The history about recruitment nursing essay

Health & Medicine, Nursing

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\n[/toc]\n \nQualifying participants will be identified by clinicians within the clinic. Clinicians will then briefly explain the study to the patient including what is involved and the potential benefits/risks. Further information on the benefits/risks are in the patient information leaflet which can be found in Appendix 2. If the patient is interested they will be given an information leaflet and a consent form. For more information, see Appendix 2 and Appendix 3 respectively. A researcher’s contact number will be given so that any questions the patient or patients family have can be answered. A signed consent form will need to be received within 4 days. The patient will be made aware that if they participate University of Manchester researchers will receive anonymous copies of their relevant medical records. The patients GP will be contacted if the patient takes part in the trial which the patient will be made aware of. Their GP will be provided with information on the patient’s involvement, test results, progress and medical concerns. The patients will have the option to leave the study at any time. The patient information

leaflet and consent form has been produced following guidance from the national research ethics service. (29)

Stratification and randomisation

Figure 4. Stratification method

The participants will be stratified as seen in figure 4. Oestrogen will affect the two sexes differently as seen in the 1999 trial so they will be stratified accordingly. (19) Female participants will then be further stratified into pre-menopausal and post-menopausal as the groups may have significantly different results due to the different levels and types of circulating oestrogens. (30)Participants will then be randomised into the placebo group or oestrogen cream group using a random number table.

Confounders

Confounders will be recorded and any difference between the groups will be controlled for in the statistical analysis. They are as followsWeight, height, BMI and ethnic background as they affect aetiology. (24)Smoking status as the risk of foot complications is increased in smokers.(31)Peripheral occlusive vascular disease as it affects aetiology. (24)Duration of diabetes. (24, 32)Ulcer site although no difference between median times to heal was found in a 2001 clinical trial, it is still important that we report each area, so sites can be compared and to enable ulcer identification if there are several. (32)Infection status as deterioration and delayed healing can result (6, 8, 32)S(AD) SAD classification as the different severities may affect healing. This is a validated classification method which we will record for each

participant.(23) For more information, see Appendix 1. Data will be obtained from various sources. For more information see Appendix 4.

Research procedures

All patients will be seen in clinic weekly and receive standard care according to NICE guidance as explained previously. Cream will be applied topically to the wound on a weekly basis by the research nurse. The placebo groups will receive aqueous cream; Oestrogen groups will receive Premarin™ 0. 625mg/g cream. The creams will be placed in identical plain tubes by the researchers and the nurse and participant will not be aware of which cream is being used. A thin layer of cream is to be applied over the surface of the wound and wound edges, roughly 0. 5g for a half hand area. (33) The ulcers should then be dressed and treated as directed by the NICE guidelines. Wounds will be measured using digital planimetry as it has been shown to be a reliable method. (34) It is inexpensive and practical to use. Importantly it has been shown to measure surface area accurately and quickly (30-60 seconds). Clinicians will require time to make the measurements and some training to ensure they have enough expertise. The university will provide training to each nurse who will be responsible for measuring the ulcers. A placom KP-90N digital planimeter will be used.(22) Wound margin will be defined as where tissue (red/yellow/black) meets normal skin. White/lilac coloured/macerated is ‘ normal skin’. (34) Measurements will be recorded in cm^2. It is important throughout the trial to monitor for any ulcer deterioration or adverse effects. The nurse should report any concerns to the university researchers who will document changes. If there is a concern surrounding adverse effects the trial should be stopped. Blood glucose should be

monitored each week as there is a risk that the oestrogen cream could increase blood sugar. (35)If an amputation is performed, death occurs or the ulcer heals these outcomes will be recorded and the patient will be included as having completed the study. If patients miss an appointment this should be recorded with the given reason. The patient should then be allowed to continue to partake in the trial if they wish. If patients drop out of the trial before the end of the trial but after treatment has commenced, their previous measurements may be included in the analysis. Reasons for leaving the trial should be recorded and arrangements for referral to other NHS services that may be required such as counselling should be made.

Data analysis plan

Statistical analysis

The ulcer measurement will be area and therefore continuous data, the main features of the sample will be described using statistics as follows; mean, standard deviation, standard error. Each subgroup (male, female post-menopausal, female pre-menopausal) exposed to oestrogen will be compared to its equivalent placebo group using a mean value and a t-test if the distribution is normal. If a normal distribution cannot be assumed a Mann-Whitney U test should be carried out. Categorical data to compare two groups will be done using chi squared test. Significance will be evaluated using p-value, less than 0. 05 will be regarded as significant, over 0. 05 will not be accepted as significant. SPSS will be used for analysis.(36-38)

Sample size

A 2001 study estimated healing times of diabetic foot ulcers receiving standard treatment and found that healing was seen at 70 days for many of the ulcers. For neuroischemic ulcers the mean wound area at day zero was 26. 6mm² ±7. 0, which decreased to 6. 25mm²±1. 7 at day 70. Neuropathic foot ulcers mean initial wound area was 61. 2mm²±17. 1, at day 70 the mean wound area was 3. 2mm²±1. 5. (24) We want to reduce this healing time significantly with HRT cream to 60, 55 or 50 days. To detect the smallest change of 10 days and for 90% confidence the calculation shows a total of 14 patients would be needed to demonstrate a significant change. As the study involves a large amount of commitment from patients, who are likely to be older and already receive intensive treatment a high number of dropout cases are expected. For this reason we will seek a larger study population however, we must balance the benefits of additional participants with the additional cost. We will try to recruit 20 participants for each arm of the study giving a total of 40 patients. This is a number which we can reasonably expect to be able to recruit and will meet sample size requirements even if half of participants withdraw.