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The benefits of thermal clothing during winter in patients with heart failure: a pilot randomised controlled trial

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ABSTRACT

Objectives: To examine whether providing thermal clothing to heart failure patients improves their health during winter.

Design: A randomised controlled trial with an intervention group and a usual care group.

Setting: Heart failure clinic in a large tertiary referral hospital in Brisbane, Australia.

Participants: Eligible participants were those with known systolic heart failure who were over 50 years of age and lived in Southeast Queensland. Participants were excluded if they lived in a residential aged care facility, had incontinence or were unable to give informed consent. Fifty-five participants were randomised and 50 completed.

Interventions: Participants randomised to the intervention received two thermal hats and tops and a digital thermometer.

Primary and secondary outcome measures: The primary outcome was the mean number of days in hospital. Secondary outcomes were the number of general practitioner (GP) visits and self-rated health.

Results: The mean number of days in hospital per 100 winter days was 2.5 in the intervention group and 1.8 in the usual care group, with a mean difference of 0.7 (95% CI −1.5 to 5.4). The intervention group had 0.2 fewer GP visits on average (95% CI −0.8 to 0.3), and a higher self-rated health, mean improvement −0.3 (95% CI −0.9 to 0.3). The thermal tops were generally well used, but even in cold temperatures the hats were only worn by 30% of the participants.

Conclusions: Thermal clothes are a cheap and simple intervention, but further work needs to be done on increasing compliance and confirming the health and economic benefits of providing thermals to at-risk groups.

Trial registration: The study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12612000378820)

ARTICLE SUMMARY

Article focus

- Despite having mild winters, many Australian cities experience a large increase in deaths and hospitalisations during winter.
- Insulating peoples' homes has been shown to improve health during winter, but it is not known whether warmer personal insulation could also improve health.

Key messages

- Thermal clothes were generally well accepted and showed promising signs of improving health via fewer visits to general practitioners and better self-rated health.
- Compliance was poor among those who did not feel the cold or did not like tight-fitting clothes; compliance with the hat was also poor.

Strengths and limitations of this study

- This is the world's first study to examine the potential health benefits of improved clothing using a randomised controlled trial.
- This was a small study using mainly self-reported data; larger trials with more detailed health and economic data are needed to determine the potential health benefits of thermal clothing.

INTRODUCTION

Australia has a generally warm and temperate climate, with hot summers and mild winters across most of the country. Despite the pleasant climate, there are large increases in the number of deaths and hospitalisations during winter in many Australian cities.[1 2] In Brisbane, an estimated 5000 years of life are lost to cold-related deaths each year.[3] This is surprising as Brisbane has a subtropical climate, with an average July (winter) minimum daily temperature of 10 °C (Australian Bureau of Meteorology data from 1999 to 2012).

Places with mild winters have a greater risk of cold-related deaths than places with harsh winters. Previous European studies have shown that warm countries like Greece and Portugal have larger increases in the number of deaths during winter than Scandinavian

countries.[4 5] A greater impact of cold in warmer climates has also been found by comparing winter deaths in southern and northern cities in the USA.[6] Observational studies comparing clothing and housing in northern and southern Europe found that people in warmer southern European countries wore fewer and less appropriate clothes on cold days,[5 7] and that houses in cold climates were better insulated and warmer on cold days.[5 8] If clothing and housing in warm climates were improved, then the large increases in the number of deaths and hospitalisations during winter could be reduced. Recognising and addressing the problem now is particularly important given the ageing population and predicted increase in people living with heart failure, which will increase the population at risk of cold-related morbidity and mortality.[9]

Flu outbreaks are partly responsible for the increases in morbidity and mortality during winter, but cold temperatures are an important independent risk factor. A recent review of winter ill health in the UK led by Michael Marmot concluded that cold indoor temperatures are the 'main cause' of the increase in deaths during winter, with flu as a 'contributory factor'.[10] Many studies have shown independent effects of cold temperatures after adjusting for flu outbreaks directly, or by adjusting for season using a non-linear spline with a large number of degrees of freedom,[3] or by using a case-crossover design. There is also a strong biological plausibility of a direct effect of cold. Cold air temperatures impact the body via a colder skin temperature and by breathing in colder air. A colder skin temperature causes vasoconstriction, which leads to increased resistance in peripheral circulation and an increase in blood pressure.[11–15] Other physiological changes after cold exposure include increased blood viscosity,[11 15] reduced heart rate[14] and increased inflammatory factors such as plasma cholesterol,[11 16] fibrinogen[16] and C reactive protein.[17]

Improving the thermal quality of homes using either insulation or heating has been shown to improve residents' health.[10] Studies of improved insulation and heating in Scotland demonstrated improvements in the residents' blood pressure and self-rated general health.[18 19] A randomised controlled trial in New Zealand found home insulation to be associated with better self-rated health, fewer days off school and work and fewer visits to the general practitioners (GPs).[20] These studies provide strong evidence that keeping people warmer in winter has many health benefits. If home insulation and heating can improve health, then this strongly suggests that better personal insulation should also improve health.

To our knowledge, there are no studies of the health benefits of thermal clothing during winter. Thermal clothing protects people whether they are outside or inside, or in a heated or unheated room. Thermal clothing is a cheap, convenient and accessible intervention compared with heating, which has ongoing costs that can deter some people from using it.[21] It is also a simple intervention compared with heating, which some elderly people do not use because they do not understand the heating controls.[21]

We aimed to show if there were any health benefits of wearing thermal clothing during winter in a population vulnerable to cold temperatures. Our hypothesis was that people with systolic heart failure provided with thermal clothing would spend less time in hospital during winter.

METHODS

We used a parallel randomised controlled trial with two groups—an intervention group that received thermal clothing, and a control group that received the usual care. This was a pilot trial to test the logistics of distributing thermals and whether thermals would be used by this population. We also aimed to refine our design for a larger trial by asking participants open-ended questions at the end of the pilot study on the thermals and the trial procedures. We have applied for funding for a larger trial using a sample size calculation based on the pilot data.

Participants

Participants were eligible for inclusion if they had known systolic heart failure (with ventricular or systolic dysfunction), were over 50 years of age, and lived in south-east Queensland. The participants were excluded if they lived in a residential aged care facility, had incontinence or were unable to give informed consent.

Heart failure patients were chosen as a group vulnerable to cold temperatures based on an Australian study of the seasonal patterns in cardiovascular disease, which found that heart failure deaths were 24% higher in winter compared with the year-round average.[1] There is also a strong biological plausibility between cold skin temperatures and heart failure via vasoconstriction and the subsequent increase in blood pressure,[12 22] and via an increase in C reactive protein.[17]

Heart failure patients were recruited from inpatients and those attending routine check-ups at the Heart Failure Clinic in The Prince Charles Hospital, a large tertiary referral public hospital in Brisbane. The study was approved by The Prince Charles Hospital Ethics Committee (HREC/12/QPCH/79). The study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12612000378820).

We aimed to recruit 50 participants per group to give an 85% power to detect a halving in the average hospital bed days during winter from 6 days in the control group to 3 days in the intervention group. A halving in bed days was based on a halving in hospital admissions from a randomised controlled trial of home insulation.[23]

A 1:1 randomisation list was created by the study statistician (AGB) using randomly permuted blocks of 10 using the R software (http://www.r-project.org). The

randomised groups were written in numbered ordered opaque envelopes. The research nurse opened each envelope in turn after the participant had signed the informed consent form. The participants in the intervention group were given two thermal tops and two thermal hats made of 100% polypropylene (figure 1), an instruction sheet on when to wear the thermals (see online supplementary appendix A), a digital thermometer with batteries fitted, a paper diary, a pen and a prepaid envelope for returning the diary. The instruction sheet recommended wearing the thermals when the temperature was below 18 °C. This temperature was based on the association between outdoor temperature and death in Brisbane.[3]

Data

The paper diary was used by the participants in the intervention group to record when they wore the hat and top, and the indoor temperature. They were asked to complete the diary and record the temperature at the end of the day.

At the end of winter, all the participants were phoned by the research nurse and asked questions on their general health, recent GP visits and some details about their home. The research nurse also asked about the dates of any hospital visits during the winter. The participants were also asked for their comments on the thermals. The participants' hospital notes were used to obtain their age, gender and diagnoses details.

The primary outcome was the number of bed days in hospital after enrolment. Secondary outcomes were the participants' self-reported general health and number of GP visits. The general health question was from V.1 of the SF-36 questionnaire, with five responses ranging from 'Excellent' to 'Very poor'. The GP visit numbers were self-reported in the previous month.

Statistical methods

The primary outcome was the number of bed days in hospital from enrolment to the end of winter (30 September). We planned to analyse this data using Poisson regression with treatment group as the independent variable and an offset of the number of days from enrolment to the end of winter to adjust for varying the participant-times at risk.[24] However, after collecting the data, the assumption of independence between days was clearly not valid. We therefore used the bias corrected bootstrap to create non-parametric 95% CIs for the difference between the mean number of days in hospital between the two groups.[25] The number of GP visits was also compared by examining the mean difference between groups with a 95% bootstrap CI.

Self-reported general health was compared between the two groups assuming that a reported health of 'Excellent' scored one and 'Poor' scored five. We assumed that the scores had an approximate normal distribution with a common variance. The key statistic was the mean difference between groups. We verified the normal assumption by using a non-parametric bootstrap test.

The daily wearing of the hat or top (yes or no) was regressed against the daily indoor temperature in order to investigate how temperature influenced wearing of the thermals. The regression model was a generalised linear mixed model using a binomial distribution with a random intercept for each participant to control for repeated results from the same participant.[24] The association between temperature and wearing of the thermals could be non-linear, so we tried one-to-six degrees of freedom for the association using a natural spline,[26] and also tried a model with a random participant-specific slope for temperature. The best models for the average hat and top wearing were those with the smallest Akaike Information Criteria (AIC).[27]

All analyses were conducted using the R software (http://www.r-project.org). No subgroup analyses were planned or performed.

Figure 1 The thermals and thermometer supplied to the intervention group.

RESULTS

The start of the study was delayed from late autumn to mid-winter, so the final numbers were short of the target of 50 per group. The first participant was recruited on 21 June 2012 and the last on 31 July 2012. The flow of participants is given in figure 2. Around 45 participants who were initially approached were ineligible because they did not have ventricular or systolic dysfunction, or they lived outside the study's geographic area. Around 20 participants declined to participate because they either did not like close-fitting clothes or said they did not feel the cold. Two participants (4%) did not respond after randomisation (one in each group) and three participants in the usual care group could not participate owing to illnesses unrelated to the cold weather. Fifteen participants (56%) in the intervention group returned the diary.

The basic characteristics of the participants and their homes are in table 1. Around 80% had homes with heating, air conditioning or insulation. However, seven participants (14%) reported that they never or rarely used their heating. Three participants lived in caravans, which can be especially cold during winter owing to their generally poor insulation.

The results for the primary and secondary outcomes are in table 2. The mean number of bed days in hospital

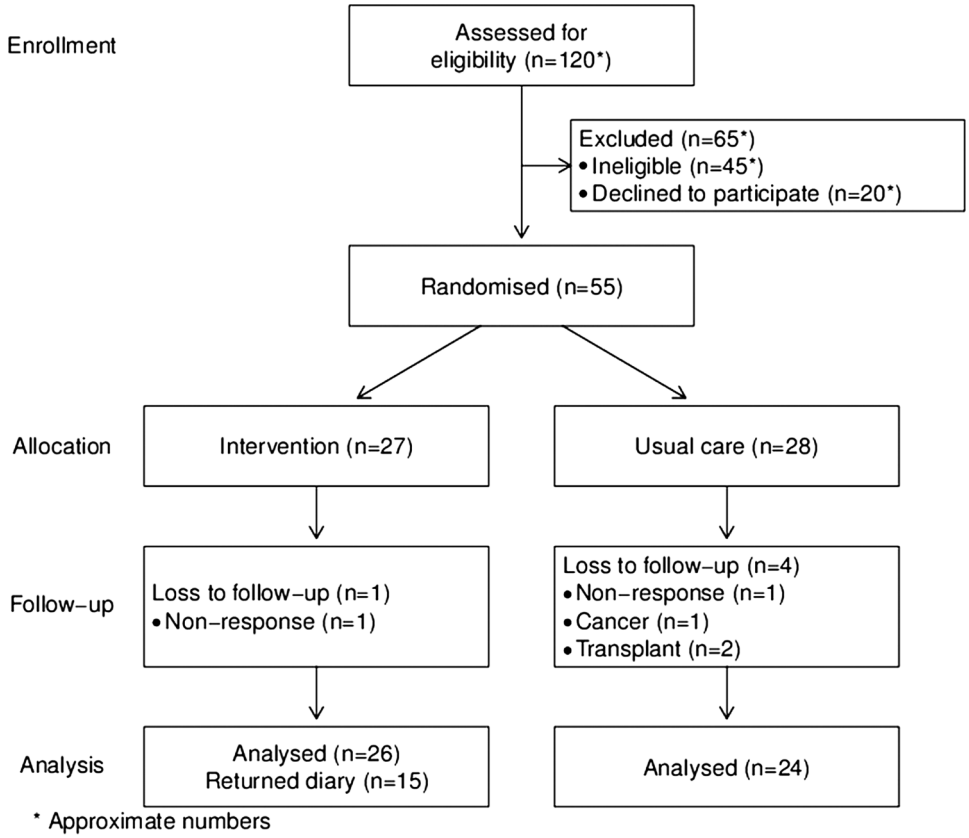

Figure 2 Flow of participants from enrolment to analysis.

per 100 winter days was 2.6 in the intervention group and 1.9 in the usual care group, with a mean difference of 0.7 days more in the intervention group (95% CI −1.5 to 5.4).

The secondary outcomes showed some benefit for the intervention, although the differences were not statistically significant (table 2). The average improvement in self-reported health was –0.3 (95% CI −0.9 to 0.3). There was an average of 1.2 GP visits in the intervention group compared with 1.4 in the usual care group, giving an average of 0.2 fewer GP visits in the thermals group (95% CI −0.8 to 0.3).

The estimated probabilities of wearing the hat and top by indoor temperature are in figure 3. Seven out of 15 participants (47%) never wore the hat. These participants are the flat lines close to zero in figure 3. The best model (according to the AIC) for the average hat wearing had five degrees of freedom, which is a strongly non-linear association. The average hat wearing peaked at around 30% of participants at around 14°C, and was close to 0% above 18°C. Reasons for not wearing the hat included concerns about appearance, overheating and a lack of perceived need.

Four participants wore the top regardless of the temperature, as shown by the flat lines at higher probabilities in figure 3. For the other participants, the probability of wearing the top declined sharply around 20°C. These two different behaviours by temperature explain why the best model (according to the AIC) was the random slope model, as it allows for such large between-participant differences.

CONCLUSION

Thermal clothing did not reduce the number of days in hospital during winter (table 1). Instead, the number of days in hospital was higher in the group given thermal tops and hats. Small benefits were seen for the secondary outcomes of self-reported health and self-reported GP visit numbers, which were both better in the intervention group, although the improvements were not statistically significant. These health benefits could be because participants in the thermal group were kept warmer during winter. The benefits of keeping warm have been demonstrated using improved home insulation and heating, with high quality studies showing improved self-reported health and fewer visits to GPs.[19 20] The biological mechanisms of these benefits include lower blood pressure and inflammation markers, which increase in cold weather,[17] and improved mental health.[10]

The thermal tops were generally well used, especially at cold temperatures (figure 3). However, the hats were not well used, with participants raising concerns about need, overheating and appearance. This concurs with previous research from the UK on dealing with cold, which found that hats were disliked because they were 'unbecoming'.[28] Hats are effective at reducing the surge in blood pressure after cold exposure.[29] Hats can be easily removed if the temperature warms up, which makes them useful, given that some participants raised concerns about overheating as the day warmed up. Despite the poor compliance in this study, thermal hats could still be a worthwhile intervention for cold, and we

Table 1 Basic characteristics of the participants and their homes (n=50)

	Usual care (n=24)	Intervention (n=26)
Participant		
Age, years, mean (SD)	64 (9)	64 (8)
Female, n (%)	6 (25)	5 (19)
Diagnosis=dilated cardiomyopathy, n (%)	9 (38)	14 (54)
Diagnosis=ischaemic cardiomyopathy, n (%)	12 (50)	9 (35)
Diagnosis=other, n (%)	3 (13)	3 (12)
Ejection fraction (%), mean (SD)	35 (12)	36 (12)
Diabetic, n (%)	6 (25)	5 (19)
What is a cold outdoor temperature (°C)?, median, IQR	17 (12–18)	15 (14–18)*
Home		
Type=house	17 (71)	21 (81)
Type=apartment/unit	4 (17)	2 (8)
Type=townhouse/semi-detached	1 (4)	2 (8)
Type=caravan	2 (8)	1 (4)
Home age, years, median (IQR)	23 (15–36)	20 (16–39)
Any heating in home, n (%)	18 (75)	21 (81)
Any air conditioning in home, n (%)	18 (75)	21 (81)
Roof insulation, n (%)	20 (83)	18 (72)

*One participant felt that it never gets cold in Queensland.

plan to try to increase their use in a larger trial by using better education about their value and a more acceptable design.

Cold is an underrated health problem. It is often seen as something to put up with, and some people even believe that exposure to cold makes them hardy.[21] Some people declined to participate in our study, or participated but then declined to wear the thermals, because they 'did not feel the cold'. This may be related to an impaired ability to feel cold with increased age.[30] Ideally, everyone with heart failure would protect themselves against the cold, as people with heart failure have a much greater risk of cold-related death and hospitalisation than the general population. The complacent attitudes to the dangers of cold in this population are a matter of concern, and are likely to be part of the reason why Australia experiences such large increases in deaths during winter.[3] If larger trials of thermals are able to show health benefits, then these attitudes could be reversed. Participation in the trial did change the minds of some participants in the intervention group, who reported an improved attitude to thermals and added that they would be using them again next winter.

Twenty of the 120 participants approached refused to participate because they did not like close-fitting clothes or because they said that they did not feel the cold. This reduces the generalisability of the results to the wider population of heart failure patients, and potentially biases our results as the health benefits of thermals may be dependent on attitude towards clothing and the cold. It is possible that thermals would be of more benefit in this reluctant group, as they may do little to protect themselves against the cold and therefore have the most to gain. It is also possible that thermals would be of less benefit in this reluctant group if compliance was poor.

We asked participants what they perceived as a cold outdoor temperature in Queensland, and the median answer was 16°C, with a quarter of participants answering 14°C or less (table 1), and one participant answering that it never gets cold. These temperatures are colder than the risk threshold of 18 °C identified in a previous epidemiological study of deaths in Brisbane. This difference further highlights how people at-risk often underrate the dangers of cold. WHO recommends a minimum indoor temperature of 18 °C, with a higher minimum of 20 °C for the very old and young.[31]

Table 2 Comparisons of the primary and secondary outcomes between the intervention and usual care groups

Variable	Mean		Mean difference (95% CI)
	Intervention	Usual care	
Bed days in hospital (primary)*	2.5	1.8	0.7 (−1.5 to 5.4)
Number of GP visits (secondary)	1.2	1.4	−0.2 (−0.8 to 0.3)
Self-reported health (secondary)†	2.7	3.0	−0.3 (−0.9 to 0.3)

*Per 100 winter days.
†1=excellent, …, 5=very poor.
GP, general practitioner.

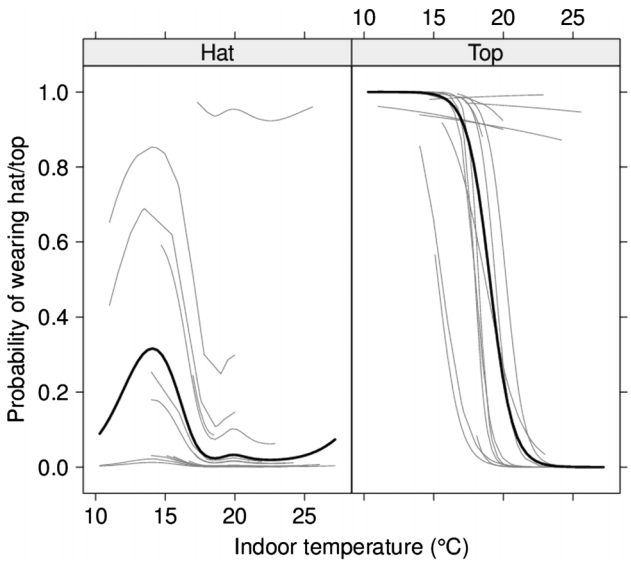

Figure 3 Estimated probabilities of wearing the thermal hat and top by indoor temperature. The thin grey lines are the individual participant estimates (n=15), and the thick black line is the average estimate.

Two participants reported that the thermals improved their sleep, which was an unexpected benefit that we plan to study as part of a larger randomised controlled trial. Patients with heart failure are well known to suffer sleep problems,[32] and improving sleep may be a key part of the health benefits of keeping warm.[33] A study in elderly people found that just a 0.4 °C increase in skin temperature almost doubled the proportion of nocturnal slow wave sleep and greatly decreased the probability of early morning awakening, and this study recommended increased clothing to improve sleep in cold rooms.[34]

Thermal clothing is a cheap intervention. The two pairs of thermal tops and hats cost $A 70 per participant, and each digital thermometer cost $A 13. The clothes can be reused in subsequent winters, and many participants stated their intention to reuse them next winter. For thermal clothing to be cost-effective at the willingness to pay a threshold of $A 64 000 per quality adjusted life year (QALY)[35] would require a QALY gain of just 0.003 years (or 1 day) per person given thermal clothing. This uses a cost of $A 150 per participant, which includes 30 min of nurse staff time per person.

The health benefits of thermals need to be tested using larger and more comprehensive randomised controlled trials. Trials could also be run in other countries and climates, as thermals could be beneficial in any location that experiences an increase in heart failures during winter. This small study relied on self-reported data for many outcomes. Future studies could use routinely collected data to obtain detailed times and costs on healthcare use throughout winter (eg, Medicare), which could also be used to build an economic argument for freely distributing thermals to at-risk people. We also relied on self-reported temperature, whereas automatic indoor temperature monitors would be more accurate and have less missing data. A larger study could also expand the study population to other types of cardiovascular or respiratory disease that are known to be associated with cold weather, such as myocardial infarctions and stroke.

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Contributors AGB conceived the idea for the study, ran the statistical analysis and wrote the first draft. AGB is a guarantor. ML and DP recruited the participants. AGB, ML, DP, EW and JF provided input for the study design and drafts of the paper, and approved the final version.

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Competing interests None.

Patient consent Obtained.

Ethics approval The Prince Charles Hospital Ethics Committee (HREC/12/QPCH/79).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement All the data collected as part of this study are available to interested researchers through ethical approval from the Human Research Ethics Committee of The Prince Charles Hospital. Please contact Adrian Barnett (a.barnett@qut.edu.au) if you are interested in accessing the data.

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