

SETTING UP RANDOMISED CLINICAL TRIALS IN WOUND CARE

Carolina Weller

Monash University, Melbourne, Victoria, Australia

Aims: To outline the steps and background of setting up randomised clinical trials (RCT) in wound management clinical practice. To describe how the CONSORT statement can help novice researchers in setting up and reporting of RCTs in wound clinical practice.

Methods: RCTs are generally considered to produce the most solid evidence for the effectiveness of interventions. This method if designed and conducted correctly, randomisation reduces bias by allowing the researcher to control for factors that would otherwise confound the results. Given this important contribution we would expect the scientific wound community to be good at designing, conducting and reporting these studies. Sadly, this is not always the case in wound care. Scientific rationale and procedures and a set of procedures based on the CONSORT statement for other clinical researchers to consider when developing study designs will be discussed using the researcher's example of setting up a multi centre RCT in 4 States in Australia. Epidemiological and biostatistical aspects of RCTs including calculation of sample size for wound studies will be outlined. The presentation will describe the author's journey setting up a multi centre Phase II/III RCT across 4 states in AUSTRALIA.

Discussion: Discussion will include: how to select participants, how to specify invention/ control, how to specify primary and secondary objectives, how to determine sample size, why the need to randomise, the importance of allocation concealment and blinding, statistical methods in RCTs, recruitment and baseline data in clinical trials, intention to treat principle, subgroup analysis, reporting harms and generalising results.