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Rayguard - heat, medicate, relieve

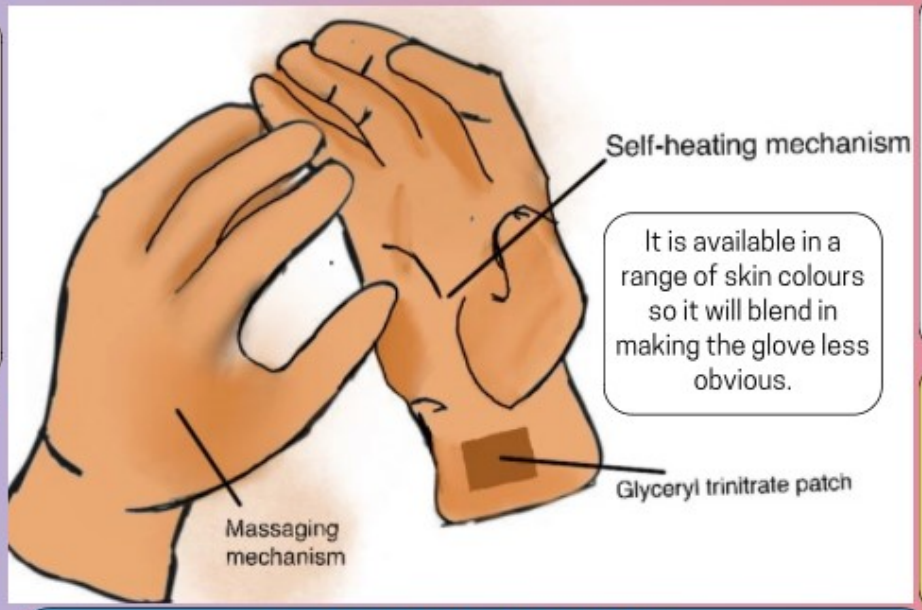
Our proposal: Heated gloves with glyceryl trinitrate patch with massaging technology.

What is Raynaud's?

Vascular condition that affects blood flow, usually to the fingers and toes. It occurs when cutaneous arteries constrict excessively causing vasospasm, leading to a series of colour changes in the skin and loss of sensation.

Primary Raynaud's - fingers and toes feel numb and cold in response to cold temperature or stress. It isn't serious or dangerous, but can disrupt daily activities.

Secondary raynaud's - more serious and aggressive than primary Raynaud's and is related to another health issue, especially autoimmune conditions like scleroderma or lupus.



Massaging mechanism

To design massage gloves that ensure good circulation and constant blood supply to finger tissues, you can integrate solenoids. Solenoids are electromechanical devices that convert electrical energy into mechanical motion. By strategically placing small solenoids within the gloves, they can create a rhythmic compression and release motion, simulating a massage. This action will stimulate blood flow and improve circulation in the fingers. The solenoids can be controlled via a small microcontroller, allowing you to adjust the intensity and pattern of the massage for optimal effectiveness.

Self-heating mechanism

Our heated gloves — like heated jackets — are powered by rechargeable batteries, typically lithium-ion or lithium polymer. The battery packs are usually removable, so they charge separately from the gloves. Once fully charged, you just place the packs in their designated pockets, then turn the gloves on. When the battery is turned on, an electrical current is passed through those wires causing them to heat up.

Why should we treat Raynaud's disease?

Raynaud's phenomenon affects up to 20% of adults worldwide, with around 10 million cases in the UK. While usually harmless, severe cases can permanently damage tissue and disruption of wellbeing and deterioration of mental health. There is no cure, and NHS treatments focus on symptom management and reduce the frequency and severity of the episodes. Finding a solution is crucial to improve the quality of life for sufferers.

How we plan to prevent:

We plan to prevent Raynaud's through three things:

- administration of drugs, avoiding cold temperatures, improving circulation.

Drug Trials

Non-clinical

- Animal cells & tissues
- Mammals
- Check for toxicity

Clinical

Healthy volunteers - trial a small dosage

- investigate side effect

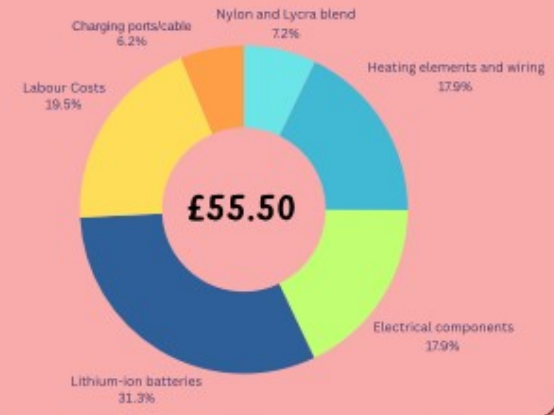
Double blind trial

- Raynaud's occurs more in women than in men (ratio: 9:1). Stratified sample can be used. Sample of women: sample of men =9:1
- One group with new drug, another with placebo. Neither of patients nor doctors know which group they are in - prevent biased result (accuracy)
- Low dose to start with, then the dose increases until the optimum dosage is found. Compare the results of the two groups — check for efficacy. Issue results on medical journals and peer-review

Drugs administered by patches

Nitroglycerin, also known as glyceryl trinitrate, is a vasodilator as it opens up the arteries and veins. GTN is a nitric oxide donor and thus its vasodilatory response is endothelial independent. This increases blood supply to the fingertips. The available findings from in vivo and in vitro studies in both humans and animals show that nitroglycerin can be absorbed through the skin. Therefore, we are going to place a transdermal patch with GTN inside the glove above the wrist. GTN is sealed in the patch and is exposed only after the protective liner is removed. This makes sure the patient won't get a constant diffusion of GTN into their blood and only be used when they need it. The patches can be replaced after use as each patch is only one time use as it contains a small concentration of GTN.

Cost breakdown



Ethics to consider in trials

- Conduct non-clinical trial before clinical trial
- Participants must give informed consent and they have the right to withdraw from the test whenever they want
- The data collected is anonymous and will not be shared unless they consent to share their data for research purposes
- Non-clinical trial: reduce the number of animals used in experiments by improving experimental techniques
- Reduce harm to animals by conducting experiment on cell cultures

+ Pros +

- Rapid onset- GTN works quickly, which is beneficial during acute episodes of Raynaud's
- Treatment is localised, so blood vessels in the rest of the body can function normally and respond appropriately in response to changing temperatures.
- Medication is delivered gradually in low doses, so the patient's body is not overdosed.
- Long term use can allow the body to become tolerant to side effects over time.
- Easier to use for elderly patients that may find it difficult to consume oral

-- Cons --

- There are a few common side effects of GTN such as headaches, feeling nauseous, sick, dizzy and flushing. Speak to a doctor or pharmacist if the advice on how to cope does not help and a side effect is still bothering you or does not go away.
- May be hard for some patients to put it on during an attack and remove the protective liner on the patch
- Have to charge the glove, which can be inconvenient and people may forget to do so
- There might be some GTN still left on the patch, which can be a waste
- Nylon and lycra are made from non-renewable resources, so are not

Feasibility and affordability

Our product is portable and handy, useful for all day wear. Our nylon and lycra mix fabric is light, thin and breathable, therefore very comfortable for the user.

The price of our glove will be around £60. We think this is an affordable price for an average UK citizen, considering our glove has a guarantee of three years of use. The patches will be made by 3D printing, which will reduce our costs. Furthermore, GTN is a widely available drug with a low cost. The lithium battery is inexpensive and lasts 2-3 years.