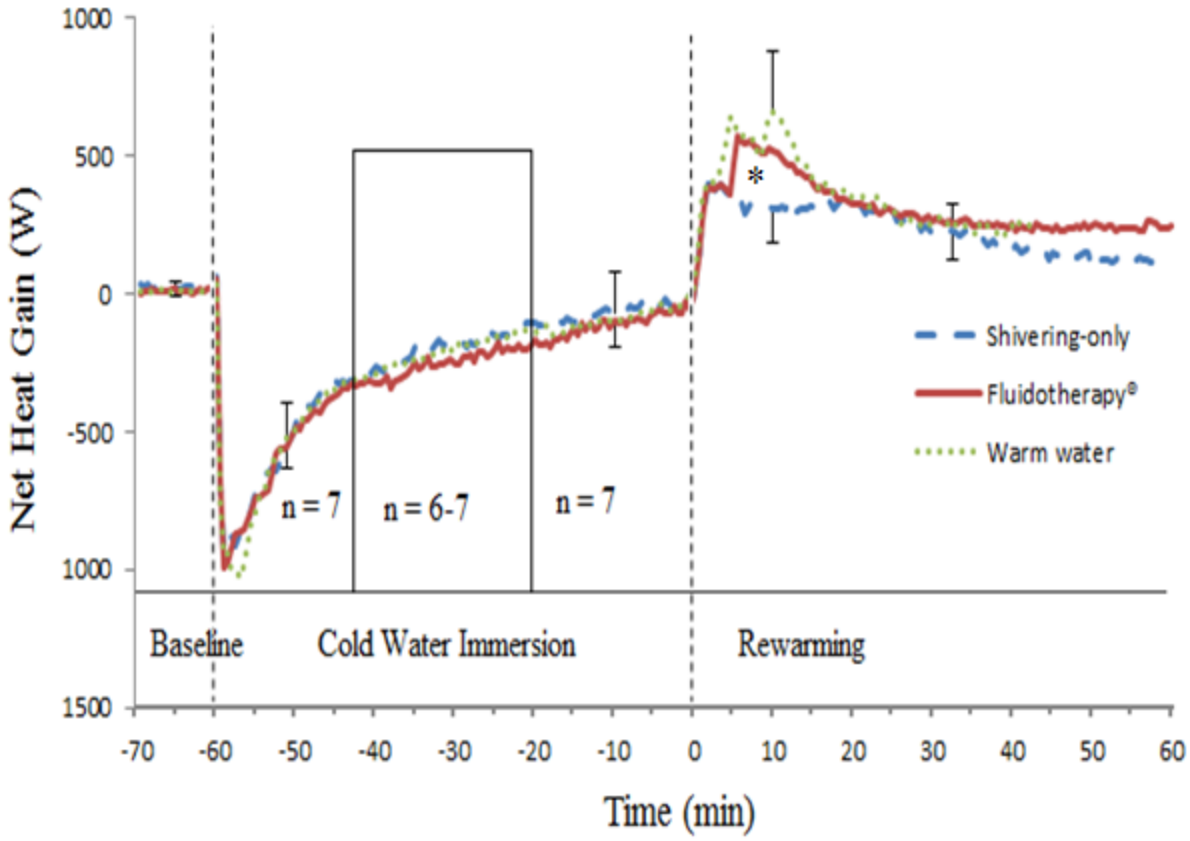


Table 5. Mean metabolic heat production and heat transfer (Q) values (W) for three rewarming conditions from 5 to 35 minutes of rewarming because the average duration of warm water rewarming phase was 36 minutes; lowest among the three rewarming conditions.

* Significantly different from shivering only ($p<0.05$). ** Significantly different from shivering only ($p<0.01$). # Significantly different from Fluidotherapy® ($p<0.05$).

	Shivering-only	Fluidotherapy® (46.1 ± 1°C)	Warm water (44.1 ± 1°C)
Metabolic heat production	322.2 ± 142	166.2 ± 42*	180.8 ± 45*
Respiratory heat loss	29.0 ± 13	15.0 ± 4*	16.3 ± 4*
Q (distal extremities)	-15.8 ± 6	-158.4 ± 23**	-205.3 ± 42**#
Q (anterior torso)	8.1 ± 9	-26.9 ± 16**	-6.0 ± 14#
Q (Total)	4.8 ± 23	-215.4 ± 38**	-233.5 ± 70**
Net heat gain	288.4 ± 115	366.6 ± 47	398.0 ± 52*

SUBJECTS' OPINIONS

Five out of the seven subjects had lower back pain during the rewarming treatments. Three subjects felt that the water was too hot to get into and one of them mentioned that it was associated with the initial feeling of pins and needles. In contrast, Fluidotherapy® was referred to as relaxing and soothing in the initial phase of the rewarming period by two of the subjects. However, apart from the initial discomfort, warm water was the treatment of choice by six of the seven subjects.

DISCUSSION

This study was the first to use Fluidotherapy® application to the distal extremities for hypothermia rewarming and compare it to distal extremities rewarming with warm water, and shivering-only. Seven subjects were cooled in three different trials in 8°C water, for either 60 minutes or until their T_{es} decreased to 35°C. In each of these trials, each subject was rewarmed with either shivering-only, distal extremities in Fluidotherapy®, or warm water for either a maximum of 60 minutes or until their T_{es} reached 37°C. Both Fluidotherapy® and warm water rewarming resulted in increased skin temperature of the distal extremities, and thereby inhibited shivering. The warm water condition provided more heat donation through distal extremities compared to the Fluidotherapy® and shivering-only conditions, and a higher net heat gain compared to shivering-only condition. The warm water condition led to a three times higher rewarming rate compared to the other two conditions.

As more subcutaneous fat can play a role in the rewarming rates,[88] this study also analyzed afterdrop, afterdrop length and rewarming rate for subjects with BMI < 30. The relative results were similar to the overall results indicating warm water provided highest rewarming rate compared to other two rewarming methods.

We hypothesized that Fluidotherapy® would provide more heat, have less shivering heat production, have a smaller T_{co} afterdrop, and provide a higher rewarming rate compared to warm water and shivering-only conditions. These hypotheses were not supported by our results, as Fluidotherapy® provided a lower net heat gain and rewarming rates compared to the warm water condition. There was no significant difference in the T_{co} afterdrop between the three conditions. Our hypothesis that Fluidotherapy® would

have less shivering heat production than with warm water immersion was also not supported by the results. Thus, overall, Fluidotherapy® did not provide more heat, less shivering heat production, less afterdrop or higher rewarming rate compared to warm water immersion.

RELATION TO PREVIOUS LITERATURE

There was no significant difference in T_{co} afterdrop between the three conditions. These values (0.6 – 0.7°C) are consistent with other rewarming conditions in which the shivering mechanism was intact.[14, 15, 24] Fluidotherapy® provided a rewarming rate similar to shivering-only, and consistent with the rewarming rates of other superficial rewarming modalities such as forced air rewarming and body-to-body rewarming.[14, 15]

Consistent with previous studies, there was increased metabolic heat production and respiratory heat loss in the shivering-only condition.[12, 24] Shivering-only provided a rewarming rate of 2.0°C/h, which was lower than previous studies conducted in our lab [14, 15, 24] where shivering-only provided rewarming rates ranging from 2.4°C to 3.5°C/h. However, it is important to note that the mean exit T_{co} in the present study (35.9°C) was higher than that in previous studies where it was 33.9°C/h (with a rewarming rate of 3.5°C/h),[12] 34.3°C/h (with a rewarming rate of 3.4°C/h),[24] 35°C (with a rewarming rate of 3.0°C/h),[15] and 34.6°C (with a rewarming rate of 2.4°C/h).[14] In these studies the rewarming curve is steeper initially with a higher rewarming rate (3.0 to 3.5°C/h) with an inflection to a lower rewarming rate (1.5 to 2.0°C/h) at T_{co} of approximately 36°C. In the present study with a mean exit T_{co} of 35.9°C there was no inflection in the mean rewarming curve for the shivering-only condition. This was consistent with the latter period of rewarming (after T_{es} of 36°C) of the previous studies.

In the present study, the warm water condition was associated with the highest rewarming rate of 6.1°C/h and a high heat transfer to distal extremities. This is consistent with the previous study done in our lab.[24] The Fluidotherapy® rewarming rate was not higher than the warm water condition, but was comparable to shivering-only and other external heating conditions.[14, 15, 24]

POSSIBLE MECHANISMS FOR THE RESULTS

Fluidotherapy® did not provide greater heat donation than warm water. This study intended to apply Fluidotherapy® at a temperature 5°C higher than warm water (50°C vs 45°C), however none of the subjects tolerated the proposed temperature of 50°C with Fluidotherapy®. The warmest mean temperatures that subjects could tolerate were 46.1°C (Fluidotherapy®) and 44.1°C (warm water). Thus, the temperature difference between these treatments was approximately 2°C instead of the proposed 5°C. A previous study on normothermic individuals used Fluidotherapy® at a temperature of 48°C,[27] but only hands or feet were warmed at the same time. The fact that all four extremities including the lower arms and legs were warmed at the same time might explain why subjects could not tolerate higher temperatures in the present study. Also, high temperature tolerance with Fluidotherapy® depends on pain gait mechanism through stimulation of skin mechanoreceptors.[25] In the present study, the skin temperature of the subjects was lower after the cooling phase compared to a previous study done on normothermic individuals. Cold skin has been shown to have an inhibitory effect on skin mechanoreceptors.[89] Thus, the inhibition of mechanoreceptors with cooling might have resulted in reduced temperature tolerance with Fluidotherapy®.

At same temperature, the thermal conductivity of water is approximately 25 times that of air. Although the thermal conductivity of cellulose particles in air is not known, but it would be greater than air and less than water. Because we were not able to obtain a very large treatment temperature difference between Fluidotherapy® and warm water treatments (2°C only), it is not surprising that heat transfer in warm water was more than Fluidotherapy® rewarming. Although the target surface areas in both Fluidotherapy® and warm water immersion were about the same, with Fluidotherapy®, the area may not be as uniform as in the warm water immersion. This factor might have played a role in obtaining lesser heat transfer with Fluidotherapy®.

Metabolic heat production in the shivering-only condition (322 W) was significantly higher than that in the Fluidotherapy® (166 W) and warm water (181 W) conditions. Consistent with previous studies external heat application led to an increased T_{skin} and thereby decreased shivering heat production.[15, 24]

The rewarming rate depends upon metabolic heat production, the amount of external heat provided to the body, and the size of the effective perfused mass (e.g. thermal core). The rewarming effect of a given amount of heat increases as it is applied to a smaller perfused mass. Both the Fluidotherapy® and the warm water conditions provided similar metabolic heat production. Given the fact that heat donation was actually 9% greater with the warm water than Fluidotherapy®, it is not surprising that the rewarming rate was higher with warm water immersion. However, this small increase in heat donation does not explain the magnitude of the increase (threefold) in rewarming rate. Also, the net heat gain in warm water condition was 31W higher but not significant. The effective perfused mass is controlled by body's thermoregulation (depending upon

the skin and core temperatures) and physical forces. Since mean skin temperature and core temperature were similar during early rewarming (first 20 minutes), therefore different effective perfused mass is not expected. But the physical forces of water (hydrostatic pressure) on distal extremities may have led to decreased limb blood volume and/or flow contributing to a smaller effective perfused mass than with Fluidotherapy®. Decreased effective perfused mass with similar heat donation may have contributed to higher rewarming rates in the warm water condition compared to the Fluidotherapy®.

Similar to the previous study with distal extremities warm water immersion, the rewarming rates in the warm water condition in the present study were three times higher than the shivering-only condition. However warm water rewarming rates in the present study (6.1°C/hour) were lower than the previous study (9.9°C/hour). This could be partly due to the fact that average water temperature in the present study was 44°C (instead of 45°C used in the previous study) and the exit T_{co} during cooling was lower in the previous study (34.3°C) compared to the present study (36°C). At T_{co} of 36°C, the thermal core of the body (affected by both T_{skin} and T_{co}) is greater compared to that at T_{co} of 34.3°C. Therefore same heat donated to a greater mass might have led to a slower rewarming rate.

PRACTICAL IMPLICATIONS

Based on the results of the present study, Fluidotherapy® is not a recommended treatment for mild hypothermia as it decreases shivering heat production, provides low rewarming rate, and increases the duration of T_{co} afterdrop period.

Warm water rewarming because of its benefits can be used in hypothermia rewarming. Also, it might not be practical to rewarm severely hypothermic patients in this forward bent sitting position, as most severely hypothermic patients are unconscious and this position may be difficult to achieve and maintain in that population.

LIMITATIONS

Because of some technical problems, the metabolic system failed in one of the trials during the cooling period; the system was restarted and 13 minutes of data was lost. Data for this period was extrapolated based on the trend of values before and after the failure.

Fluidotherapy® rewarming was applied to a body surface area that was less than in warm water (hands and forearms up to the level of elbow, and feet and lower legs up to the level of knee). The height of Fluidotherapy® chamber prevented the immersion of distal extremities in the agitated cellulose to these levels. This study still compared both Fluidotherapy® and warm water at their maximum potential.

The participants in this study were young and healthy, which is not a representation of the whole population. In other population comparatively similar results are expected, although the absolute rates may differ (e.g. disease states causing reduced limb blood flow may result in lower heat transfer and therefore lower rewarming rates).

The planned Fluidotherapy® temperature of 50°C could not be tolerated. This could be because more surface area was heated in the present study (all four distal extremities) compared to the previous study (with only hands or feet). This study still used Fluidotherapy® at its maximum potential.

FUTURE RECOMMENDATIONS

Hypothermia rewarming study with distal extremities immersion in a position, that is easily tolerated by to the subjects (sitting or supine lying) can be done in the future, to find an easier rewarming position for the victim.

A study to understand the effect of different exit core temperatures from cold water on rewarming rates can be done in future to better understand human thermoregulation.

CONCLUSION

The results of the present study indicate that distal extremities immersion in warm water provided higher heat donation to distal extremities and higher rewarming rates compared to Fluidotherapy® and shivering only; and higher net heat gain compared to shivering-only. Fluidotherapy® decreased shivering heat production, provided higher heat donation through the distal extremities, and overall led to a similar rewarming rate compared to shivering-only.

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APPENDICES

APPENDIX A

UNIVERSITY OF MANITOBA | BANNATYNE CAMPUS
Research Ethics Boards

P126 - 770 Bannatyne Avenue
Winnipeg, Manitoba
Canada R3E 0W3
Telephone 204-789-3255
Fax 204-789-3414

BIOMEDICAL RESEARCH ETHICS BOARD (BREB)
CERTIFICATE OF FINAL APPROVAL FOR NEW STUDIES
Full Board Review

PRINCIPAL INVESTIGATOR:	INSTITUTION/DEPARTMENT:	ETHICS #:
Dr. G. Giesbrecht	UofM / Kinesiology and Recreation Management	B2013:039
BREB MEETING DATE:	**APPROVAL DATE:**	**EXPIRY DATE:**
March 25, 2013	April 8, 2013	March 25, 2014
STUDENT PRINCIPAL INVESTIGATOR SUPERVISOR (If applicable):		

PROTOCOL NUMBER:	PROJECT OR PROTOCOL TITLE:
NA	Hypothermia rewarming effectiveness of distal limb warming with either Fluidotherapy or warm water immersion (Linked to B2012:024)
SPONSORING AGENCIES AND/OR COORDINATING GROUPS: NSERC	

Submission Date(s) of Investigator Documents:	REB Receipt Date(s) of Documents:
March 11 and April 4, 2013	March 11 and April 5, 2013

THE FOLLOWING ARE APPROVED FOR USE:

Document Name	Version(if applicable)	Date
Protocol:		
Protocol	2	Apr 4, 2013
Consent and Assent Form(s):		
Research Participant Information and Consent Form		13/04/04
Other:		
PAR-Q & YOU Questionnaire		2002
Script to be read out loud for recruitment purposes		Mar. 08, 2013
Participant inclusion interview questions		Mar. 08, 2013

CERTIFICATION
The University of Manitoba (UM) Biomedical Research Board (BREB) has reviewed the research study/project named on this ***Certificate of Final Approval*** at the ***full board meeting*** date noted above and was found to be acceptable on ethical grounds for research involving human participants. The study/project and documents listed above was granted final approval by the Chair or Acting Chair, UM BREB.

BREB ATTESTATION
The University of Manitoba (UM) Biomedical Research Board (BREB) is organized and operates according to Health Canada/ICH Good Clinical Practices, Tri-Council Policy Statement 2, and the applicable laws and regulations of Manitoba.

In respect to clinical trials, the BREB complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations of Canada and carries out its functions in a manner consistent with Good Clinical Practices.

QUALITY ASSURANCE

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

CONDITIONS OF APPROVAL:

1. The study is acceptable on scientific and ethical grounds for the ethics of human use only. ***For logistics of performing the study, approval must be sought from the relevant institution(s).***
2. This research study/project is to be conducted by the local principal investigator listed on this certificate of approval.
3. The principal investigator has the responsibility for any other administrative or regulatory approvals that may pertain to the research study/project, and for ensuring that the authorized research is carried out according to governing law.
4. **This approval is valid until the expiry date noted on this certificate of approval. A Bannatyne Campus Annual Study Status Report** must be submitted to the REB within 15-30 days of this expiry date.
5. Any changes of the protocol (including recruitment procedures, etc.), informed consent form(s) or documents must be reported to the BREB for consideration in advance of implementation of such changes on the **Bannatyne Campus Research Amendment Form.**
6. Adverse events and unanticipated problems must be reported to the REB as per Bannatyne Campus Research Boards Standard Operating procedures.
7. The UM BREB must be notified regarding discontinuation or study/project closure on the **Bannatyne Campus Final Study Status Report**.

Sincerely,

Lindsay Nicolle, MD, FRCPC
Chair, Biomedical Research Ethics Board
Bannatyne Campus

Please quote the above Human Ethics Number on all correspondence.
Inquiries should be directed to the REB Secretary **Telephone:** (204) 789-3255/ **Fax:** (204) 789-3414

APPENDIX B

MEDICAL SCREENING

Physical Activity Readiness Questionnaire (PAR-Q)

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 ever faint or do you lose your balance because of dizziness?
☐	☐	5. Do you have a bone or joint problem 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?

Although your participation is voluntary, in consideration of permitting you to participate in the program, you must sign your name in the space below, which will evidence and indicate that you agree to be bound by the following Release:

I hereby release and discharge the University of Manitoba, the Recreation Services, the Instructors or the Program (The University), from and for all and any actions, claims and demands by me and my Heirs, Executors, or Assigns, for, upon, or by reason of omission of the University in this Program. I also authorize the University to take photographs during Recreation Services activities, and to display and otherwise use these photographs without charge solely for the purpose of promotional material in connection with Recreation Services.

Signature_____ Date_____

(of Participant or the Participant's legal guardian if under 18)

APPENDIX C

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: Hypothermia rewarming effectiveness of distal limb warming with either Fluidotherapy or warm water immersion.

Protocol number:	NSERC Discovery Grant (2010-16)
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

You are being asked to participate in a Clinical Trial (a human research study). Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this clinical trial and you may discuss it with your regular doctor, friends and family before you make your decision. This consent form may contain words that you do not understand. Please ask Dr. Giesbrecht or his study staff to explain any words or information that you do not clearly understand.

The Principle Investigator (Dr. Giesbrecht) is receiving financial support (from the Natural Sciences and Engineering Research Council) to conduct this study.

Public registration of the study

A description of this clinical trail is available on http://ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Hypothermia rewarming effectiveness of distal limb warming with either Fluidotherapy or warm water immersion.

Purpose of Study

This Clinical Trial is being conducted to study rewarming methods for mild hypothermia. 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 eight participants will participate in this study.

The purpose of this study is to compare the core rewarming effectiveness of the Fluidotherapy and warm water immersion in rewarming of mildly hypothermic individuals.

This research is being done because Fluidotherapy has been previously shown as more effective in heat donation in humans at normal temperature. This benefit can help to treat hypothermia victims, but it has never been studied in hypothermic conditions.

Study procedures

The order of experiments will follow a randomized balanced design. The order of the three rewarming methods will be randomly assigned to each participant so that all participants have a different order of treatments. This design allows the researchers to ensure that all participants do not undergo the experiments in an exactly same order.

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:

You will be asked to participate in three experimental trials on three separate occasions, separated by at least 48 hours. On each of the three trials, you will be submersed in 21˚C water up to the level of the sternal notch. The water temperature will then be lowered to 8˚C over a period of 5-10 min by addition of ~60 kg of ice. You will remain in the water until either:

1) You wish to exit;
2) The investigator or physician advises stopping for safety or other reasons;
3) Your core body temperature decreases to 35˚C; or
4) 60 minutes of immersion elapses, whichever comes first.

You will then exit the water, be dried off and one of the three warming procedures will be administered:

A. Spontaneous rewarming (Shivering only) - In this control condition, no external heat will be provided and you will rewarm spontaneously with the heat produced from shivering. You will be covered with a sleeping bag.

B. Distal extremity rewarming with Fluidotherapy: After drying off, you will be made to sit on a chair and insert your legs till knee and arms till elbow into a warm Fluidotherapy chamber at 50℃. The cellulose particles inside the Fluidotherapy chamber will move with air to give you heat. A blanket will be put over your back and shoulder.

C. Distal extremity rewarming with warm water: After drying off, you will be made to sit on a chair and insert your legs till knee and arms till elbow into warm water kept at 45℃. A blanket will be put over your back and shoulder.

Treatment will continue either for a period of 60 minutes or until your core temperature returns to normal values (~36.5-37˚C). Following that, you will be placed in a warm water bath (40-42˚C), until you are comfortable and core temperature returns to normal values (~36.5-37˚C).

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

- You will be visiting the laboratory 3 times in a period of up to 4 months. You will be required to visit at same time of the day, during weekdays.
- You will be asked to complete a PAR-Q-Activity questionnaire prior to participating. An example of questions asked in PAR-Q is**:** Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor? You will also be asked a series of verbal questions to determine if you have any cardiorespiratory disease or any conditions that are stimulated by cold exposure.
- Either males or females between the ages of 18-45 years can participate in this study. There is no other screening procedure other than the PAR-Q and verbal questionnaires.
- You will be instructed to abstain from alcohol, medications or vigorous physical activity for a 24 hour period prior to the study.
- You will be instructed to have a small breakfast and no other food 2-3 hours prior to the immersion.
- Anthropometric data will be collected and recorded. This includes age, weight, height, and measurements of skin fold thickness at four sites- biceps, triceps, subscapularis, and suprailiac. This will be used to calculate your body surface area and % body fat.
- Each testing session will involve cooling of the skin. You will be submersed in 21˚C water up to the level of the sternal notch. The water temperature will then be lowered to 8˚C over a period of 5-10 min by addition of~60 kg of ice. Your heart rate and electrocardiogram will be monitored continuously throughout this period. You will be asked several times throughout the study if you would like to stop. The trial will be stopped when:

  - You wish to exit (you can communicate by either asking to be removed or giving a thumbs-up hand signal);
  - The investigator advises stopping for safety or other reasons;
  - Your core body temperature decreases to 35˚C;
  - Or 60 minutes of immersion elapses, whichever comes first.
- You will be instrumented as follows:
  - 12 heat flux disks (2 cm in diameter) will be taped to the skin on the legs, arms, torso and head to measure skin temperature and heat transfer from the skin.
  - Three ECG leads will be affixed to the skin.
  - 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.
  - Metabolic rate will be continuously monitored; you will be asked to wear a face mask which will collect the expired breath, during the cooling period. You will be able to speak and communicate with the investigators throughout the trials.
- After the experiments you will be dried off you will be warmed by one of the three rewarming methods: A. Spontaneous rewarming in a hooded sleeping bag; B. Distal limb rewarming with Fluidotherapy equipment; and C. Distal limb rewarming by immersion in water. Treatment will continue either for a period of 60 minutes or until your core temperature returns to normal values (~36.5-37˚C). Following that, you will be actively rewarmed by entering a warm water bath of 40-42˚C.
- You will be asked to participate in three experimental trials. Each trial will last about 4 hours (1 hour for setup, 1 hour for cooling, and 2 hours for rewarming and removal of instrumentation). Your trials will be at least 48 hours apart and the three tests will be completed within three-four months (April-July). Thus, your total commitment will be about 4 hours per visit and three total visits within a period of 4 months. Same procedures will be carried out for each visit except the rewarming treatment method.

Participation in the study will be for a period of up to 4 months, until you have visited the laboratory 3 times.

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 talk to the study staff first.

If you are interested, we will provide an electronic copy of a summary report of the study once it is completed.

Risks and Discomforts

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

1) Hypothermia – The study in which you have been asked to participate involves lowering of body core (esophageal) temperature by a maximum of 2.0ºC (to a minimum of 35.0ºC). Submersion in cold (8℃) water may result in an unpleasant, cold sensation and may cause a transient increase in breathing; this will soon subside. As well, you may experience vigorous shivering, which is a natural response. The criterion for stopping cooling is a maximal decrease in core temperature to the upper threshold of clinical/mild hypothermia – 35.0ºC. Therefore, cooling will be terminated before you become clinically hypothermic. The investigators have previously conducted many cooling studies of this type and no complications were experienced as a result of the change in core temperature.

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.

3) Skin numbness – On rare occasions, extended exposure of toes and fingers to 8˚C water can cause short-term skin numbness on these areas. Although this rare problem will resolve itself (normally within a few days), this problem will be prevented by insulating the feet (with neoprene boots) and having the subject keep their hands out of the water (by holding on to a bar placed above the water).

Benefits

By participating in this study, you will be providing information to the study investigators that will show the effects of distal limb rewarming with Fluidotherapy vs. warm water immersion for the treatment of mild hypothermia. 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 mild hypothermia in the future.

Costs

You will be responsible for your own parking while in the study. There will be no other expenses for you as a result of participation in this study.

Payment for participation

You will be given $100 per completed study visit to a maximum of $300 upon termination of your participation in this research study.

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

Alternatives

Not Applicable

Confidentiality

Information gathered in this research study may be published or presented in public forums, however your name and other identifying information will not be used or revealed. All study related documents will bear your initials, date of the experiment, and the name of the experiment. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed.

The University of Manitoba Biomedical Research Ethics Board may review research-related records for quality assurance purposes.

All records which can be identified as yours will be kept in a locked secure area and only those persons identified will have access to these records. If any of your medical/research records need to be copied to any of the above, your name and all identifying information will be removed. No information revealing any personal information such as your name, address or telephone number will leave the University of Manitoba.

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.

Adverse Events or Medical Care for Injury Related to the Study

In case of any adverse event due to this study or if you are distressed in any way after leaving the laboratory, you will inform Dr Giesbrecht (business – 474-8646; residence – 269-5685; cell – 995-6599) for assistance. All adverse events and unanticipated problems will be reported to the Bannatyne Campus Research Ethics Board as described on the following website: http://umanitoba.ca/faculties/medicine/ethics/Adverse%20Event%20Reporting%20and%20Safety%20Information.html. Once you start any immersion you will be

paid an amount of $100 for that trial, irrespective of whether you complete the trial or not.

You are not waiving any of your legal rights by signing this consent form nor releasing the investigator(s) or the sponsor(s) from their legal and professional responsibilities.

Questions

You are free to ask any questions that you may have about your treatment and your rights as a research participant. If any questions come up during or after the study or if you have a research-related injury, contact the study investigator and the study staff: Dr. Gordon Giesbrecht at 474-8646.
For questions about your rights as a research participant, you may contact The University of Manitoba Biomedical Research Ethics Board at (204) 789-3389

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Statement of Consent

I have read this consent form. I have had the opportunity to discuss this research study with Dr. Gordon Giesbrecht and or his/her study staff. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statement or implied statements. Any relationship (such as employee, student or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this clinical trial is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

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:_____

I am willing to be contacted regarding 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: _____

Participant signature_____ Date _____
(day/month/year)

Participant printed name: _____

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent

Printed Name: Dr. Gordon Giesbrecht Date _____
(day/month/year)

Signature: _____

Role in the study: Primary Investigator

Relationship to study team members:_____[eg. teacher/professor or family member.]

APPENDIX D

Kinanthropometric Research Data Form

Laboratory for Exercise and Environmental Medicine

Department of Kinesiology and Recreation Management - University of Manitoba

A						
	1	Subject (last, first)				
	2	Subject Number				
	3	Consent Form Complete				
	4	PAR-Q Form Complete				
	5	Gender (m=1, f=2)				
B						
	6	Date of observations (yyyy/mm/dd)				
	7	Date of Birth (yyyy/mm/dd)				
	8	Measurement sequence number				
	9	Body mass (kg)				
	10	Stature (m)				
C						
	11	Triceps skinfold (mm)				
	12	Subscapular skinfold				
	13	Biceps skinfold				
	14	Iliac crest skinfold				
	15	Suprailiac (supraspinale) skinfold				
	16	Abdominal skinfold				
		Abdominal skinfold with Bathing suit				
		Thickness of bathing suit (doubled over)				
	17	Front thigh skinfold				
	18	Medial Calf skinfold				
	19	Chest (male only)				
	20	Posterior thigh (female only)				
D						

	21	Arm girth relaxed				
	22	Chest girth				
	23	Forearm girth (max. relaxed)				
	24	Waist circumference				
	25	Thigh girth (1cm distal to gluteal line)				
	26	Calf girth (max)				
	27	Mid thigh girth				
E						
	28	Trial Order				
	29	Future Contact for Other Projects				
	30	Notes/Comments				

APPENDIX E

Equations for calculating body density given by Durnin and Womersley.[84]

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