

Supplementary material for the EWMA document: Gethin et al, Evidence for person-centred care in chronic wound care. A systematic review and recommendations for practice. J Wound Care 2020 29:Sup9b, S1-S22 <https://doi.org/10.12968/jowc.2020.29.Sup9b.S1>

An overview of studies included in the document

Intervention: Healthcare Professional Education

Author, year, country of origin	Health setting	Design, duration	Intervention	Sample /Size	Wound aetiology	Outcome	Significance level	Additional information
Innes-Walker <i>et al</i> 2019, Australia	9 Nurse-led, inter-disciplinary, Co-operative Wound Clinics (CWC) in GP practices	Longitudinal; pre and post test design over 24 weeks	A new model of care delivery, with a local wound expert (Nurse Practitioner) providing training and coaching to staff. Model based on Leg Clubs using a patient centred approach. Initial training followed by clinic visits once/fortnight to mentor	Health professional = 36 Patients = 81	Range of wound types; largest wound type represented = 17 with venous LU	<p>Health professional knowledge/confidence (n=9): -<u>Increase on all measures in those somewhat or very confident</u>, e.g.,</p> <ul style="list-style-type: none"> -Assessment: 56% increased to 100% -Using investigations to diagnose: 22 up to 100% -Role of other professionals: 78-89% -Psychosocial 56-67% -Documenting a plan: 67-89% -Implementing a plan: 56-100% -monitoring: 67-100% <p><u>Patient satisfaction</u>: 73% reported that they were more able to help themselves 87-93% agreed that their care, decision making and treatments were of a high quality</p> <p><u>Feasibility of the model in GP</u>: role of nurse practitioner was essential; socialisation aspect was difficult due to space; a lot of missing documentation on follow-up</p> <p><u>Patient Outcomes</u>: 23 patients had healed wounds at 24 weeks</p>	No statistical analysis	<p>Only 9 staff completed both pre and post surveys, so % results relate to a very small sample</p> <p>Only 15 patients completed the questionnaires</p> <p>Only 5 patients returned QoL data at study end</p> <p>Clinical data on wound status only available for 23 patients at the end of the study</p>

						Wound size decreased by 85.4%	Baseline: (-0.002, 1) 3 month: (0.53-1) p<0.001 95%CI (75.7-95) 95% CI at 3 months (3.08, 6.39) p<0.001	
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Intervention: Patient Education

Author and date	Health setting	Design	Intervention	Sample /Size	Wound aetiology	Outcome	Significance level	Additional Relevant information
Adarmouch et al., 2017, Morocco	Outpatient clinic	Pre-post prospective quasi-experimental study, 1 month Questionnaire-mediated assessment after recruitment and after 1 month	¹ Self-management education (SME): Interactive educator-led group discussion using different materials: a narrative video, a PowerPoint presentation and a printed guide.	N=133 No control group	No active ulcers	<u>Foot care score:</u> foot-care score mean was 3.5 ± 2.9 days prior to the SME session. One month later, the mean was 5.9 ± 1.8 days. Mean variation was 2.4 ± 3.1 days. <u>Literacy</u> was associated with higher likelihood of a favourable variation of foot-care practices (OR = 2.82; 95%CI: 1.09–7.31) while previous education about diabetic foot was associated with lower likelihood of a favourable variation (OR = 0.26; 95%CI: 0.08–0.78)	multivariate analysis p < 0.001	Longer-term evaluation is needed to ascertain the persistence of knowledge and skills developed after the SME
Dominguez et al, 2018, Brazil	Community	RCT, 12 weeks	² IG: Nursing guidelines regarding lifestyle with a focus on physical exercises, intermittent rest, importance of compression therapy – all lasting an average 40 minutes. Four meetings were held every 4 weeks plus phone calls to patients.	102 randomised (IG n=49; CG n=53). After loss to follow up final analysis included: IG n=35; CG n= 36	VLU	<u>Pain:</u> No statistically significant differences between groups of within groups. <u>Health:</u> No statistically significant differences between groups. IG was significant for baseline to week 12. <u>Wound size reduction:</u> No statistically significant difference between groups. CG was significant for baseline to week 12. <u>Quality of Life:</u>	P = 0.001 P = 0.04	

¹ SME = Self-management Education

² IG = Intervention Group

			³ CG: Routine information on the study and routine guidelines of the unit and patients returned every 15 days as per standard protocol			No statistically significant difference between groups. CG was significant for baseline to week 12. Total ⁴ PUSH Score: The IG had significant results at days 60 and 90 compared with baseline	P = 0.048 Sig level not reported	
Finlayson <i>et al</i> , 2009, Australia	Community; own home or Leg Club	RCT for 24 week	CG: ABPI check; referrals; EB treatment; advice and support; follow up and prevention IG: as above plus weekly leg club (or home visit), peer support, goal setting, social interaction	N=67 Control: 33 Intervention: 34	VLU	Mean: QoL increase: 0-10 scale C=0.25;I=1.35 ⁵ ADL increase: 0-6 scale C=0.07;I=0.46 ⁶ PGC morale increase: 0-17 scale C=0.27;I=3.57 Self esteem: 10-40 scale C=-0.62;I = +1.52 Ulcer area cm2 reduction: C=2.14;I=6.37 Overall pain reduction; 0-100 C=8.74;I=31.48 NS: depression or social support	p=0.014 p=0.044 p<0.001 p=0.006 p=0.004 p=0.003 ALL measures in favour of the intervention	Computer generated allocation Group Sequential Analysis: ITT Multiple outcomes measure >10% drop out in both groups
Fardazar <i>et al</i> , 2018, Iran	Diabetes outpatient clinic	RCT for 12 weeks, quasi-experimental study	Control: routine care. Intervention: routine care + Foot Care Principles program (educational intervention, 4 sessions: lectures, practically doing feet examination and special feet exercises, films, practicing, group discussion, providing educational pamphlets	N=104 Intervention: 52 Control: 52	No diabetic foot	Mean score of diabetic foot care behaviour after intervention significantly higher for experimental group compared to the control group one month and three months after the intervention. C=12/8; I=27/5 Mean score of patients empowerment about diabetic foot prevention after intervention significantly higher in the experimental group than the control group. C=19/8; I=34/7	P < 0.001 P < 0.001	Empowerment assessment questionnaire + Foot care behaviour checklist Significant relationship between empowerment and self-care Empowerment of patients could be a critical component in improving foot care behaviours

³ CG = Control Group

⁴ PUSH: Pressure Ulcer Scale for Healing

⁵ ADL = Activities of Daily Living

⁶ PGC = Philadelphia Geriatric Centre Morale

			and CDs, individual counselling about foot care and psychological counselling, suitable socks for diabetic foot)					
Gonzalez 2014, USA	Outpatients	Single group: pre and post, 9 week follow up	Educational intervention in patients home; 45 mins plus brochure and handout All sessions provided by the same person Follow-up by telephone	N=30 first wound occurrence	VLU	<u>Disease</u> (0-6 scale) and <u>self-care</u> (0-7) knowledge on Checklist for Patient Learning (Total 0-13 scale) Pre: 4.33+/- 0.22 Post: 12.33 +/- 0.43 9 weeks: 11.1 +/- 0.56 Reduction in wound size: 2 weeks = 28/30 9 weeks = 24/30 Recurrence at 9 weeks: 15/30	Baseline to post intervention p=0.002; Baseline to 9 weeks: p=0.003 No statistical analysis	No control group Very little clinical data provided
Gonzalez 2017, USA	Community	Retrospective control group; 2 intervention groups; 36 week follow up	Intervention: 45 mins, one-to-one at home with resource materials A. Education in an earlier study; follow up at 36-week B. Prospective group at 2, 9 and 36 weeks C. Control: retrospective chart review	N=95 36 week follow up; n=28 prospective group=22 control = 45	VLU Intervention (both groups) healing ulcer present for at least 5 weeks control: 41 weeks treatment, no education after week 5	<u>Disease</u> (0-6 scale) and <u>self-care</u> (0-7) knowledge on Checklist for Patient Learning (Total 0-13 scale) A: baseline 4.13+/-0.43 Post intervention: 12.06 +/-0.29 At 36 weeks; 10.7 +/- 0.42 B: baseline 4.22+/-0.23 Post intervention: 12.0 +/-0.33 At 36 weeks; 10.9 +/- 0.87 <u>Healing had begun</u> A: 27/28 at week 2 B: 20/22 at week 2 <u>Recurrence</u> A: 14:28 B: 10:22 C: 13:14	Baseline to post intervention p=0.002; Baseline to 36 weeks: p=0.04 Baseline to post intervention p=0.002; Baseline to 36 weeks: p=0.003 Diff between A and B: NS Descriptive data only Descriptive data only	Convenience sample No random allocation to group Limited data presented at follow up Non-significant deterioration in knowledge over time.

Chaboyer et al., 2016, Australia	Inpatient setting	Pragmatic cluster randomized trial	Intervention: PUPCB (patient-centred pressure ulcer prevention care bundle) based on patient participation and clinical practice guidelines: Training aids for patients were DVD, brochure and poster to keep them moving, look after their skin and eat a healthy diet; Nurses in intervention hospitals were trained in partnering with patients in their pressure ulcer prevention care. Control: standard care	N=1600; Randomised n=8 clusters Intervention n=800; Control n=800	Inpatients at high risk of PU	6.1% in the PUPCB group and 10.5% in the control group developed a ⁷ HAPU. The HAPU incidence rate was 9.6 per 1000 person-days in the PUPCB group and 20.1 per 1000 person-days in the control group (incidence rate ratio 0.48; 95% CI: 0.33, 0.69). The crude hazard ratio of 0.48 (95% CI: 0.20, 1.21) indicated a 52% reduction in the risk of HAPU associated with the intervention compared with standard care. There was NS difference between intervention and control groups in the severity of new PU or in patient participation in PUP (mean (SD) scores on the PU care scale: Intervention 3.3 (0.77), Control 3.0 (0.97))	p < 0.0001 NS p = 0.124	The pressure ulcer prevention care bundle was associated with a large reduction in the hazard of ulceration
Kafaie et al 2012, Iran	Home visit	Single group: pre and post, 3 month follow up	One-to-one visits by a dermatologist, once a month for 3 months covering all aspects of foot care	N=80	Patients with diabetes	Knowledge: Pre and post questionnaire; scale of 12-60 with 36 defined as 'adequate' knowledge. Baseline: 27.06+/- 8.77 Post: 43.23 +/- 7.37 Focal lesions at baseline 98.1% and 11.5% had inter-digital lesions; 83% healed at 3 months 49.2% had nail problems at baseline: 62.8% healed	p<0.001 No statistical analysis	Non controlled study Very little clinical details
Kelechi et al 2014, USA	Outpatient clinics: 2 sites	Comparative study over 8 weeks	Intervention: Motivational enhancement (10 mins) and conditioning activity for leg function (MECALF): nurse directed and patient centred for 6 weeks plus 2 further visits with no ME	N=21 MECALF= 12 CALF = 9	Critically colonised/infected chronic leg ulcers Patients did not currently do exercise	Study feasibility: nurses found it to be 'somewhat feasible' Pain: Overall Pain reduction: I = 0.5 +/- 2.0 C = 2.4 +/-2.0 Motivation: Motivation difference I = 3.8 +/- 3.1	P=0.046 (in favour of control) NS	Convenience sample but sites randomly allocated to intervention type At the end of the study it became clear that several patients were on physical therapy but not reported in (in control); 2 patients in CALF dropped out due to not wishing to do the exercises

⁷ HAPU = Hospital Acquired Pressure Ulcer

			Control: Conditioning activities alone (CALF); handout only at baseline; weekly visits for 8 weeks Both groups: plus standard wound care		nor were they part of Physical Activity program	C = 4.4 +/-2.9 Self-efficacy: Self-efficacy difference I = 1.2 +/- 3.6 C = 0.6 +/-6.0 Physical activity: Physical activity, including leg strength and range of motion	NS NS on any measure	
McBride et al 2016, UK	Out-patient, single site clinic	Pilot RCT; 12 weeks	Control: usual care (formal assessment, debridement, off-loading, infection control, vascular intervention; treatment advice) Intervention: Usual care plus Decision Navigation (a multi component intervention to facilitate shared decision making, including a treatment decision aid, personalised goals, trained assistant psychology support, audio recording and written summary of consultations)	N=56 Controln= 26 Interventio n=30	Newly diagnosed or considering new treatment DFU with ≤30% reduction in 2 weeks post initial contact with clinic	<u>Decisional Self-Efficacy Questionnaire</u> Adherence: 5-item questionnaire (1 for clinician perspective and 1 for patient perspective) Decision Conflict: 16 item scale. Increased over time for I from 17.1 to 23.75 Decision regret; 5 items HRQoL (EQ-5D) <u>Patient Acceptability</u> : Intervention group only – all patients would opt to use it again and would recommend to other patients.	NS NS for either p=0.049 for I NS for control NS NS	Computer generated allocation 7 lost to follow up Intention to treat analysis Baseline confidence levels described as ‘extremely high’: possible ceiling effects No evidence to support this approach “at this progressed stage in the disease trajectory” (p.1488)
Protz et al., 2019, Germany	Outpatient and inpatient setting	Quasi-randomised prospective controlled trial	Control: received a questionnaire on their theoretical and practical knowledge and skills about VLU and compression therapy. Intervention: received the brochure “Compression therapy—easy and well-fitting. Patients were asked to read the brochure carefully at home,	N=136 Control: 68 Interventio n: 68	VLU	Patients in the intervention group had significantly more knowledge than patients in the control group: - 98.5% of the Intervention group (IG) knew that compression therapy improves wound healing, and 56.9% of the control group(CG) did not know this - patients in the IG had significantly more knowledge about self-care and vein sport activities than the patients in the CG (85.3% vs 16.2%)	P =0.000 P =0.000	An informative brochure, adapted to the patient's needs, can help to strengthen adherence, to improve empowerment, and to improve healing of VLU. Brochures can support education by medical and nursing personnel by complementing a personal educational conversation. The use of such a brochure can lead to HCP's time saving

			to bring it back to their next appointment + informed about answering a questionnaire there.			- patients in the IG had significantly more knowledge about effects of compression therapy and care of compression materials than the patients in the CG (100% vs 79.4%)	P =0.000	
Roberts et al., 2015, Australia	Inpatient setting	Pilot RCT assessing the feasibility of conducting larger trial, 3 days	Control: standard nutrition care Intervention: nutrition intervention tailored to individual patients circumstances: Patient education on the role of nutrition for PU prevention; Patient participation in their nutritional care (self-monitoring of oral intake, guided nutrition-related goal setting)	N=80 (66 included in the analyses) Control: 41 (35) Intervention: 39 (31)	Patient at risk of PU	Energy requirement: no statistically significant differences in the percentage of estimated energy requirements or estimated protein requirements met between control and intervention groups on any study day. There were significantly more patients in the IG whose intakes improved in terms of energy (IG: 12; CG: 4;) and protein (IG: 9; CG: 3;) from study days one to three compared to the control group Adherence to the intervention: 38.7% patients completed all 3 days' food charts independently, there was good correlation between the researcher's observed energy and protein intakes, and patients' documented energy and protein intakes over the 3 study days.	NS P = 0.032 P = 0.050 (Pearson's correlation 0.965–0.993, p < 0.001)	The use of an intervention focusing on patient participation and education on nutrition for PUP is likely to be feasible in the hospital setting
Stanton <i>et al</i> 2016, UK	5 outpatient clinics	Monitoring of service KPIs over 35 months	Development of a therapeutic relationship with patients to increase concordance with compression via staff training and encouraging patients to report negative aspects of compression treatment so these could be amended; staff also worked with families; staff also used educational assessments tools and patient leaflets.	20 staff over 5 sites, over 35 months 438 patients treated over the 35 months	VLU	Concordance scores at the start: 80% This rose to 90%. All patients received some degree of compression Healing Rates for all patients; mean of 84 days, with an average of 15 appointments	Descriptive only	The service uses concordance, quality of life, and experience and expectation surveys as part of their Key Performance Indicators. This is now their routine practice.

Whitty et al., 2017, Australia (sub study of Charboyer et al 2016)	Inpatient setting	Cost-effectiveness and cost-benefit analyses of PUP performed from the health system perspective using data collected alongside a cluster-randomised trial.	Intervention: PUPCB (patient-centred pressure ulcer prevention care bundle) based on patient participation and clinical practice guidelines: Training aids for patients were DVD, brochure and poster to keep them moving, look after their skin and eat a healthy diet; Nurses in intervention hospitals were trained in partnering with patients in their pressure ulcer prevention care. Control: standard care	N=1598; Randomised n=8 clusters Intervention n=799; Control n=799 Direct costs related to the intervention and preventative strategies were collected from trial data and supplemented by micro-costing data on patient turning and skin care from a 4-week substudy (n=317)	Adult inpatients at high risk of PU	Cost: The care bundle cost AU\$ 144.91 (95%CI: \$74.96 to \$246.08) more per patient than standard care The care bundle was estimated to cost an additional \$3296 (95%CI: dominant to \$144,525) per pressure ulcer avoided In a cost-benefit analysis the net monetary benefit for the care bundle was estimated to be -\$2320 (95%CI -\$3900, -\$1175) per patient, suggesting the care bundle was not a cost-effective use of resources.		The largest contributors to cost were clinical nurse time for repositioning and skin inspection. This study suggests a PUPCB consisting of multicomponent nurse training and patient education strategies may encourage good nursing practice but may not be cost-effective in preventing HAPU
Keller-Senn et al, 2015, Switzerland	Recruited from acute care settings.	Pilot RCT, follow up at 6 months and 12 months	IG: 5-week nurse-led education programme for high-risk patients with DFU in addition to standard care. The programme included education, counselling and skills training CG: no education programme but received standard care of inpatient	19 patients: IG = 8 CG = 11 All being treated for a DFU or had a history of amputation of the lower limb	DFU	<u>Foot Care Self efficacy:</u> Measured using Foot Care Confidence Scale (FCCS) scores range from 12 to 60 with higher score indicating high self-efficacy. IG: Baseline 40.5; after education 55. CG: Baseline 56; after standard care 54.	IG: baseline to week 5 p 0.018. CG: baseline to week 5, p = 0.919. Baseline IG versus CG n/s Week 5, IG versus CG n/s	

			out patient, physician prescribed, wound care.					
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