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**Title: Identifying risk factors and protective factors for venous leg ulcer recurrence  
using a theoretical approach: a longitudinal study**

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**Title: Identifying risk factors and protective factors for venous leg ulcer recurrence using a theoretical approach: a longitudinal study**

**Abstract**

**Background:** The high recurrence rate of chronic venous leg ulcers has a significant impact on an individual's quality of life and healthcare costs.

**Objectives:** This study aimed to identify risk and protective factors for recurrence of venous leg ulcers using a theoretical approach by applying a framework of self and family management of chronic conditions to underpin the study.

**Design:** Secondary analysis of combined data collected from three previous prospective longitudinal studies.

**Setting:** The contributing studies' participants were recruited from two metropolitan hospital outpatient wound clinics and three community-based wound clinics.

**Participants:** Data were available on a sample of 250 adults, with a leg ulcer of primarily venous aetiology, who were followed after ulcer healing for a median follow-up time of 17 months after healing (range: 3 to 36 months).

**Methods:** Data from the three studies were combined. The original participant data were collected through medical records and self-reported questionnaires upon healing and every 3 months thereafter. A Cox proportion-hazards regression analysis was undertaken to determine the influential factors on leg ulcer recurrence based on the proposed conceptual framework.

**Results:** The median time to recurrence was 42 weeks (95% CI 31.9–52.0), with an incidence of 22% (54 of 250 participants) recurrence within three months of healing, 39% (91 of 235 participants) for those who were followed for six months, 57% (111 of 193) by 12 months, 73% (53 of 72) by two years and 78% (41 of 52) of those who were followed up for three years. A Cox proportional-hazards regression model revealed that the risk factors for recurrence included a history of deep vein thrombosis (HR 1.7, 95% CI 1.07–2.67,  $p=0.024$ ),

history of multiple previous leg ulcers (HR 4.4, 95% CI 1.84–10.5,  $p=0.001$ ), and longer duration (in weeks) of previous ulcer (HR 1.01, 95% CI 1.003–1.01,  $p<0.001$ ); while the protective factors were elevating legs for at least 30 minutes per day (HR 0.33, 95% CI 0.19–0.56,  $p<0.001$ ), higher levels of self-efficacy (HR 0.95, 95% CI 0.92–0.99,  $p=0.016$ ), and walking around for at least three hours/day (HR 0.66, 95% CI 0.44–0.98,  $p=0.040$ ).

**Conclusions:** Results from this study provide a comprehensive examination of risk and protective factors associated with leg ulcer recurrence based on the chronic disease self and family management framework. These results in turn provide essential steps towards developing and testing interventions to promote optimal prevention strategies for venous leg ulcer recurrence.

**Key Words:** Chronic disease, Protective factor, Risk factor, Recurrence, Venous leg ulcer

#### **What is already known about the topic?**

- The most frequent aetiology of leg ulcers is chronic venous disease
- Venous ulcers are characterised by a repeated pattern of long lasting and recurring wounds
- Evidence-based guidelines for preventing venous leg ulcer recurrence focus on wearing compression hosiery, while evidence on additional conservative strategies is lacking

#### **What the paper adds**

- A history of deep vein thrombosis, previous leg ulcers, and longer duration of the previous ulcer were identified as significant risk factors for venous leg ulcer recurrence

- Protective factors identified to enhance the likelihood of preventing leg ulcer recurrence were leg elevation, higher levels of self-efficacy, and increased physical activity
- Our work does not support the use of compression therapy as a protective factor against leg ulcer recurrence

## **1. Introduction**

Chronic venous insufficiency is responsible for about 70% of chronic leg ulcers, with an overall prevalence ranging from 1-2% (Briggs and Flemming 2007; Gohel and Poskitt 2010). This chronic condition has been shown to have negative physical, financial, and psychological implications, such as pain and disability (Persoon et al. 2004); depression (Jones et al. 2006; Moffatt et al. 2009); social isolation (Moffatt et al. 2006); and decreased quality of life (González-Consuegra and Verdú 2011). It accounts for approximately 2-3% of total healthcare expenditure in developed countries (Abbade and Lastória 2005; Posnett and Franks 2008). Often, venous leg ulcers are characterised by a repeating cycle of ulceration, a long healing process and recurrence over decades (Iwuji 2008). The recurrence rate is reported to be as high as 78% of treated patients (Abbade and Lastória 2005). The high recurrence rate remains a significant management challenge for patients and healthcare professionals.

Current evidence-based practices to prevent recurrence of venous leg ulcers are limited and focus on life-long compression therapy (Nelson et al. 2000; Nelson et al. 2006) or surgical intervention (Obermayer et al. 2006; Gohel et al. 2007) as the primary strategies for prevention. Although the effectiveness of these two methods is clear, a number of limitations and challenges remain. For example, surgical intervention may primarily be beneficial to patients who suffer from superficial venous incompetence (Obermayer et al. 2006), and many patients are unsuitable for surgery due to their age and co-morbidities (Arcelus and Caprini 2002). Davies et al. (2004) noted that of 759 patients with venous leg ulcers, only 75 were able to be randomised for surgery, due mainly to problems with either no superficial insufficiency, or the presence of co-morbidities restricting patients' suitability for surgery. For compression therapy, the issues of difficulties with application, discomfort, appearance

and cost result in a significant low compliance issue (Flaherty 2005; Raju et al. 2007; Van Hecke et al. 2011).

Other prevention strategies include leg elevation and leg exercises (O'Meara et al. 2009; Brown 2012), however, little evidence is available for their effectiveness in preventing leg ulcer recurrence. Therefore, more focused investigation must be undertaken to develop and determine what alternative conservative strategies are effective for prevention. Identifying the risk and protective factors would facilitate the tailoring of intervention strategies.

Previously identified risk factors for recurrence are mostly related to the severity of the patients' venous disease; such as the size of the previous ulcer (Vowden and Vowden 2006), prolonged ulcer duration (Gohel et al. 2005), and a history of deep vein thrombosis (McDaniel et al. 2002). Other risk factors found include co-morbidities e.g. cardiac disease (Finlayson et al. 2009); decreased ankle movement (Nelson et al. 2006); and advanced age (Labropoulos et al. 2012). However, it is crucial to comprehensively and systematically examine the risk and protective factors that influence self-management using a theoretical approach, as chronic venous insufficiency and prevention of recurrence requires lifelong self-management; and successful chronic disease self-management is influenced by a broad range of factors. Few studies have applied a theoretical framework of chronic disease management to examine both risk and protective factors for recurrence. Grey et al.'s self and family management of chronic condition examines risk and protective factors from four aspects, including health and disease specific factors, individual and psychological characteristics, family factors, and environmental context (Grey et al. 2006), see Figure 1. Using a theoretical approach assists in understanding the complexity of the venous leg ulcer recurrence process and facilitates identification of interventions to target certain risk or protective factors. In this study, recurrence was defined as a breakdown of skin over the same lower leg of the previous venous ulcer.

## **2. Methods**

### **2.1 Design and sample**

Secondary analysis was undertaken in 2012 of combined data from three previous prospective longitudinal studies, to identify risk and protective factors associated with the recurrence of venous leg ulcers. In these studies (Finlayson et al. 2009; Finlayson et al. 2011; Edwards et al. 2013) participants had been recruited from either three community-based leg ulcer clinics or two metropolitan hospitals' leg ulcer clinics in eastern Australia. The aims of these studies were: 1) to identify factors associated with leg ulcer recurrence from a sample of participants where data were collected at the time of healing, then participants surveyed at 12 to 36 months after healing (survey data collected between 2006–2007) (Finlayson et al. 2009), 2) to identify factors associated with leg ulcer recurrence, where participants were followed up every 3 months for 12 months after healing (data collected between 2006–2009) (Finlayson et al. 2011), and 3) to identify health service models of care which facilitated implementation of evidence based care in a longitudinal observational study, where participants were followed up every 3 months after healing for 18 months from recruitment (data collected from 2009–2011) (Edwards et al. 2013).

The first two of these studies (Finlayson et al. 2009; Finlayson et al. 2011) were designed using Grey, Knafl and McCorkle's (2006) conceptual framework of self and family management of chronic conditions, which has four domains of risk and protective factors for self and family management: the health status domain; the individual factors domain; the family factors domain; and the environmental factors domain. Within the framework's four domains of risk and protective factors, data were collected on the appropriate factors in each domain for research in this population.

For potential risk factors, the areas hypothesised to be related to recurrence and investigated included: (1) in the health status domain (health and disease specific factors) –



presence or history of varicose veins, deep vein thrombosis, venous surgery, impaired mobility, high or low body mass index, prolonged duration of previous ulcer and previous ulcer area, (2) in the individual factors domain - data on age, gender and depressive symptoms, (3) in the family factors domain – data on socioeconomic status, being a carer (for another member of the household) and living alone, and (4) in the environmental context domain – data on poor social support and limited use of the healthcare system for regular monitoring. These risk factors were hypothesised to increase likelihood of being associated with the recurrence of venous leg ulcers.

Potential protective factors which were hypothesised to enhance the likelihood of positive outcomes of preventing recurrence of venous leg ulcers within the four domains included: (1) in the health status domain - health or lifestyle/self management factors such as physical activity, skin care, leg elevation, and wearing compression hosiery, (2) in the individual domain - characteristics like high self-efficacy levels, (3) in the family domain – higher socio-economic status, marital/family structure status, and (4) in the environmental context domain - social support and health service use.

Recruitment for the third contributing study (Edwards et al. 2013) was from the same clinical sites and teams, thus similar data were collected on the same measures as the first two studies for consistency. As noted by Grey et al. (2006), the main goal of chronic disease management is to improve health outcomes. In this secondary data analysis, the primary outcome measure was the recurrence of venous leg ulcers. Additional outcome measures (e.g. on health service use) from Grey's individual and environmental outcome domains have been reported in Finlayson et al. (2014), however, it was beyond the scope of the study reported here to examine outcomes from all of the framework's conceptual domains.

Inclusion criteria for cases included in this secondary analysis were patients with a healed leg ulcer of primarily venous aetiology; an Ankle Brachial Pressure Index between 0.8 and 1.2; and a venous leg ulcer completely healed (defined by full epithelialisation maintained for at least 2 weeks). Patients with leg ulcers which were primarily of non-venous aetiology, or those with cognitive impairment were excluded. A power analysis was undertaken which found a total sample of 275 cases would be required, using the following parameters: 90% power, 5% significance, able to detect a 0.2 difference between proportions who recurred (0.2 and 0.4), and allowing for 20% extra for adjustment for confounding in a multivariable model.

Ethical approvals for all of the contributing studies, and for the secondary analysis of data for this study were obtained from the university, hospital and community health service organisations' Human Research Ethics Committees. All participants offered written informed consent.

## **2.2 Data collection and measures**

Data were collected in all the original contributing studies from medical records and self-reported questionnaires at baseline (upon ulcer healing), then at follow up times as described above in Section 2.1 after healing from 2006 to 2012. The data collected in the health status domain included: health and medical history, such as height and weight, mobility level of physical activity, and co-morbidities (cardiac disease, hypertension, osteoarthritis, rheumatoid arthritis; venous history and ulcer characteristics including size, duration and healing date of the most recent venous ulcer, history of deep vein thrombosis (DVT), venous surgery, time since first ulcer, and number of previous ulcers; follow-up care and treatment provided after healing, self-care preventive activities, and any ulcer recurrences. In the individual factors domain, data were collected on age, gender, self-efficacy and depressive symptoms. In the family factors domain, data were collected on marital status, income,

socio-economic status and living alone. In the environmental context domain, data were collected on social support and follow-up health service use.

Data on demographic variables, medical history and current treatments were obtained from medical records. Self-reported questionnaires were collected at baseline and follow-up questionnaires were posted to the eligible participants to measure level of physical activity, self-care activities, ulcer recurrence, psychosocial characteristics, family and environmental factors. The participants were offered the option of a telephone survey if this was preferable to filling in the questionnaire by hand. These measurements are described in more detail below.

The Yale Physical Activity Survey (YPAS) (Dipietro et al. 1993) was used to assess level of physical activity and exercise. The 36-item YPAS is measured and scored in three subscales of activity, namely total time index, energy expenditure, and total activity index. Studies have reported moderate to good reliability (Dipietro et al. 1993; Pennathur et al. 2004) and validity (Harada et al. 2001; Resnick et al. 2008).

The measurements related to self-care regimens included: level, type and length of time (days/week) in compression hosiery; frequency and length of time of leg elevation above the level of the heart (minutes/day); frequency and length of time of any ankle or leg exercises (minutes/day); and any special skin care on their lower legs or other activities undertaken. At each data collection time-point, participants were asked to report on these questions on their usual levels of these activities in the previous four weeks.

Participants were asked if they had any ulcer recurrences, how many, and the time to first ulcer recurrence since healed. Recurrence was defined as a breakdown of skin over the same lower leg of the previous venous ulcer.

Psychosocial and family factors measured included socio-economic index, the Geriatric Depression Scale – short form (GDS-SF) (Sheikh and Yesavage 1986) and General Self-Efficacy Scale (GSE) (Schwarzer and Jerusalem 1993).

Socioeconomic status measured using the participants' postcodes and Index of Relative Socio-Economic Advantage and Disadvantage (IRSAD) (Australian Bureau of Statistics 2008). The IRSAD was one of the indexes of the Socio-Economic Indexes for Area (SEIFA). SEIFA contains four indexes which provide summary measures derived from the 2006 Census to measure different aspects of socio-economic conditions by geographic area (Australian Bureau of Statistics 2008). The IRSAD summarised a range of variables related to relative advantage and disadvantage, such as low or high income, internet connection, occupation and education. The IRSAD score summarises the characteristics for a particular geographic area and is standardised against a mean of 1000 with a standard deviation of 100. A low score indicates relatively greater disadvantage and a lack of advantage in general, while a high score reflects relative advantage (Australian Bureau of Statistics 2008).

The GDS-SF is a 15-item scale to measure risk of depression, in which scores of 0-4 indicate a little risk of depression; 5-8 are considered indicative of mild depression; 9-11 suggest moderate depression and 12-15 indicate a high risk of depression. The GDS-SF has demonstrated good reliability, sensitivity and specificity (Brink and Yesavage 1982; McDowell and Newell 1996).

The revised General Self-Efficacy (GSE) scale comprises 10 items to determine the level of confidence in ability to cope with challenging and difficult situations. Each item is answered on a four point Likert Scale. The total scores are on a scale of 10 to 40, where higher scores indicating higher level of confidence. Internal consistency in this sample was checked and was good, with Chronbach's Alpha = 0.896. Good reliability, stability, and

validity has been established in numerous studies (Leganger et al. 2000; Luszczynska et al. 2005; Luszczynska et al. 2005).

In the environmental context, the Medical Outcomes Study Social Support Survey (MOS SSS) (Sherbourne and Stewart 1991) was employed to measure social networks and support for the participants. The scale consists of 19 items to assess social support in four dimensions, including emotional and informational support, tangible support, affectionate support, and positive social interaction support. Each item is answered on a five point Likert scale, indicating how much support was available. The total score is calculated from 0 to 100, with higher scores indicating greater social support. Internal consistency was checked with this sample, with a Chronbach's Alpha of 0.972 obtained. Good evidence of validity and reliability is reported with high internal consistency ranging between 0.91 and 0.96 for the four sub-scales and 0.97 for the overall scale (Sherbourne and Stewart 1991). Health service use was assessed by asking participants what type of health services they accessed after healing of their ulcer to provide advice and follow-up care and how often they accessed these health services. However, these data were only collected in two of the contributing studies, thus unable to be included in this analysis.

### **2.3 Data analysis**

Data analysis was undertaken using IBM SPSS Version 21. Descriptive analyses were conducted for all variables, utilising frequencies, means and/or medians and ranges according to the distribution of the variable data. Data were unavailable on some variables due to the nature of the longitudinal study design; hence, only available data were used for the analyses, as shown in the results tables. A survival analysis approach was taken for recurrence outcomes, to allow for the differences in follow up times. Using Kaplan-Meier survival curve analysis, the median time to recurrence was calculated. At the bivariate level, Chi square, t-tests or Mann-Whitney U tests to determine variables associated with recurrence. A BMI cut-

off level of 22 or less was used to identify those who were underweight, as recommended by the USA and Australian Nutrition screening guidelines developed for older adults (Lipski 1996). All variables significantly associated with recurrence ( $p < 0.05$ ) were included in the multivariable regression model. For the multivariate analysis, a Cox proportional-hazards regression was undertaken to determine the independent significant influential factors for leg ulcer recurrence based on the proposed conceptual framework, as well as adjusting for potential confounders, such as age. The dependent variable was event of recurrence. Survival analysis techniques examine the length of time to an event (in this case, ulcer recurrence) and can determine relationships between predictor variables and the time to recurrence (Tabachnick and Fidell 2007). It is thus useful when there are differing follow up times in a database. Participant data was censored at the time of last follow-up data collection if this time was less than 36 months from healing. Statistical significance was reported at  $p < 0.05$  level (two-tailed).

### **3. Results**

In the first and second studies contributing to this database, and 147 and 93 patients respectively were eligible for inclusion; with 122 and 80 consenting, giving response rates of 83% and 86%. In the third contributing study, of patients with venous leg ulcers, there was a 84% consent rate (48 of 57). The sample characteristics are described in Table 1. The mean age was 73 years (SD = 13.6, age range = 26 – 96), 52% (n = 130) of the sample were female, 43% were married (n = 93), and 64% relied on the age pension for income (n = 154). Almost half of the participants lived alone (46%, n = 115), and more than one third of participants required an aid to mobilise (35%, n = 87). The most common co-morbidities were varicose veins (65%, n = 159), hypertension (43%, n = 106), and osteoarthritis (39%, n = 95). Around

80% (n = 165) of participants reported experiencing multiple previous leg ulcers and the median duration of the most recent ulcer was 36 weeks (range = 4 – 747 weeks).

Using Kaplan Meier survival curve analysis, the median time to recurrence was 42 weeks (95% CI 31.9 – 52.0). About 22% (n = 54) of participants had recurred within 3 months of healing; 39% of those who had at least six months follow-up (91 of 235 participants); 57% of those who had 12 months follow-up time (111 of 193 participants); 73% of those with two years follow-up (53 of 72 participants); and 78% of those who were followed up for three years (41 of 52 participants).

Bivariate analyses were undertaken to guide selection of variables into the multivariable regression model, and revealed there were no statistically significant differences in relation to recurrence in the hypothesised individual factors of age and gender (Table 2). However, both the Geriatric Depression Scale and General Self-Efficacy Scale scores showed significant associations with risk of recurrence (see Table 3), in addition to a number of health and previous ulcer characteristics, including a BMI  $\leq 22$  Kg/m<sup>2</sup> ( $\chi^2_1 = 7.0$ , p = 0.008), participants who required aid to mobilise ( $\chi^2_1 = 6.34$ , p = 0.012), a history of multiple previous leg ulcers ( $\chi^2_1 = 33.2$ , p < 0.001) and longer ulcer duration. In terms of self-care factors, increased physical activity, leg elevation for at least 30 minutes per day, and wearing compression hosiery (whether Class 2 i.e. 20–25mmHg; or Class 3 i.e. 30– 40mmHg) for 5 or more days per week had lower rates of recurrence (Tables 2 & 3).

In regard to family and environment factors (see Table 3), the results of Index of Relative Socio-Economic Advantage and Disadvantage (IRSAD) (95% CI 10.6-31.8,  $t_{230} = 0.98$ , p = 0.327), and the MOS Social Support Survey (95% CI 0.9-14.4,  $t_{220} = 1.73$ , p = 0.085) indicated there were no significant differences between the mean scores of participants who recurred and who did not recur.

### 3.1 Cox regression model

In order to avoid the potential risk of colinearity, only one of the YPAS summary indices was included in the model as the YPAS summary indices were found to be significantly correlated in the correlation matrix. Results from the Cox regression model showed that a history of a past deep vein thrombosis (DVT), total duration of previous ulcer, history of multiple previous leg ulcers, age, elevating legs for 30 minutes a day, walking around for at least 3 hours/day and general self-efficacy were significantly associated with recurrence after adjusting for all variables included in the model (see Table 4).

Looking at risk factors, participants who had a history of DVT were 1.7 times (95% CI 1.07 – 2.67) more likely to recur than participants who did not have a history of DVT. Additionally, participants who had experienced more than one ulcer in the past were 4.4 times (95% CI 1.84 – 10.55) likely to recur. For each additional week of duration of the previous leg ulcer, the risk of recurrence increased by 1.005 (95% CI 1.003 – 1.007). Interestingly, participants who were younger had a higher risk of recurrence (for each year of age, hazard ratio 0.98, 95% CI 0.97 – 0.99,  $p = 0.024$ ).

In this study, three of the hypothesised protective factors of the Grey et al. framework were confirmed. These were elevating legs for 30 minutes a day, walking around for at least 3 hours/day, and higher levels of general self-efficacy. Participants who elevated their legs for at least 30 minutes a day were 3.0 times (95% CI 1.77 – 5.08) less likely to recur than participants who did not elevate their leg for at least 30 minutes a day; while those who were walking around during their normal day for at least three hours/day were 1.6 times (95% CI 1.05 – 2.31) less likely to recur than participants who were mobilising for less than three hours each day. A perceived higher level of general self-efficacy was inversely associated with recurrence. For every score increase on the General Self-Efficacy Scale (range 10 to 40), the hazard of recurrence decreased by 0.95 (95% CI 0.92 – 0.99).



#### **4. Discussion**

This study was a secondary analysis of data collected during three previous prospective longitudinal studies (Finlayson et al. 2009; Finlayson et al. 2011; Edwards et al. 2013), conducted to examine the risk and protective factors for recurrence of a venous leg ulcer using a comprehensive and systematic approach by applying a framework of self and family management of chronic conditions (Grey et al. 2006). The incidence of recurrence in this study was 52% with the highest rates of recurrence within the first three months after healing (22%). This high recurrence rate was similar to rates reported in the literature in studies that did not include controlled interventions (Abbade and Lastória 2005; Finlayson et al. 2011). As such, the first three months since healing appear to be crucial and it is important for intensive prevention strategies to take place and close follow-up for the prevention of venous leg ulcer recurrence to be undertaken.

The present study identified four key risk factors for recurrence of venous ulcers, namely, age, history of deep vein thrombosis, history of multiple previous leg ulcers, and total duration of the previous ulcer. Although findings on signs of more severe venous disease i.e. past DVT, multiple ulcers and longer ulcer duration are all supported by previous studies (McDaniel et al. 2002; Gohel et al. 2005; Finlayson et al. 2009), the findings for age were unexpected. In contrast to Labropoulos et al's (2012) study, the current study did not find that increasing age was associated with recurrence. At the bivariate level, participants who recurred had a higher mean age than those who did not recur, however when controlling for all other risk and protective factors in the multivariable model, younger age was associated with a higher risk of recurrence (see Table 4). This study was limited by a lack of vascular investigation data (e.g. plethysmography or Duplex ultrasonography) to determine the type and degree of venous insufficiency, which may be of more significance to outcomes than age and should be investigated in future studies. Another consideration is that the prevention of

ulcer recurrence heavily relies on self-care regimens and lifestyle modifications (Brown 2012; Heinen et al. 2012), which may be more difficult to adhere to in younger adults who are of working age.

Leg elevation, walking and self-efficacy were the protective factors which were found to enhance the likelihood of preventing recurrence of venous leg ulcers. In terms of self-care protective factors, physical activity and leg elevation were significantly inversely associated with recurrence in the multivariate model. These findings highlight that leg elevation and lower leg exercise programs could be further investigated and utilised as significant prevention strategies for recurrence. The result is in line with two previous studies (Brooks et al. 2004; Finlayson et al. 2009) and these strategies are generally recommended in evidence based guidelines for prevention and management of venous leg ulcers (The Australian Wound Management Association and the New Zealand Wound Care Society 2011). However, the guideline recommendations are based on expert opinion, as the evidence on the benefits of and required doses of these strategies are still yet to be established (Brown 2012). This study provides information on the potential dose and frequencies necessary to prevent recurrence to guide future intervention studies in this area, e.g. 30 minutes a day of leg elevation, three hours/day casual walking exercise, see Tables 2 and 4.

Surprisingly, use of compression therapy did not quite reach statistical significance in the multivariable model, although the results appear clinically significant (i.e. 69% of participants who did not recur reported wearing compression hosiery at least 5 days/week, compared to 39% of the participants who recurred). Use of compression hosiery is supported in the literature as an effective preventive strategy (Nelson et al. 2000; Nelson et al. 2006; Heinen et al. 2012). Current clinical practice guidelines for the prevention and management of venous leg ulcers (The Australian Wound Management Association and the New Zealand Wound Care Society 2011) recommend compression therapy as the first line prevention

strategy for preventing recurrence, which aims to manage the underlying cause and reduce the venous pressure. A recent systematic review (Nelson and Bell-Syer 2012) recommended the use of compression hosiery in reducing the recurrence of venous leg ulcers and concluded that high-compression hosiery seems to be more effective than medium-compression hosiery in preventing recurrence. However, the use of self-report measures of frequency of use of compression hosiery may have resulted in some inaccuracy in the data in this study, particularly as compression is widely recommended by health professionals, yet is well known to be difficult to apply and an uncomfortable treatment.

In regard to physical activity, level II evidence from a guideline for the prevention of venous ulcers suggested that regular exercises would enhance calf muscle pump function, which in turn would prevent venous ulcers (Padberg et al. 2004; Robson et al. 2008). However, the evidence on physical activity, specifically for preventing recurrence of venous leg ulcers is very slim. A relevant randomised controlled trial study on investigating the effects of adherence to compression therapy and physical exercise in leg ulcer patients found that the participants in the intervention group had less wound days, while there was no significant time differences for recurrence between the control and intervention group (Heinen et al. 2012). As a recent literature review summarised, there is some evidence on increasing physical activity, improving mobility and foot exercises, which may be helpful in preventing ulcer recurrence (Brown 2012). Further information on the effectiveness of physical activity to prevent recurrence such as, specifically tailored physical activity and the quantity of the activity and exercise is required.

A higher level of general self-efficacy was identified as a protective factor for prevention of venous leg ulcer recurrence in this study. This finding supports the literature that perception of higher levels of self-efficacy is associated with improved self-care or management and health outcomes in the context of other chronic diseases (van der Bijl and

Shortridge-Baggett 2001; Curtin et al. 2008; Dutton et al. 2009). The key prevention strategies for venous leg ulcers require life-long commitment to self-care regimens and lifestyle modifications, however, non-adherence to self-care regimens is well-documented in the literature (Raju et al. 2007; Van Hecke et al. 2009; Labropoulos et al. 2012). This result underscores the importance of interventions that target enhancing self-efficacy to promote self-care and studies that may shed light on issues of non-concordance.

Other hypothesised risk factors that were statistically significant at the bivariate level but did not retain significance in the multivariable model included requiring an aid to mobilise,  $BMI \leq 22 \text{ Kg/m}^2$  and Geriatric Depression Scale scores. The literature suggests that reduced mobility and poor nutrition are associated with venous leg ulcers (Gohel and Poskitt 2010; Regmi and Regmi 2012), however there are few studies that have assessed whether requiring aid for mobilisation or having a low BMI are associated with the recurrence of venous leg ulcers. Similarly, there is little evidence on the relationships between depression and recurrence of chronic leg ulcers, although higher levels of clinical depression have been found in patients with leg ulcers (Jones et al. 2006; Moffatt et al. 2009). Further studies are required to determine whether these three hypothesised risk factors have a role in recurrence. This is particularly vital for older adults as the prevalence of venous leg ulcers increases with age (Graham et al. 2003; Iwuji 2008) and older adults tend to be more susceptible to malnutrition (Watson et al. 2006), mobilisation issues and depression (Lyness 2008).

#### **4.1 Limitations**

This study was unable to study all aspects of the conceptual model, as data on health care systems, access and utilisation was unavailable. Data were also unavailable on the type and degree of venous insufficiency, which would influence rates of recurrence. The study is limited by the possibility of recall bias and response bias as measurements on the lifestyle

and self-care factors, psychosocial characteristics, family and environmental factors were obtained from self-report questionnaires.

## **4.2 Conclusion**

In conclusion, results from this study provide a comprehensive examination of risk and protective factors associated with leg ulcer recurrence based on the chronic disease self and family management framework. This study identified four significant risk factors for venous leg ulcer recurrence: age, history of deep vein thrombosis, history of previous leg ulcer, and total duration of previous ulcer. On the other hand, significant protective factors included elevating legs for 30 minutes a day and higher levels of physical activity and self-efficacy. These results provide essential information to guide development and testing of optimal prevention strategies for venous leg ulcer recurrence in experimental studies.

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**Conflict of interest:** No conflict of interest has been declared by the authors.

## **Author Contributions**

KF, HE were responsible for the study conception and design. KF &M-LW collated and analysed data. M-LW drafted the manuscript. KF, HE & M-LW made critical review and revisions to the paper. KF, HE & M-LW provided statistical expertise. KF and HE supervised the study.

**Figure 1. Conceptual framework of self and family management of chronic conditions**

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**Table 1. Characteristics of study sample**

<b>Factor</b>	<b>N (%)</b>
	<b>Total = 250</b>
<b>Gender</b>	
Male	120 (48%)
Female	130 (52%)
<b>Marital status</b>	
Married	93 (43%)
Single	40 (18%)
Widowed	85 (39%)
<b>Income</b>	
Aged pension	154 (64%)
Disability pension	29 (12%)
Employed	42 (17%)
Self-funded retired	16 (7%)
<b>Age, mean (SD)</b>	72 (13.5)
<b>Lived alone</b>	115 (46%)
<b>Mobilise with aid</b>	87 (35%)
<b>Medical history</b>	
Cardiac disease	71 (29%)
Hypertension	106 (43%)
Osteoarthritis	95 (39%)
Rheumatoid arthritis	26 (11%)
Stroke	24 (9.8%)
Varicose veins	159 (65%)
DVT	60 (24%)
Venous surgery	68 (29%)

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BMI $\leq$ 22 (Kg/m <sup>2</sup> )	35 (17%)
History of previous leg ulcer(>1)	165 (81%)
Total duration of previous ulcer (wks), median (range)	36 (4-747)
Previous ulcer area (cm <sup>2</sup> ), median (range)	3.6 (0.3-104.6)
<b>Lifestyle/regimen</b>	
Current smoker	13 (5%)
Skin care	193 (85%)
YPAS Moving Index: moving feet at least 3 hours/day	104 (53%)
Elevating legs for 30 minutes/day	97 (43%)
Wore compression hosiery for 5 or more days/week	124 (53%)

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Abbreviations: SD, standard deviation; DVT, deep vein thrombosis; BMI, body mass index, YPAS, Yale Physical Activity Survey.



**Table 2. Characteristics of those who recurred in comparison to participants who remained healed**

<b>Factor</b>	<b>Recurred</b>	<b>No recurrence</b>	<b>Test value</b>	
	<b>n = 130</b>	<b>n = 120</b>		<b>p</b>
	<b>n (%)</b>	<b>n (%)</b>		
<b>Age, mean (SD)</b>	72.8 (14.1)	71.5 (13.1)	$t_{250} = -0.76$	0.45
<b>Gender</b>				
Male	66 (51%)	54 (45%)		
Female	64 (49%)	66 (51%)	$\chi^2_{1} = 0.83$	0.36
<b>Marital status</b>				
Married	48 (39%)	45 (47%)		
Single	27 (22%)	13 (14%)		
Widowed	48 (39%)	37 (39%)	$\chi^2_{2} = 0.23$	0.412
<b>Income</b>				
Aged pension	86 (67%)	68 (60%)		
Disability pension	18 (14%)	11 (10%)		
Employed	20 (16%)	22 (20%)		
Self-funded retired	4 (3%)	12 (10%)	$\chi^2_{1} = 9.30$	0.157
<b>Lived alone</b>	62 (48%)	53 (44%)	$\chi^2_{1} = 0.38$	0.538
<b>Mobilise with aid*</b>	54 (43%)	33 (28%)	$\chi^2_{1} = 6.34$	0.012
<b>Medical history</b>				
Cardiac disease	41 (29%)	30 (25%)	$\chi^2_{1} = 1.70$	0.192
Hypertension	54 (43%)	52 (43%)	$\chi^2_{1} = 0.01$	0.940
Osteoarthritis	54 (43%)	41 (32%)	$\chi^2_{1} = 1.96$	0.162
Rheumatoid arthritis	16 (11%)	10 (8%)	$\chi^2_{1} = 1.23$	0.266
Stroke	15 (12%)	9 (7.5%)	$\chi^2_{1} = 1.35$	0.244
Varicose veins	77 (61%)	82 (70%)	$\chi^2_{1} = 2.11$	0.146

DVT	30 (24%)	30 (25%)	$\chi^2_{1} = 0.00$	1.000
Venous surgery	33 (27%)	35 (31%)	$\chi^2_{1} = 0.487$	0.485
BMI $\leq 22$ (Kg/m <sup>2</sup> )*	27 (23%)	8 (9%)	$\chi^2_{1} = 7.00$	0.008
History of previous ulcers(>1)**	112 (94%)	53 (63%)	$\chi^2_{1} = 33.2$	<0.001
Total duration of previous ulcer in weeks, median (range)**	44 (4-747)	30 (5-137)	M-W U <sup>‡</sup> = 9710	<0.001
Previous ulcer area (cm <sup>2</sup> ), median (range)	4.2 (0.3-105)	3 (0.3-62)	M-W U <sup>‡</sup> = 8353	0.121
<b>Lifestyle/regimen</b>				
Current smoker	6 (5%)	7 (6%)	$\chi^2_{1} = 0.14$	0.707
Skin care	109 (85%)	84 (85%)	$\chi^2_{1} = 0.00$	1.000
YPAS Moving Index: moving on feet at least 3 hours/day*	44 (45%)	53 (65%)	$\chi^2_{1} = 15.3$	0.001
Elevating legs for at least 30 minutes/day**	27 (22%)	70 (70%)	$\chi^2_{1} = 53.1$	<0.001
Wore compression hosiery for 5 or more days/week**	50 (39%)	74 (69%)	$\chi^2_{1} = 19.9$	<0.001

Abbreviations: SD, standard deviation; DVT, deep vein thrombosis; BMI, body mass index, YPAS, Yale Physical Activity Survey. \*\*p < 0.001; \*p < 0.05.

‡ M-W U = Mann-Whitney U

**Table 3. Health status, individual, family and environmental context factors**

<b>Factor</b>	<b>Recurred</b>	<b>No recurrence</b>	<b>All subjects</b>		
	<b>Mean (SD)</b>	<b>Mean (SD)</b>	<b>Mean (SD)</b>	<b>t-test</b>	<b>p</b>
<b>Health status</b>					
Physical activity (YPAS)					
Total Time Index**	18.29 (18.75)	28.91 (24.16)	22.68 (21.74)	t <sub>196</sub> -3.61	0.001
Energy Expenditure**	3341.45 (4232.97)	5695.16 (5247.98)	4322.16 (4811.48)	t <sub>178</sub> -3.33	0.001
Total Activity Index**	26.09 (17.74)	35.89 (19.58)	30.13 (19.10)	t <sub>197</sub> -3.48	<0.001
<b>Individual factors</b>					
Geriatric Depression Scale*	5.02 (3.42)	3.84 (3.51)	4.48 (3.51)	t <sub>232</sub> -2.54	0.010
General Self-Efficacy (GSE)**	28.99 (5.78)	32.05 (5.30)	30.26 (5.77)	t <sub>198</sub> -3.82	< 0.001
<b>Family factors</b>					
Socioeconomic status (IRSAD)	1013.75 (74.61)	1003.17 (89.25)	1008.83 (81.74)	t <sub>232</sub> -0.98	0.327
<b>Environment factors</b>					
Social networks					
Total MOS Social Support Survey	63.26 (29.03)	70.13 (27.87)	66.16 (28.75)	t <sub>223</sub> -1.71	0.088

Tangible support	59.22 (33.28)	65.63 (32.12)	61.99 (32.87)	t <sub>220</sub> -1.44	0.015
Affectionate support	69.79 (33.62)	73.32 (31.46)	71.32 (32.68)	t <sub>220</sub> -0.80	0.426
Positive social interaction	60.99 (30.71)	67.76 (31.80)	63.92 (31.30)	t <sub>220</sub> -1.60	0.110
Emotional/informational support	63.44 (31.03)	71.11 (29.64)	66.76 (30.61)	t <sub>220</sub> -1.86	0.064

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Abbreviations: SD, standard deviation; IRSAD, Index of Relative Socio-economic Advantage and Disadvantage; YPAS, Yale Physical Activity Survey; GSE, General Self-Efficacy Scale. \*\*

**Table 4. Risk and protective factors associated with venous leg ulcer recurrence**

Factor	$\beta$	Hazard Ratio ‡	95% CI	P value
Age	-0.17	0.98	0.97-0.99	0.024*
Gender (Female = referent)	0.21	1.24	0.82-1.86	0.313
Previous DVT	0.53	1.69	1.07-2.67	0.024*
Total duration of previous ulcer	0.01	1.005	1.003-1.007	<0.001**
BMI ( $\leq 22$ (Kg/m <sup>2</sup> ))	0.32	1.38	0.83-2.29	0.220
History of previous leg ulcers (more than 1)	1.48	4.41	1.84-10.55	0.001*
Mobilise with aid	-0.08	0.92	0.59-1.44	0.720
Elevating legs for 30 minutes/day	-1.10	0.33	0.19-0.56	<0.001**
Class 2 or 3 compression hosiery for 5 or more days/week	-0.33	0.72	0.48-1.08	0.112
YPAS – Walking for at least 3 hrs/day	-0.41	0.66	0.45-0.98	0.040*
Geriatric Depression Scale	-0.05	0.95	0.89-1.01	0.123
General Self-Efficacy Scale	-0.05	0.95	0.92-0.99	0.016*

Abbreviations: DVT, Deep Vein Thrombosis; BMI, Body Mass Index; Class 2 compression hosiery: 20–25mmHg; Class 3 compression hosiery: 30–40mmHg; YPAS, Yale Physical Activity Survey. \*p < 0.05, \*\*p < 0.001

‡ Cox proportional hazards regression model

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