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RESEARCH INSIGHT

RCTs in general practice: Consider the influence of patient expectation on your recruitment strategy

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SUMMARY
Despite the focus on a common condition presenting frequently in general practice, our study failed to recruit the requisite numbers. The attrition rate was difficult to interpret. It is plausible that people presenting with warts to general practitioners have already decided that they need cryotherapy and are reluctant to consider alternative experimental treatments even though the evidence for effective treatment with cryotherapy is poor. Patient expectation and the perceived pressure to acquiesce to patient demands in primary care greatly affected the recruitment potential of this trial.

Key Words
warts; cryotherapy; primary health care; musa; therapeutics

INTRODUCTION

Cutaneous warts caused by the human papilloma virus (HPV) are highly prevalent in the population.[1] The literature suggests that most simple warts clear spontaneously over a matter of months or years.[2,3] Without treatment, one-half resolve within one year and two-thirds within two years, so any active treatment would have to significantly improve on this figure to be considered effective.[4,5]

To date, cryotherapy is regarded as the treatment of choice for cutaneous warts.[6] The recommended regimen is four treatments at two weekly intervals.[6] Previous trials have compared the use of cryotherapy with topical salicylic acid with the conclusion that cryotherapy was the most effective therapy in primary care.[7]

Treatment with cryotherapy is moderately effective but painful. As many of the patients who are brought for treatment of warts are children, an alternative method that is more effective, or at least more acceptable, is needed. Research on more effective treatments continue, however, at least some involve minor surgery.[8]

Empirical and anecdotal evidence from clinical practice suggests that the peel of the Musaceae musa (bananas) can be used to treat warts.[9] The aim of this work was to conduct a randomised clinical trial testing the hypothesis that the treatment of cutaneous warts with banana peel is at least twice as effective as treatment with cryotherapy. The null hypothesis is that there is no difference between these treatments.

SUMMARY

Participants who presented with cutaneous warts to a general practice in Western Australia were randomised to receive either occlusion of the wart with banana peel overnight or cryotherapy treatment. Treatment effect was reviewed at two, four, six, 10, and 16 weeks. Participants who had no resolution of their warts by four weeks were crossed over to the alternate treatment. A sample size of 112 participants was required to investigate a substantial difference in outcomes.

The primary outcome measure was agreement between the participant and a nurse that the lesion had been eradicated. Secondary outcome measures included patient-reported pain, use of analgesia, and treatment satisfaction.

After one year, only 30 eligible participants were recruited. There was substantial loss to follow-up (Figure 1). Twenty participants were randomised to commence with banana peel treatment. Thirteen were subsequently allocated to cryotherapy. Ten participants commenced with cryotherapy and one was subsequently crossed over to banana peel treatment. There was no difference in resolution of warts between the groups, whichever treatment was used first. Cryotherapy was significantly more painful and both treatments were considered equally satisfactory to participants.

LESSONS LEARNED

It has been shown that it is difficult to recruit participants to clinical trials in general practice.[10] However, the team began with great optimism for this trial.[11] The extrinsic incentives for practitioners to participate seemed compelling:

- Involvement of a respected local academic institution and leadership by a general practitioner;
- Funding by a recognised national peak body as well as a local health foundation; and
- The scope for publicity if the trial was successful.

Furthermore, a number of intrinsic factors were also promising:

- Delegation of the informed consent process (time consuming); and
- A focus on a common and difficult problem to treat in practice.

The practice was inducted to the project by the lead investigator with reference to two senior clinicians. The protocol was approved by the participating general practitioners with reference to the practice nurses. In addition, the practice seemed optimistic about recruitment of the numbers of participants required. Therefore, it appeared to satisfy all the criteria noted in a previous literature review of recruitment strategies in primary care.[10]

There were several reasons why we think this trial may have failed. It became clear in the course of the study that many potential participants were reticent to be recruited to a trial on the management of warts when they had presented with a specific request, namely, to have the warts "frozen". The offer to be involved in a trial was often met with the rebuttal: *"I've tried all sorts of things already so no thanks doctor, just freeze them off, please"*. It may be that doctors became aware that the consultation about the warts was for a specific treatment and not for advice. Often participants had previously had a wart treated in this way or had heard that cryotherapy was the only effective treatment. It was not clear if the participants were aware of the limited evidence for benefit from cryotherapy or that the treatment may have to be administered four times before it can be said to have failed. We posit that eligible participants were not recruited and that this was consistent with the perceived pressure to acquiesce to patient demands in primary care.[12]

We noted very significant attrition during this trial. The most significant attrition was in the cryotherapy group (6/10 vs. 5/20). This suggests that either the cryotherapy may have been less acceptable because of the need for repeated attendance or because it was painful, or that resolution was attained and participants did not return. In contrast, it was surprising that some participants refused to accept the banana peel treatment because they found it unappealing. This is despite the advice that they were only required to carry out the treatment overnight and could wear a sock during this time. It was evident in the reticence to comply with banana treatment that some people have an aversion to the smell and texture of the brown/black remains of the banana peel when it has been in contact with skin for many hours. This is consistent with the observation that there are many factors associated with what people consider palatable and acceptable.[13] We propose that any future attempt to test the treatment would require the banana peel to be rendered a more desirable option.

The major lesson learned from this trial was that potential participants often come with their own ideas about what they wish to achieve in a consultation regardless of what is on offer. Despite the positive indicators for a successful trial in a busy clinical practice, recruitment is contingent on treatment acceptability and patient expectation.

CLINICIAN INSIGHT

As a practicing podiatrist reflecting on this paper, there are a number of identifiable factors, which may have

limited recruitment, participation, and the overall success of the study. From a professional perspective, it can be difficult to propose a treatment such as banana peel with no set clinical guideline that is undertaken predominantly while at home (as opposed to within the treatment room). Clients may assume that treatment is going to be ineffective and therefore accept it as a waste of time and experimental leading to their refusal to participate.

Secondly, cryotherapy is rarely used anymore within the podiatry profession for the treatment of warts. A variety of treatment options, including salicylic acid, cantherone, and Faulknor's needling method are now more commonly used due to their supposed increased success rate. I feel a limitation of this study is that few podiatrists would use cryotherapy so the comparative intervention should better reflect current and preferred clinical protocols.

Finally, we need to deviate the consistent view held by the public aligned with "freezing off" warts as the only effective treatment. Further research trials that reflect clinical practice, and the development of an evidence-based treatment protocol for clinicians to follow will make this achievable.

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PEER REVIEW

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CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

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ETHICS COMMITTEE APPROVAL

The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry Trial ID: ACTRN12613000930785 and submitted for Human Research Ethics Committee review prior to commencement of participant recruitment. The project was reviewed by the Curtin Human Research Ethics Committee (ACTRN12613000930785, HR 136/2013).

FIGURES AND TABLES

Figure 1. Participant Recruitment