Research & Reviews: Journal of Nursing & Health Sciences

Electromagnetic Hydrotherapy: A Pilot and Feasibility Study

Marcy C. Purnell[1,2]*, Matthew, Butawan[3], Gary H. Lipscomb[1,5], George E. Relyea[6], Richard J. Bloomer[3], Carle C. Kalsi[1,7,8], Risa D. Ramsey[1,9]

[1]The Loewenberg College of Nursing, University of Memphis, Memphis, TN, USA

[2]Baptist Health Sciences University, Memphis, TN, USA

[3]School of Health Studies, University of Memphis, Memphis TN, USA

[4]Family Medicine, University Clinical Health TN, USA

[5]Department of OB/GYN, University of Tennessee Health Science Center, Memphis TN, USA

[6]School of Public Health, University of Memphis, Memphis, TN, USA

[7]St. Jude Children's Research Hospital, Department of Pediatric Medicine, Memphis, TN, USA

[8]Emergency Room and Chest Pain Center, St Francis Hospital, Bartlett, TN, USA

[9]University of Tennessee Health Science Center, Memphis, TN USA

Method

Date of Submission: 13 Sep, 2022, Manuscript No. jnhs-22-74034; **Editor Assigned:** 15 Sep, 2022, Pre QC No. P-74034; **Reviewed:** 29 Sep, 2022, QC No. Q-74034; **Revised:** 04 Oct, 2022, Manuscript No. R-74034; **Published:** 11 Oct, 2022, DOI: 10.4172/JNHS.2022.8.10.47

***For Correspondence**

Marcy C. Purnell, The Loewenberg College of Nursing, University of Memphis, Memphis, TN, USA

Email: marcy.purnell@baptistu.edu

Abstract

Background: Electromagnetic therapies have been used for generations and have historically shown interesting phenomena suggesting health benefits. This electromagnetic hydrotherapy delivers 2.5 amperes of direct current via a saline water solution to living organisms. Over the last 20 years, anecdotal reports have suggested possible health benefits and molecular studies have shown a reduction in cellular stress with this hydrotherapy. This pilot study was conducted to evaluate feasibility of subject recruitment, retention, assessment procedures, methodology and implementation of this intervention for future efficacy studies.

Methods: Twenty human subjects (10 male and 10 female) participated in the study sessions by submerging their feet in a saline water solution while the electromagnetic water module delivered 2.5 amperes of a direct current to the solution. The study participants completed six, 30-minute sessions three days a week for two weeks for a total of six sessions. Serum blood laboratory values, 12-lead EKG, vital signs, physical exams and questionnaires were conducted with the subjects during the course of the study.

Discussion: This pilot study did not reveal feasibility issues in enrolled research participants. Additional efficacy studies may be performed to further determine the value of this device with regards to clinical applications for health and wellness.

Keywords: Direct current, Electromagnetic field, Bio-electrodynamics, Health

INTRODUCTION

Bio-electrodynamics is a branch of medical physics that studies how electric and magnetic fields affect the physiology of living organisms [1]. This electromagnetic hydrotherapy produces a direct current (DC) driven electromagnetic field (EMF) and is applied to living organisms (plants, animals, humans) through a medium of saline water **(Figures 1 and 2)**. This device was invented in Australia in 1996 as hydrotherapy or an immersion footbath/body bath application and was, at that time, a novel invention that spawned an interest from countries around the globe [2]. Anecdotally, humans have since then reported experiences such as, increased stamina; normalization of blood pressure, pain relief, improved wound healing, normalization of liver and renal dysfunction etc.

Figure 1 Hydrotherapy Water Module consisting of seven conductive rings. The apparatus is comprised of five coaxially

arranged rings (#2 through #6) between two electrically conductive plates (#1 & #7). Plate #1 and rings #3, #5, and plate #7 are connected to the negatively charged track (anode) and rings #2 and #6 are connected to the positively charged track (cathode). Ring 4 is formed from copper. This module is placed in saline water in a basin with the feet of the participant and is powered with 2.5 amperes of DC current during the footbath sessions that last 30 minutes.

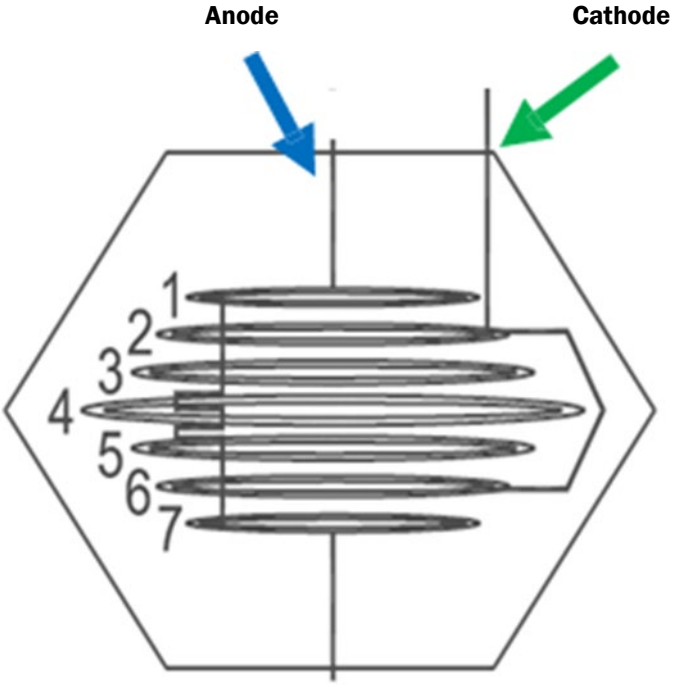

Figure 1 Hydrotherapy water module.

Recent studies suggest that the electromagnetic signals that are delivered by this electromagnetic application have the potential to modulate our cell membranes (via chloride ion channels in the plasma and mitochondrial membranes) and ultimately cell physiology as demonstrated in previously published studies conducted by this nursing research team[3-8]. Research performed using this electromagnetic application has included *in vitro* experiments on cancerous and noncancerous cells [3-8]. We have observed a significant decrease in epithelial cell stress (endoplasmic reticulum stress) and enhanced cell migration in fibroblasts (possible wound healing application) when these cells are grown in media that has been reconstituted with electromagnetically enhanced saline water *in vitro* [4,6].

Subsequently, after completion of these recent *in vitro* experiments using this electromagnetic application along with the observance of the anecdotal reports over the last 20 years, this pilot study was designed to evaluate feasibility of recruitment, retention, assessment procedures, new methodology and/or implementation of this hydrotherapy intervention. It should be noted that this device is currently declared exempt from IDE requirements.

METHODS

Study design and participants

The Institutional Review Board (IRB) at the University of Memphis approved the pilot and feasibility study (protocol number: PRO-FY-2017-9). The pilot study was conducted at the University of Memphis, Loewenberg College of Nursing to evaluate the feasibility of the electromagnetic hydrotherapy sessions in a healthy human subjects' population. Interested participants were screened for eligibility using defined inclusion and exclusion criteria. Research screening participants were required to have a body mass index (BMI) less than 40 kg/m^2 and no medical history of chronic health conditions. In order to meet eligibility requirements females could not be pregnant or nursing and had to be using a form of birth control. Research screening participants had to also agree to refrain from elective changes to dietary supplements or medication usage during the study.

Prior to enrollment in the study, each subject who was interested in participation attended an information session performed by the Principal and Co-Investigators. The details of the study were presented including, but not limited to: required research sessions and procedures to be performed, visit schedule requirements, bloodwork needs, and inability to make dietary, supplement or medications changes during the course of the study. Research screening participants were provided an IRB-approved informed consent for review. All questions were answered and risks and benefits were thoroughly discussed prior to the research subject signing the informed consents. A signed copy of the informed consent was provided to each research subject prior to the screening visit.

Procedures

The research screening visit for the study consisted of anthropometric measures and vital signs. Each research screening

participant had oral temperature, blood pressure, heart rate, respiratory rate, oxygen saturation, and pain level assessment by an investigator. A 12–lead electrocardiogram (EKG), Urinalysis (UA), and pregnancy tests for females were performed. Laboratory testing on research subjects included a comprehensive metabolic panel (CMP), complete blood count (CBC), and sedimentation rate (ESR). Two to three teaspoons of venous blood were collected into a vacutainer with Ethylenediaminetetraacetic acid (EDTA) and a serum-separator vacutainer for whole blood and serum, respectively. Serum was obtained by centrifuging clotted whole blood at 4°C and 1500 rpm for 15 minutes. Whole blood and serum were analyzed for CBC, CMP and ESR testing by American Esoteric Laboratories (AEL) in Memphis, Tennessee.

The research subjects also had an extensive consultation with the pilot study board certified physician including a thorough past medical history, review of systems and a physical examination. The study physician also read the EKG's and reviewed all research subject laboratory results for abnormalities. The extensive testing was performed to rule out potential research subjects who might have acute or chronic issues that would cause them to not meet the inclusion criteria for the study. Once the screening process was performed and data reviewed, it was determined if the research subjects met the defined study inclusion and exclusion criteria.

Twenty healthy male and female subjects (ten female and ten male) between 18 and 35 years of age were recruited, consented and enrolled to participate in the pilot study within two weeks of the research participant screening visit. Research subjects completed six study visits every 48-72 hours over a two-week period. Upon arrival at the study visits, participants were interviewed regarding changes in health status, recent visits to the doctor or hospital, and changes in concomitant medications, dietary supplements, or diet and the life diary was collected. All self-reported changes were documented. At each study visit the Patient-Completed Health Outcome Measures Global Health (PROMIS® v 1.1) questionnaire was also administered and completed by research subjects. Vital signs consisting of heart rate (HR), blood pressure (BP), respiratory rate (RR), and oral temperature (oral temp), oxygen (O_2) saturations, and pain level/status were recorded. The study sessions were performed on research subjects immediately after assessing vital signs, collecting any recent health status changes, and medication/supplement changes.

Following the electromagnetic hydrotherapy treatments, the research subjects had their vital signs (HR, RR, BP, oral temp, pain) and O_2 saturations rechecked and then scheduled their next study visit within the 48 to 72-hour window. Within two weeks following the final study sessions, research subjects were required to return for a final visit to assess any changes to health status. Vital signs, EKG, CMP, CBC, ESR, urinalysis and O_2 saturation tests were performed and results documented for comparison to screening/baseline values. Research subjects completed the Patient Reported Outcomes Measurement Information System (PROMIS) questionnaire and submitted life diaries to assess self-reported quality of life changes. An extensive consultation with the study physician was performed on every research subject and included a physical examination and thorough questioning about any changes in medical history or adverse events.

Lastly, Live Blood methods were conducted on the study participants, pre and post hydrotherapy sessions and these methods and results suggesting interesting changes in morphology and orientation of the blood components are currently published in Physiological Reports [7].

Device

The water module used in this study is comprised of a DC power supply, GFI power cord, DC cable and a water module that consists of a series of parallel conductive and nonconductive metal rings (**Figure 2**). The power supply used has been built to safety circuits and has been tested by the Australian Government testing facilities to ensure it complies with both electrical and medical standards. The device used in this study is made to US Patent No: US6555071 specifications. While the system is plugged into the wall and is powered by the alternating current (AC), the power supply converts the AC to DC with a power output of about 18-24 volts. Fuse protection on both the active and neutral power cables have been added and a thermally operated circuit breaker protects the user. Double bobbin construction gives double insulation between the AC and secondary DC windings. Therefore, the AC power stays on the AC side of the circuitry. There is no direct electrical connection from the main supply to the output. Due to the wide-spread use of the unit without any known adverse events and the approval of the unit by the Australian Therapeutics Goods Administration, it would fall under the category of a non-significant risk device in that it does not present a potential for serious risk to the health, safety or welfare of a subject.

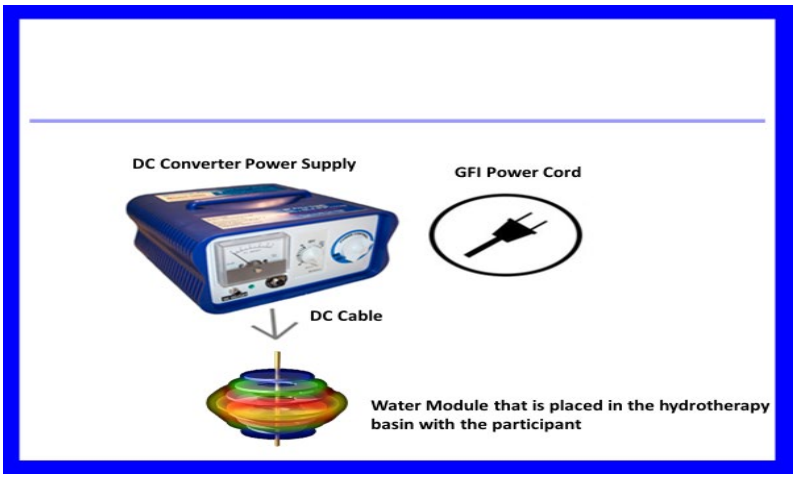

Figure 2 The electromagnetic hydrotherapy equipment consists of a Direct Current (DC) power supply, GFI power cord, DC cable and a water module. The DC cable supplies the DC to the water module that is placed in the wash basin (along with the feet of the participant) in warm salt water.

The water used in the study sessions (in the footbath basins) in the study was a hypotonic saline water solution (~3 mM). The water was composed of approximately eight liters of tap water with the addition of one to two teaspoons of Himalyan salt used to achieve 2.0 to 2.5 amperes of direct current measurement on the ampere meter of the power supply. Artesian well (tap) water used in the study was from Memphis, Tennessee and was placed in a 12 L plastic wash basin. The module was submerged in the hypotonic saline solution in the washbasin. Research subjects placed their feet in the washbasin for 30 minutes of exposure to the active electromagnetic field for each session.

Statistical analysis

In order to assess for feasibility and for any possible adverse events, the number of people who complete the study in comparison to those who terminate early were evaluated. Pre-study (screening) and post-study (Final visit one to two weeks after visit six) CBC, CMP, ESR, U/A, vital signs, PROMIS Global Health Questionnaires, and O_2 saturations mean values were analyzed (**Table 1**). Data collected over the course of the study was followed closely by the Principal Investigator, Co-Investigators and the study physicians.

RESULTS

All 20 (10 males and 10 females) research subjects, between 20-35 years of age who were screened and signed informed consent completed the study with a 100 percent visit compliance rate. There were no serious adverse events among the study participants during the course of the study. There were also no adverse events reported in this study that were deemed attributable to the study intervention. The laboratory results and vital sign measurements remained within the standard/normal mean measurements for these measures (**Table 1**). There were also no concerns identified with the feasibility of future use of recruitment, retention, assessment procedures or methodologies employed by the investigators.

Table 1 Mean and mean difference of serum labs and vital signs of study participants measured at the screening study visit and final study visit (All means remained in normal range of laboratory values and vital sign values during the course of the study).

Variables	Screen Mean	Final Mean	Mean Difference
CBC			
WBC	6.02	6.51	-0.49
RBC	4.91	4.87	0.04
Hgb	14.47	14.41	0.06
Hct	43.00	42.33	0.68
MCV	87.70	87.16	0.55
MCHC	33.63	33.99	-0.34
RDW	13.13	13.15	-0.02
PLT	238.75	243.55	-4.80
Neut	55.26	58.65	-3.39
Lymph	33.71	30.77	2.94
Eosin	2.32	1.97	0.35
Baso	0.37	0.33	0.04
CMP			
Na	141.25	139.85	1.40
K	4.91	4.71	0.20
CL	100.65	99.70	0.95

CO_2	26.50	25.30	1.20
BUN	13.35	12.45	0.90
SCr	0.89	.90	-0.01
GLU	90.05	96.70	-6.65
Ca	9.69	9.71	-0.02
TP	7.36	7.01	0.35
Albumin	4.64	4.66	-0.03
Bili	0.54	0.47	0.07
ALP	65.45	66.75	-1.30
AST	23.85	22.55	1.30
ALT	22.60	23.25	-0.65
Vital signs			
Systolic BP	109.85	119.26	-9.53
Diastolic BP	72.35	74.84	-2.89
HR	73.35	75.50	-2.15
RR	16.20	12.53	3.71
Oral Temp	98.11	98.33	-0.24
O_2 Sats	97.93	98.16	-0.14

DISCUSSION

The electromagnetic water module has been used for over 20 years across the globe with many anecdotal reports of numerous health benefits. The previously published *in vitro* work has identified bioelectric mechanisms that may drive cell physiology with the use of the electromagnetic field, thereby reducing cells stress [3-8]. There were no identified feasibility issues with the methods employed in this pilot study and the lack of reported serious adverse events and/or adverse events deemed to be associated with this application suggest that future controlled efficacy studies with larger sample sizes may be possible. Therefore, the ability to investigate this electromagnetic hydrotherapy along with the ability to reduce cell stress, may reveal new therapeutic uses of this electromagnetic field hydrotherapy in areas of wound care, athlete recovery, cancer and sickle cell disease [7, 9-16].

ACKNOWLEDGEMENTS AND FUNDING

This work was funded by the William A. and Ruth F. Loewenberg Chair of Excellence funds at the University of Memphis. We want to thank Carle Kalsi, M.D. for performance of all physical examinations for the study and review of all EKG and laboratory results for research participants. We are grateful to Gary Lipscomb M.D. for his guidance and direction in study design and protocol development. We acknowledge the assistance of Matthew Brian Butawan for processing of blood specimens.

CONFLICTS OF INTERESTS

Marcy C. Purnell is the co-holder, “Bioelectrodynamics Modulation Method” United States Patent Application Publication: US 2017/0232253. Marcy C. Purnell and Michael A. Whitt. Published 8/17/2017.

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