

**PROJECT
REPORT**

September 2022

homeglo



Effects of temperature regulation on wellbeing using B-Warms

Thermoregulation is a vital function of the autonomic nervous system in response to cold and heat stress. Thermoregulatory physiology sustains health by keeping body core temperature at $\sim 37^{\circ}\text{C}$, enabling normal cellular function. However, as we grow older, our bodies become less effective at controlling skin blood flow and generating internal heat. Coping with these conditions can stress the cardiovascular system, which is also compromised with ageing and several other illnesses.

The B-Warm heated armchair cover has been developed by Homeglow Products Ltd for those who suffer from the cold – the frail and elderly discharged patients, those with mobility problems and or those suffering from rheumatism.

Heat and slightly raised temperatures have been shown to improve wellbeing, linked to an increase in endorphins in response to heat. Endorphins are known to help relieve pain, reduce stress, and may cause a euphoric feeling. The previous study using the B-Warms established that using a B-warm heated seat cover can significantly decrease the cost of heating a home.

However, numerous testimonials from users also indicate that B-Warms also increase their sense of comfort and wellbeing. This collaboration will investigate the potential physical and mental benefits of using the B-Warm.



Introduction

Thermoregulation is a vital function of the autonomic nervous system in response to cold and heat stress. Thermoregulatory physiology sustains health by keeping body core temperature within a degree or two of 37 °C, which enables normal cellular function. However, as we grow older, our bodies become less effective at controlling skin blood flow and generating internal heat. Due to these changes, it is harder for older adults to maintain internal body temperature in the “normal” range in cold conditions. Coping with these conditions can stress the cardiovascular system, which is also compromised with ageing and several other illnesses.

HomeGlow has worked on a design for an affordable and efficient armchair warmer after his late wife Audrey, who suffered from arthritis, said she wished she could take the heated seats from the couple’s car into the house. Various car seat heaters were therefore evaluated by HomeGlow as potential chair warming pads, but they were inefficient, short-lived or extremely expensive. The B-Warm heated armchair cover has been developed by Homeglow Products Ltd for those who suffer from the cold – the frail and elderly discharged patients from the hospital, or those with mobility problems and suffering from rheumatism. It is light, portable and is easily attached and removed from most armchairs or sofas.

Heat and slightly raised temperatures, such as bath’s at approximately 40°C have been shown to improve wellbeing. Improvements to wellbeing have been linked to an increase in endorphins in response to heat, which is known to help relieve pain, reduce stress, and may cause a euphoric feeling. A previous study using the B-Warm established that using a B-warm heated seat cover can significantly decrease the cost of heating a home. However, numerous testimonials from users also

indicate that B-Warm also increases their sense of comfort and wellbeing, this collaboration will therefore investigate the potential physical and mental benefits of using the B-Warm.

Methodology

1. Participants

Delta Wellbeing used their clientele list to contact participants via phone call to ask if they would like to partake in the study. They only contacted clients that met the following criteria:

The study was aimed at older adults, with no exclusion based on gender.

Exclusion criteria:

- Are undergoing cancer treatment
- Are taking Anti-depressants

Participants were selected based on living arrangement, clients living in their own homes across the three counties chosen to participate. Once Delta Wellbeing had verbal confirmation, their staff visited the participants at their residency to provide the B-Warm and complete the pre-use questionnaire with the participant, prior to BWarm use.

Following 1 month of using the B-warm as they desired, Delta Wellbeing staff then performed the same questionnaire a second time with the participants with some additional questions about the participant's experience using the B-warm. There were **72 participants** (54 female, 18 male) with a mean age of 79.6 years. All responses were collected by Delta Wellbeing staff and sent to HTC for analysis.

2. Subjective general perception questions

Questions 16 to 21 were closed questions designed to assess the BWarm. Questions 16, 17 and 20 were designed to specifically analyse the impact of the BWarm on the pain and wellbeing of participants, rather than a broad scale to analyse general wellbeing. These questions also gave the opportunity for the participant to expand on their experience of the BWarm. Question 18 was

designed to assess the general quality of the product, and questions 19 and 21 were designed to capture the impact of the BWarm on the NHS, should it be provided to individuals via a prescription.

3. Warwick-Edinburgh Mental Well-being Scale (WEMWBS):

In order to evaluate whether using the BWarm can cause improvement in subjective wellbeing we will use the WEMWBS, a scale developed and validated by researchers at the University of Edinburgh and at NHS Scotland. The WEMWBS can be used to measure subjective Wellbeing in adults over the age of 16. As defined by the developers, mental well-being relates to a person's psychological functioning, life-satisfaction, and ability to develop and maintain mutually benefiting relationships. Psychological wellbeing includes the ability to maintain a sense of autonomy, self-acceptance, personal growth, purpose in life and self-esteem.

The total scores can range from a minimum of 14 to a maximum of 70 points. Higher scores are associated with higher levels of mental well-being. In a population sample comprised of adults ranging in age from 16 to 75+ years, the mean score was 50.7. The mean score for a sub-sample of adults aged between 65 and 74 years was 52.4 while the mean score was 51.2 for a sub-sample of adults over the age of 75.

A T-Test was used to evaluate the mean score on quantitative responses.

The T-score is a ratio between the difference between two groups and the difference within the groups. A p-value from a t-test is the probability that the results from your sample data occurred by chance. Low p-values indicate your data did not occur by chance.

4. Subjective pain ratings

Question 4 asked participants about their pain ratings on a scale of 0-10, to determine any change in the participant's average levels of perceived pain pre- and post-BWarm use. The scale was designed such that zero would be no pain at all. 1 to 3 would be considered mild pain. The range 4 to 6 would be considered moderate pain and above 7 would be severe pain. With 10 being the worst possible pain.

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5. Quantification of serotonin, dopamine and beta-endorphin in blood samples using ELISA

Blood samples were collected from participants before use of the BWarm and again after 30mins of use. A control blood measurement was also taken from the same participants before and after sitting in the same conditions for 30mins but without turning on the BWarm.

Following the collection of blood using vacutainer tubes with EDTA(K2E). The vacutainer tubes were inverted 4 times to mix the EDTA well. The blood samples were then placed into a swinging rotor centrifuge at 25°C for 15mins at 2500G. To separate the cellular components from the plasma the supernatant was carefully removed from the tube using a sterile pipette.

The number of freeze-thaw cycles each plasma sample experienced was limited (maximum of two) while being analysed for the various neurotransmitters (dopamine, serotonin and human beta-endorphin). Neat samples were used for serotonin and human beta-endorphin, while samples diluted 1:100 were used for the dopamine analysis. All dilutions were taken into consideration during data analysis.

Enzyme-linked immunosorbent assays (ELISAs) were completed as per manufacturers instructions (Novus Biologicals, UK). All reagents were brought to room temperature before use and the plate reader was allowed to equilibrate at 37°C for a minimum of 15 minutes before use. These specific kits use the competitive-ELISA principle (Figure x). Plates implemented within these kits are pre-coated with the neurotransmitters of interest. A standard curve is produced by serially diluting the reference standard using sample diluent to a range that is applicable to the ELISA kit being used (15.63-1000pg/ml for both human beta-endorphin and serotonin and 31.25-2000pg/ml for dopamine), before adding into the plate in duplicate with the samples in triplicate. A detection antibody was then added to each well immediately before the plate was allowed to incubate at 37°C for 45 mins. The plate was then washed and Avidin conjugated to Horseradish Peroxidase (HRP) was added to each well and incubated at 37°C for 30mins before being washed again. Substrate

reagent was then added to each well and the plate was incubated in the dark for 15mins at 37°C before stopping the reaction and then reading the plate at 450nm immediately.

Results / Conclusions

Questionnaire results

All questionnaire data was processed in partnership with Swansea University School of Medicine and Swansea University iLab.

Subjective perception questions after having used BWarm for 4 weeks Pain reduction:

73.9% of the participants declared a reduction in perceived pain level (question no. 16)*. This is statistically significant from a 50% chance level ($Z = 4.03$, $p < .00005$).

Subjective wellbeing improvement:

75% of the participants declared an improvement in subjective wellbeing (question no. 16)**. This is statistically significant from a 50% chance level ($Z = 4.21$, $p < .00003$)

Subjective recommendation of the BWarm:

After using BWarm for 4 weeks, 94.2% of the participants recommended the product (question no. 18). This is statistically significant from a 50% chance level ($Z = 7.45$, $p < .00000001$)

Personal willingness to contribute to pay for the BWarm:

76.7% of the participants declared they would be willing to pay a contribution toward the BWarm (question no. 21). This is statistically significant from a 50% chance level ($Z = 4.5$, $p < .00001$)

Agreement as to whether using the BWarm led to a better quality of life (question 20):

49.3% of the participants agreed and this is not different from a 50 % chance level ($Z = 0.115$, $p = \text{NS}$).

In terms of commercial offering/marketing, the present set of results allows Homeglow to make a series of valid claims, straightforwardly. Note that after using BWarm for 4 weeks, 76.7% of the participants declared they would be willing to pay a contribution toward the BWarm.

Comparison of Mental Well-being score before and after having used BWarm:

The sample of participants we used to evaluate BWarm is comparable to the one used to validate the Warwick-Edinburgh Mental Well-being Scale (i.e., not statistically different from standard data for this age range) This study obtained a mean total Wellbeing score of 48.95 before using the BWarm (Pre, $T(71)=1.17$, $p < .12$) and 49.4 after use of the BWarm (Post, $T(71)=1.46$, $p < .075$); showing marginal mean increase 0.45 after use. This difference is not statistically significant, however, evaluation of mean scores for individual questions from the Warwick-Edinburgh Mental Well-being Scale did show some significant difference.

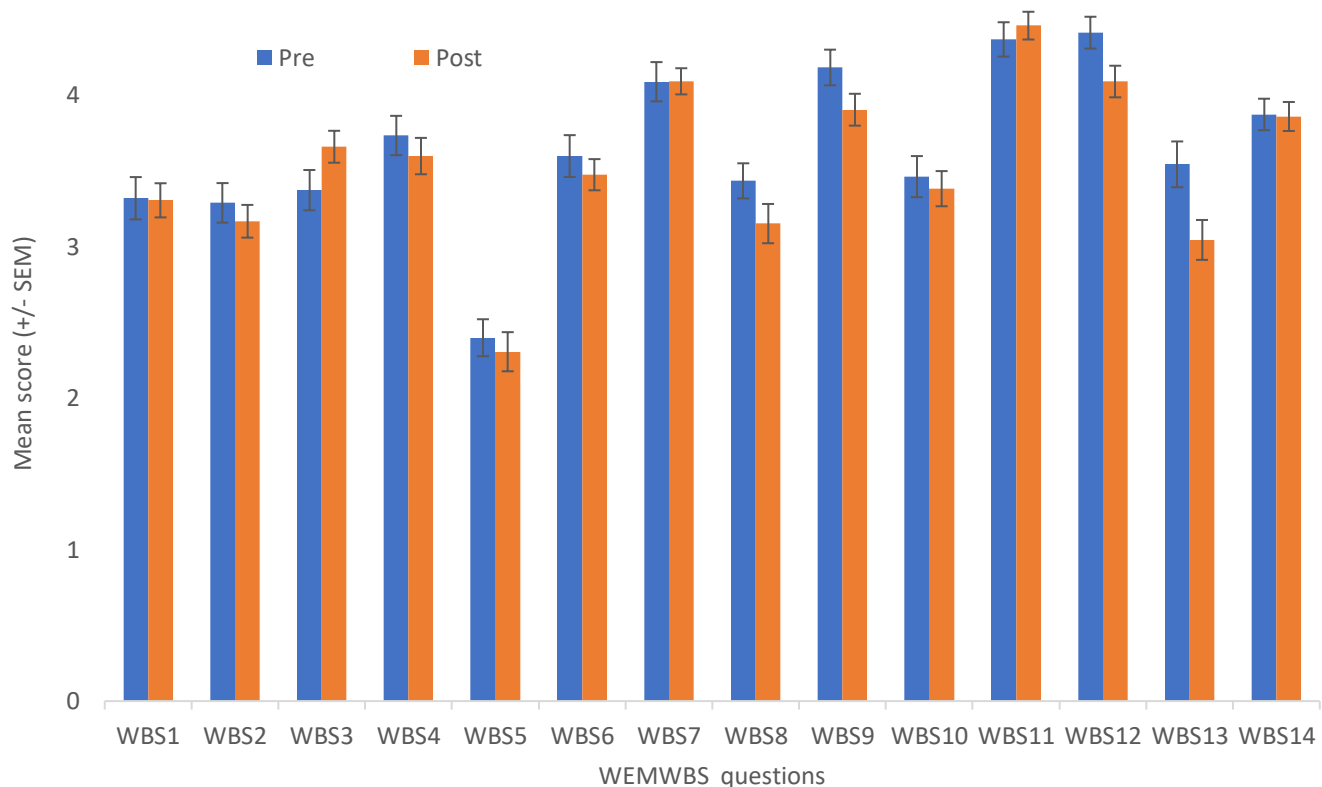


Figure 1. Scores obtained at the Warwick-Edinburgh Mental Well-being Scale before (Pre) and after (Post) using the BWarm. Error bars represent the standard error of the mean.

Figure 2. Scores were obtained using the Warwick-Edinburgh Mental Well-being Scale before (Pre) and after (Post) using the BWarm. Error bars represent the standard error of the mean ($n=71$). The resultant *Wellbeing score (WBS)* for each question asked (1 to 14) is show on the Y axis.

Statistically significant improvements in subjective wellbeing after the usage of the BWarm were found for Question 3 “*I’ve been feeling relaxed*” ($T(71) = 2.86, p < .003$) and 11 “*I’ve been able to make up my own mind about things*”, ($T(71) = 1.89, p < .031$).

Note that mean scores at other questions in the scales may seem to move in the opposite direction (worse subjective wellbeing after using BWarm) but those are only statistically significant for questions 8, 9 and 13 (“*I’ve been feeling good about myself, I’ve been feeling close to other people and I’ve been interested in new things*”). Such “mixed-bag” pattern of results is not surprising and subjective, personal

wellbeing is a multidimensional construct and we cannot reasonably expect BWarm to cause a general improvement. However, the fact that the feeling of relaxation and, its corollary, mental focus are significantly ameliorated is very encouraging.

Comparison of subjective pain ratings before and after having used BWarm:

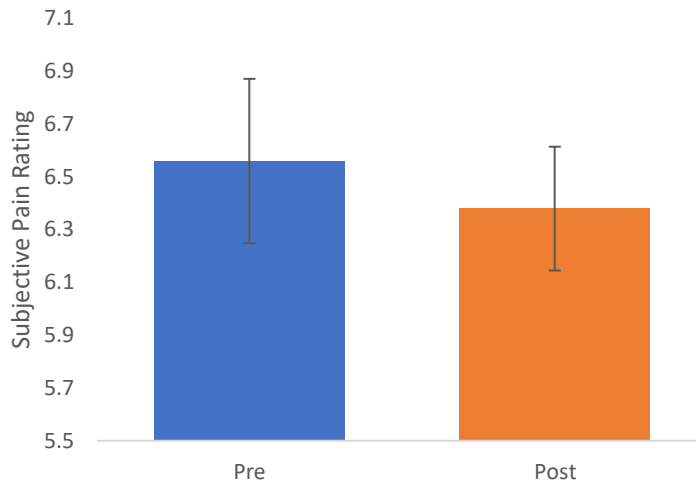


Figure 3. Subjective pain ratings scores before (Pre) and after (Post) using the BWarm. Error bars represent the standard error of the mean.

Figure 2: Subjective pain ratings scores before (Pre) and after (Post) using the BWarm. Error bars represent the standard error of the mean.

A statistically significant reduction in subjective pain ratings after using BWarm was found for question 3 (I've been feeling relaxed, $T(71) = 1.81$, $p < .036$, two sided)***.

In terms of commercial offering/marketing, the present result allows Homeglow to make a useful and valid claim.

- The results show that using the BWarm for 4-weeks led to an improvement in participants' state of relaxation"
- This study has also evidenced that using the BWarm for 4-weeks led to an improvement in participants' mental focus.

Determination of serotonin release following 30 minutes using the BWarm:

There was no discernible change in the blood serotonin content following 30 minutes using the BWarm device compared to before heat and compared to the control samples (Error! Reference source not found.).

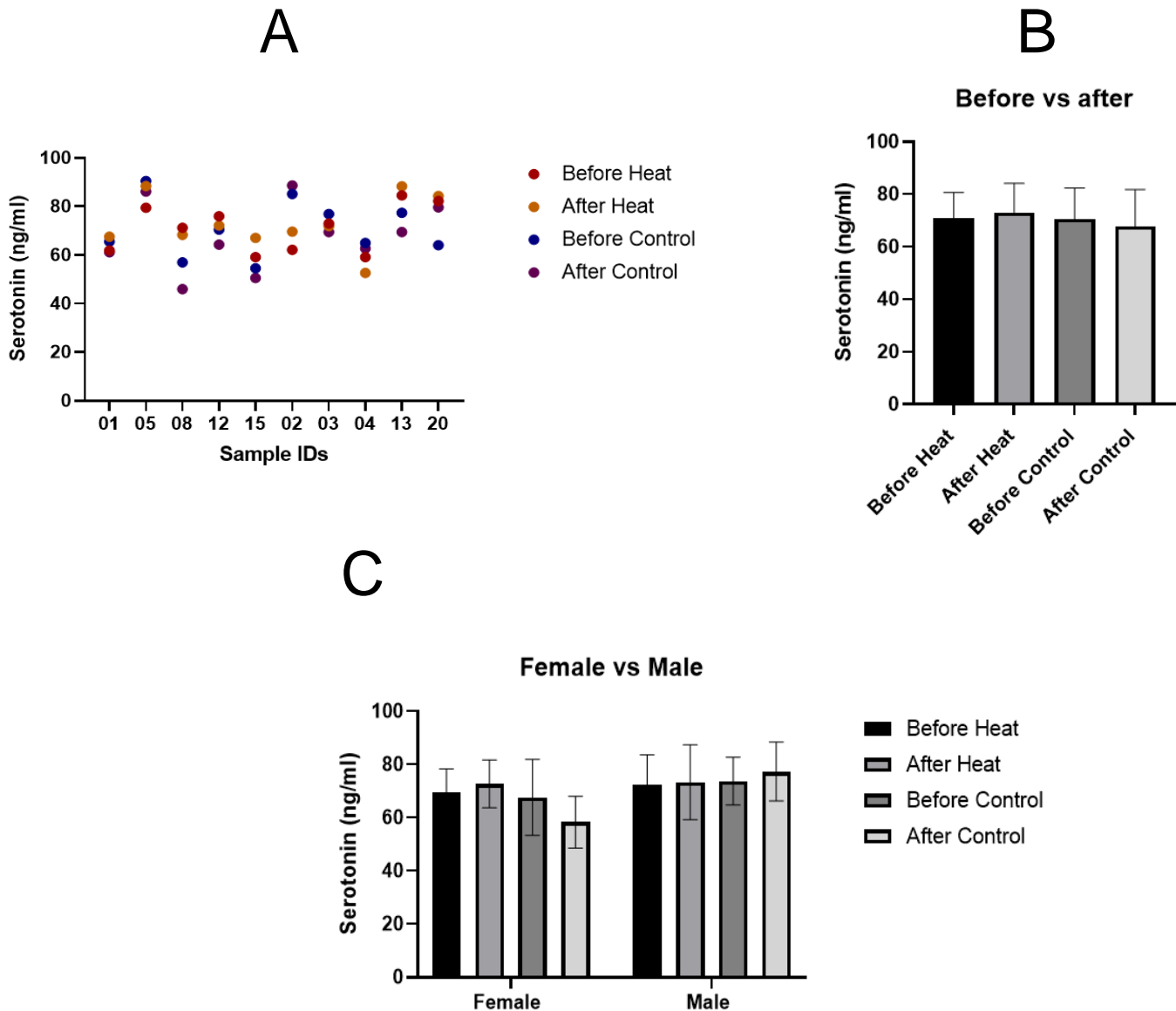


Figure 4. **Comparison of blood serotonin measurements following BWarm use by ELISA.** Blood serotonin levels were determined for 10 participants (5 female, 5 male) before BWarm use (Before Heat) and after BWarm use (After Heat), compared with before and after measurements of the same participants, untreated. Serotonin measurements were determined by ELISA. Graphs indicate A) individually plotted serotonin measurements for all participants, B) average blood serotonin values of all participants, and C) average serotonin values compared between male and female participants. Error bars represent the standard error of the mean.

V/ Determination of Human β -endorphin release following 30 minutes using the BWarm (n=5 females + 5 males)

Across all participants, there was **no significant change** in β -endorphin measurements following the use of the BWarm (**Figure 5**). However, there was an increase in the average β -endorphin levels in males following BWarm use (**Figure 5C**).

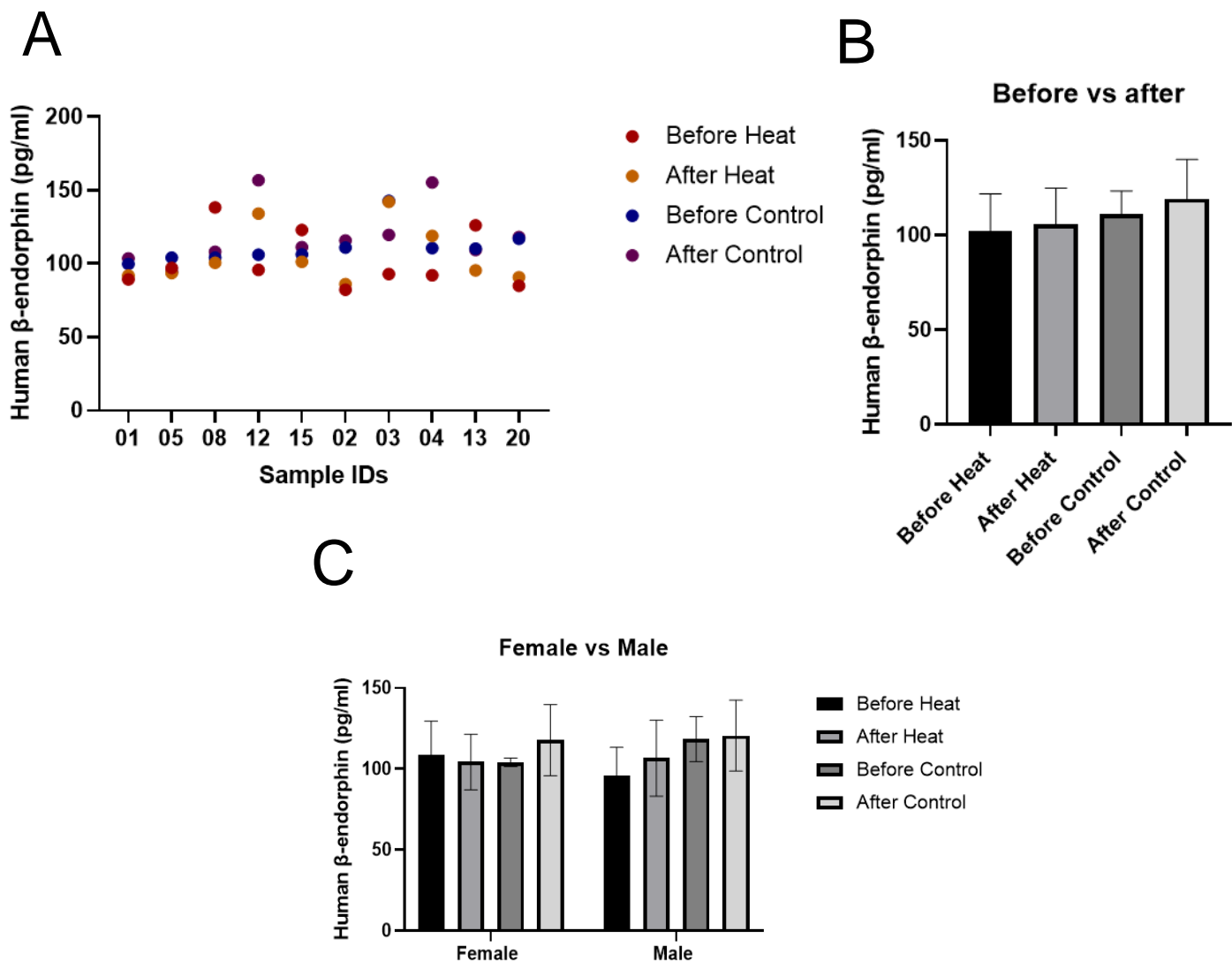


Figure 5. Comparison of blood β -endorphin measurements following BWarm use by ELISA. Blood β -endorphin levels were determined for 10 participants (5 female, 5 male) before BWarm use (Before Heat) and after BWarm use (After Heat), compared with before and after measurements of the same participants, untreated. β -endorphin measurements were determined by ELISA. Graphs indicate A) individually plotted β -endorphin measurements for all participants, B) average blood β -endorphin values of all participants, and C) average β -endorphin values compared between male and female participants. Error bars represent the standard error of the mean.

VII/ Determination of Dopamine release following 30 minutes using the BWarm

(n=5 females + 5 males)

Across all participants, the average blood dopamine levels decreased, **although this was not significant**. The average blood dopamine levels of females marginally increased following use of the BWarm, from 90.31pg/mL to 92.0465pg/mL, however, the average blood dopamine levels of males decreased from 122.98pg/mL to 86.54pg/mL following the use of the BWarm for 30 minutes.

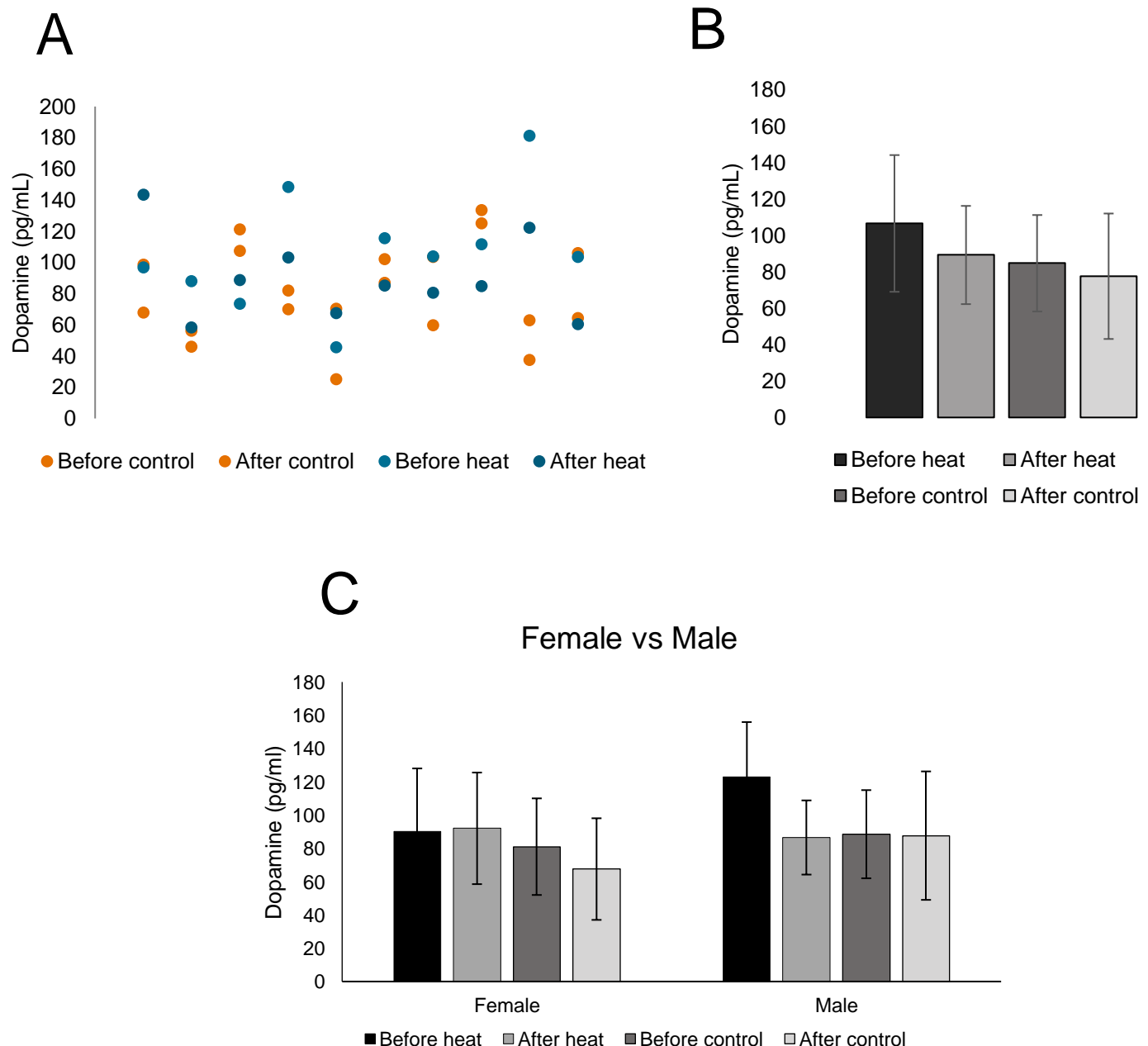


Figure 6. Comparison of blood β -endorphin measurements following BWarm use by ELISA. Blood β -endorphin levels were determined for 10 participants (5 female, 5 male) before BWarm use (Before Heat) and after BWarm use (After Heat), compared with before and after measurements of the same participants, untreated. β -endorphin measurements were determined by ELISA. Graphs indicate A) individually plotted β -endorphin measurements for all participants, B) average blood β -endorphin values of all participants, and C) average β -

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- **73.9% of participants declared a reduction in pain levels and 75% declared improved wellbeing following BWarm use.**
 - **There were no significant changes in dopamine or serotonin levels following 30 minutes using the BWarm.**
 - **There was an average increase of blood β -endorphin levels in males following 30 minutes of BWarm use.**

Recommendations

- The BWarm appeared to increase the wellbeing of participants who used it for 1 month.
- A study whereby participants would use the BWarm consistently for a longer period would be recommended to assess the longer-term impacts of the BWarm on perceived pain and wellbeing.
- Although the BWarm did not appear to change hormone levels of participants in the blood study, it is recommended that the blood study might be repeated with a larger number of participants to determine any definite changes, as well as a longer experiment time. Additionally, it may be beneficial to focus a blood study on the target group for BWarm use.



Targets

To assess the use of the BWarm device on the health and wellbeing of participants using a questionnaire and blood study.



Delivered

This report summarises the methods used for the assessment of the BWarm device on wellbeing and perceived pain.



Outputs

The BWarm increased participant wellbeing and reduced perceived pain.