



EWMA Study recommendations for clinical investigations in leg ulcers and wound care



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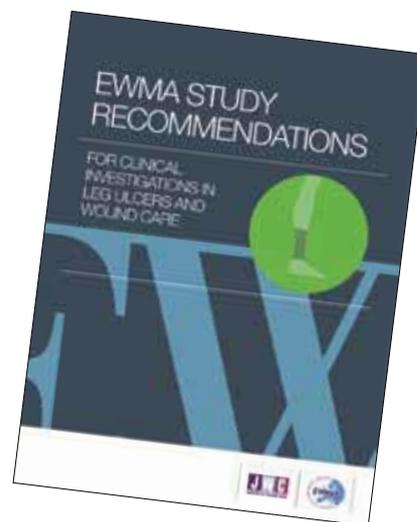
To support the drive to raise the quality of evidence in wound management studies, EWMA commissioned the Patient Outcome Group¹ to develop a series of recommendations to support researchers when planning investigating. The first of these focus on clinical investigations in leg ulcers and wound care, and was published in May 2014.

In 2010 the EWMA Patient Outcome Group (POG) published recommendations to improve the quality of evidence in wound management². As a companion piece of work, the EWMA POG has worked to provide a series of user-friendly documents to assist those new to (or inexperienced in) research in starting on the path to plan, conduct, interpret and disseminate findings from an investigation that will improve our understanding of clinical wound healing and raise the evidence level of the work undertaken in this important area. Given the range of wound types that clinicians are involved with, the POG has decided to limit the first of these to *venous* leg ulcers. In addition, as a European association, the focus will be on EU regulations and directives.

The target audience for this publication is hospital and community clinicians working collaboratively with other professions or industry. In particular, it aims to provide a clinical study guideline for the novice researcher working within wound care (leg ulcers), but the guideline may also be relevant for article reviewers, as educational material or a checklist for the experienced researcher. The text takes the format of a 'step by step' instruction manual to highlight activities to consider and outline frequent mistakes that many of us have made along the way – with the aim of helping novice researchers avoid making them, and improve the quality of studies that are undertaken. The emphasis focus on Randomised Controlled Trials (RCTs) and Cohort Studies that are prospective (i.e., retrospective studies are not included).

The initiative to produce this document was taken by the EWMA Patient Outcome Group (EWMA POG). The members of the EWMA POG are:

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The document is published by the Journal of Wound Care and can be downloaded free of charge at www.ewma.org

Throughout the document we sign post relevant existing documents and provide links to web-sites and documents where regulation specific issues are covered really well. The aim is to produce a user-friendly resource, which is practical. The format takes the form of short chapters on different aspects of the research process – with many points made in bullet format. It is not anticipated that researchers will read every page and associated web-link in order, but use it as a pathway through the process – with the text highlighting when it would be useful to take a detour into other resources to get additional information.

The information is divided into chapters that reflect the different stages of the process; many chapters have multiple subsections so that you can easily find help with a specific issue. We hope that you will find this document useful in putting together your research plans and look forward to reading the papers at some point in the future as you contribute to the evidence base for improved wound healing outcomes. ■

- <http://ewma.org/english/ewma-projects-and-studies/patient-outcome-group.html>
- Gottrup, F., Apelqvist, J., Price, P. Outcomes in controlled and comparative studies on non-healing wounds: recommendations to improve the quality of evidence in wound management. *J Wound Care* 2010;19:6,237-68.