Resolving chronic wound pain using low intensity laser therapy (LILT): a proof of concept study

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Abstract

Objective: A proof of concept study was conducted to investigate the effectiveness of using low intensity laser therapy (LILT) to manage chronic leg wound pain.

Background: There is a paucity of studies on the safe and efficacious application of LILT to resolve chronic wound pain. This study was conducted to address the lack of rigorous evidence regarding the efficacy of LILT to resolve chronic leg wound pain in the home health care setting.

Method: Using a randomised controlled trial (RCT) design, study participants were randomised into three groups: control, Polylaser Trion™ Laser (hand-held laser) and Photonic 500 Acumed™ Laser (scanning laser). Fifty-seven participants were monitored for 12 weeks, including six weeks of LILT treatment for the intervention groups upon recruitment to the study. The primary outcome measure was the reduction of pain assessed using the Brief Pain Inventory (BPI – short form).

Results: No significant differences were found between the treatment groups. Small to moderate effect sizes for pain reduction favoured the hand held laser group compared to the control and scanning laser groups in the initial 2 and 6 weeks.

Conclusion: This proof of concept study provides evidence for the safe use of LILT technology by nurses in a clinic setting. Recommendations for further investigations to aid preparation for large clinical trials are provided with specific reference to the use of LILT by home health care services.

Keywords: Wound pain, low intensity laser therapy, chronic wounds, pain reduction, community nursing.

Introduction

Chronic wounds have a profound impact on an individual's health and quality of life[1-4]. More than half the people living with a chronic wound report significant and unremitting pain[5]. Wound pain can prevent adherence to best practice leg ulcer care[1,2,4], which can lead to delayed healing.

Promising findings have emerged from clinical trials for the effectiveness of low intensity laser therapy (LILT) in the treatment of nerve pain[6], pain associated with arteriosclerosis[7], rheumatoid arthritis[8], and neck pain[9]. A systematic review of the effect of LILT on pain associated with acute injuries or surgical wounds linked LILT with modulating inflammatory pain[10]. Eight of nine included trials observed that LILT performed significantly better than a placebo in at least one of the outcomes assessed.

Few studies have considered the effectiveness of LILT in relation to chronic wound pain. These reports include case study or small sample, single arm pre- and post-evaluations suggesting pain reduction for malignant external ulceration[11], chronic venous leg ulcers[12], and for people with Buerger's disease[13].

Furthermore, few studies have explored the safe and efficacious application of LILT to resolve chronic wound pain in the home health care setting, even though the prevalence of wound care delivery by these services has been estimated to range between 25% and 36%[14,15]. Of the two nurse-led and community-based studies conducted, LILT was used safely and wound size was found to reduce; however, these were small evaluation studies that included only seven and eight participants respectively[16,17].

Given the paucity of research available, the use of small samples and interventions that have not been systematically controlled or described, there is presently insufficient or inadequate evidence to guide practice regarding the use of LILT to address chronic wound pain management.

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A proof of concept study was conducted to address the lack of rigorous evidence regarding the efficacy of LILT to resolve chronic leg wound pain. The goal of this investigation was to examine the feasibility of a randomised controlled trial (RCT) assessing the effectiveness of LILT on wound pain and to generate more precise effect size estimates upon which power analyses for future research could be based. For the purpose of the evaluation, it was hypothesised that participants receiving LILT would report significantly lower levels of wound pain compared to participants in the control group.

Materials and methods

The study used a non-blinded, RCT study design. Participants were clients receiving in-home or clinic-based care from a large community nursing organisation in Victoria, Australia. Participants were randomised to one of the three study groups: control, Polylaser Trion™ (hand-held laser), and Photonic 500 Acumed™ (scanning laser) during a 14-month recruitment period (2008–2009). The trial was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12608000503325) and ethics approval was received from the Royal District Nursing Service Human Research Ethics Committee.

Participant eligibility

Inclusion criteria:

(1) Aged ≥18 years.

(2) Receiving care for a chronic leg wound of either pressure, venous, arterial, mixed venous/arterial, injury, burn, or vasculitis aetiology (as recorded in the client history).

(3) The wound was older than six weeks, ≤10 cm in diameter, and ≤2 cm in depth.

(4) The wound was healing by secondary intention (wound healing is delayed and occurs by a process of granulation, contraction and epithelialisation[18]).

(5) Had wound pain (≥1 on a 0–10 numeric pain rating scale).

(6) Experienced wound pain at times other than (but could be in addition to) wound dressing changes.

(7) The wound pain had not responded to a minimum of two weeks of standard pain management.

(8) The client was willing to attend a clinic setting for some of their care during the study period.

Exclusion criteria:

(1) Diagnosis of, or in receipt of treatment for, a malignancy (wound or other).

(2) Lack of support for client participation from the local medical officer/wound specialist.

(3) Any planned absences during the 12-week study period.

If the client presented with multiple wounds, the wound that was the most painful was monitored in the trial as the "study wound". A sample size of 60 participants was sought (20 participants per study group) to achieve a sample which was sufficient to enable generation of effect sizes upon which future trials could be based.

Recruitment

Prior to commencing recruitment, all nursing staff at the study sites participated in a two-hour Wound Pain Management Education Program to establish a standardised level of pain management care. This included the reinforced, standardised assessment practices within the organisation, care planning and evaluation of pain management.

Screening, recruitment, treatment and data collection were coordinated by the study-trained wound management clinical nurse consultants (WMCNCs). Eligible clients were provided the study plain language statement and consent form by their primary care nurses. A WMCNC subsequently attended to participant recruitment. Interpreters were engaged as necessary, and carers and guardians involved as appropriate.

Participants were then randomly allocated, according to computer-generated lists that were stratified by site, to one of the three study groups (control, hand-held laser, and scanning laser). Random allocation was completed using sealed, opaque envelopes.

During the study, participants received wound dressing products at no cost and taxi vouchers were provided, if required, to assist participants to attend the clinic for treatment and data collection.

Data collection and measures

The primary outcome measure for this study was the reduction of pain. Pain was assessed using the Brief Pain Inventory (BPI – short form) (copyright CS Cleeland and Pain Research Group, 1991) which generates two scores (domains) of pain: severity and interference. Four items are used to generate a pain severity score and seven items used to generate a pain interference score. The BPI interference score is reported for every fortnight (approximately 14 days) for the 12-week study period, or less if the wound healed. Due to a missed item from the BPI severity scale, this measure is reported for the LILT Treatment Phase only (baseline to six weeks).

The study groups were compared on additional measures at baseline. Wound size measurements were determined using SilhouetteMobile™ (ARANZ Medical Ltd), a portable imaging and measurement device, that has demonstrated high intra- and inter-rater reliability[19]. Included in these data were measures of Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (IADL) that constitute the minimum data set requirements for Home and Community Care (HACC) services in Victoria, Australia. Clinical signs of infection or critical colonisation were collected according to published guidelines and assessment tools[20-22]. Nutritional risk was assessed using the 11-item HACC Nutritional Risk Screening and Monitoring Tool[23]. Data were recorded on paper forms and subsequently entered into an Access database (Microsoft Office, 2003).

Treatment protocol

The 12 weeks of study participation included two phases: LILT Treatment Phase (0–6 weeks) and Monitoring Phase (6–12 weeks). For the first six weeks, participants randomised

to either of the LILT groups received LILT three times each week during usual wound treatments. Participants in the control group received twice-weekly wound care unless more frequent treatment was indicated. The LILT treatment was discontinued if pain was resolved for two weeks, or upon the conclusion of the six-week treatment phase. During the Monitoring Phase, participants attended the clinic every two weeks for wound care and data collection. Other wound care was attended as determined by the individual's care plan either in the home or clinic as per the client's preference.

For the purposes of this study, care during the Treatment Phase, and fortnightly care during the Monitoring Phase was attended in a clinic setting. For most clients this differed to their usual in-home care with treatment being provided by advanced WMCNCs rather than generalist nurses. This variation was adopted to ensure participant and clinician safety, given that the use of LILT was a novel treatment for the community nursing service. As the scanning laser was not a portable device it required clinic administration.

The laser treatments were delivered by WMCNCs employed by the nursing service where the study was implemented and who received certification following a three-day course provided by the Australian Institute of Laser Therapy prior to commencing the study. These WMCNCs received further clinical supervision and telephone support as needed throughout the study from an experienced LILT clinician. A LILT treatment guideline was developed for use in the study to standardise practice[24]. The LILT treatment guideline[24] also indicated the length of LILT care in addition to usual wound management processes, the duration of which varied considerably in response to wound size and the laser to which the participant was randomly allocated.

Figure 1. Administering the Polylaser Trion™ (hand-held laser).

This study included two types of lasers: a Polylaser Trion™ hand-held cluster laser and a Photonic 500 Acumed™ scanning laser (Reimers & Janssen GmbH). They are semiconductor diode lasers with a gallium aluminium arsenide medium and are classified as Class 3b lasers, emitting power outputs in the milliwatt (mW) range below 1 watt. Both lasers are listed with the Therapeutic Goods Administration of Australia for use in photo-induced biomodulation, which is non-thermal in its effects.

The Polylaser Trion™ hand-held cluster laser (hand-held laser; Figure 1) is comprised of 12 laser diodes. Consisting of 4 x 655 nm visible red light with a power output of 5 mW and 4 x 655 nm visible red light at 40 mW power and 4 x 785 nm infrared wavelength at 55 mW power output. The hand-held laser was selected for the study for its portability; a feature which could conceivably permit future exploration of providing in-home laser therapy.

The Photonic 500 Acumed™ (scanning laser; Figure 2) version is a free-standing scanning laser simultaneously emitting 655 nm visible red laser light at a power output of 50 mW and 810 nm infrared laser wavelength, at a power output of 500 mW. This laser was selected for its ability to deliver laser light

Figure 2. Administering the Photonic 500 Acumed™ (scanning laser).

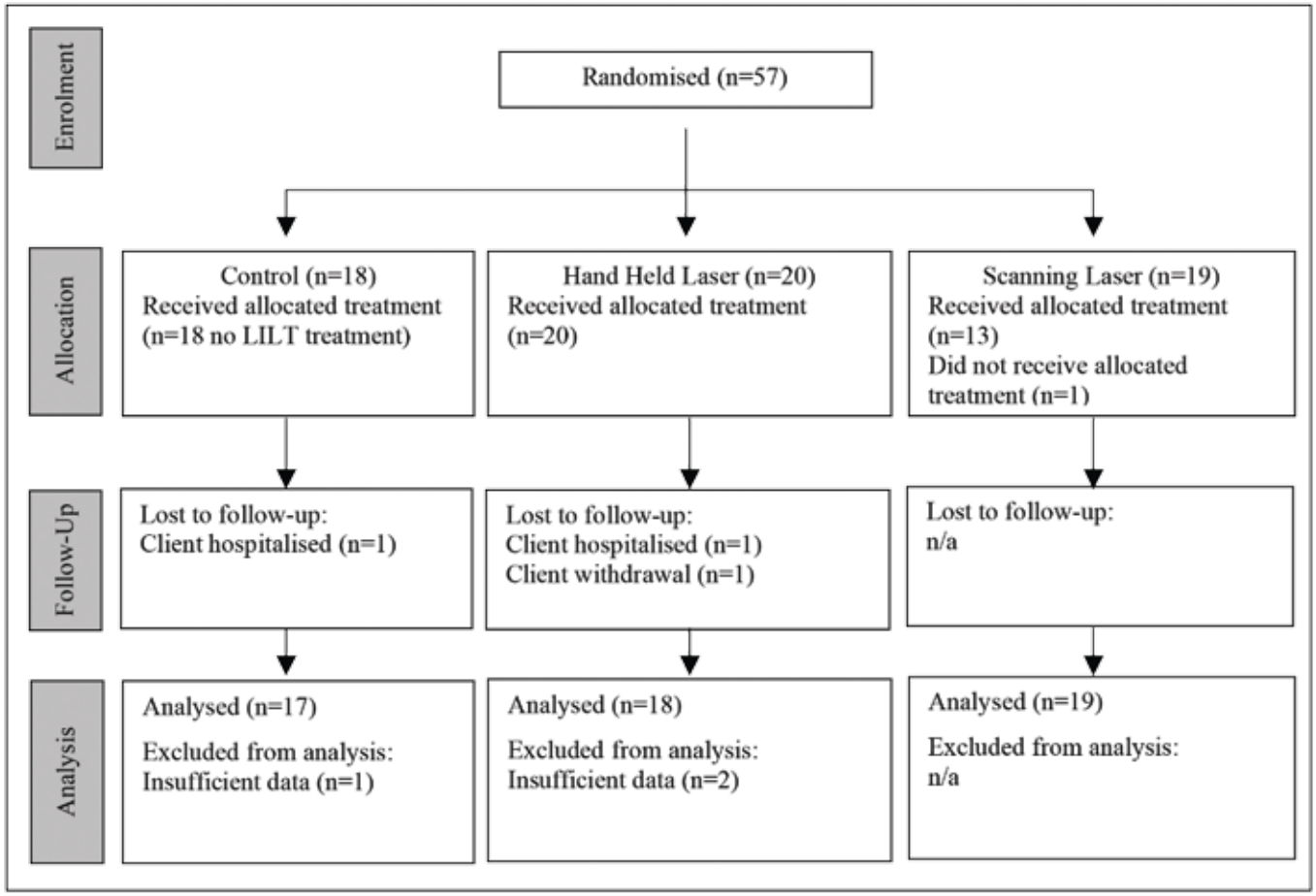

Figure 3. Participant flow diagram.

energy at specific pulse repetition rates[25]. Although offering more power and a greater range of functions in contrast to the hand-held laser, some of which is reflected in the treatment protocol, the full extent of the options provided by the scanning laser were not exercised in this study due to the need to standardise and simplify its application in this setting for research transparency in reporting and repeatability.

Statistical analysis

The Statistical Package for the Social Sciences (SPSS) for Windows Release 19.0 (SPSS Inc., 2010) was used to analyse these data. The effect of treatment group on change in pain severity and interference were analysed using linear mixed models (LMM). Analyses of Covariance (ANCOVA) were conducted assessing differences between treatment groups at each fortnight for pain. Differences between the adjusted means and standard deviations from the ANCOVA analysis for pain were used to compute effect and sample size estimates.

Results

Fifty-seven participants were recruited to the study. Their progress from recruitment through to analysis is shown in Figure 3. Data from 54 participants were included in the primary analysis (scores on the BPI interference measure) representing a high follow-up of participants (95%). Data were not gathered regarding the size of the population screened for eligibility for the trial or reason for client exclusion.

Participants who failed to receive >3 of their randomised laser sessions (of a possible 18 sessions) were classified as "did not receive allocated treatment". This classification applied to one participant who declined ongoing treatment with the scanning laser after three sessions. Participants were analysed

Table 1. Demographics and health status by treatment group.

		Control	Hand-held laser	Scanning laser	Total	Sig.
		(n=17)	(n=18)	(n=19)	(n=54)	(P=)
Gender (% female)		77.8 (n=14)	63.2 (n=12)	57.9 (n=11)	66.1 (n=37)	P=0.42
Age (years; M ± SD)		79.61 ± 14.72	81.05 ± 8.45	77.21 ± 11.22	79.29 ± 11.58	P=0.60
Has diabetes mellitus diagnosis (%)*		6.3 (n=1)	6.3 (n=1)	23.5 (n=4)	12.2 (n=6)	n/a ^
Nutritional risk	(% at risk)	64.7 (n=11)	77.8 (n=14)	78.9 (n=15)	74.1 (n=40)	n/a ^
	(M ± SD)	1.59 ± 1.66	1.61 ± 1.38	2.26 ± 2.05	1.83 ± 1.73	P=0.41
Number ADL/IADL-dependent		3.77 ± 3.38	4.17 ± 3.57	4.05 ± 3.15	4.00 ± 3.31	P=0.94

* Sample size variations are due to missing data

^ Insufficient sample to conduct statistical analysis

as per their randomisation. Analysis was also repeated, removing the participant who did not receive the allocated treatment, and as comparable findings were observed these results are not detailed.

One participant reported pain resulting from exposure to the air whilst the LILT treatment was being delivered, resulting in pain. This participant withdrew from the trial. There were three instances of hospitalisation associated with deterioration in the study wound; one instance in each of the control, hand-held laser, and scanning laser groups.

Sample

Demographic and clinical characteristics of the participants are presented in Table 1 and wound and pain characteristics of participants are presented in Table 2. The treatment groups were comparable on all baseline characteristics with the exception of pain duration which approached significance [F(2,51)=3.15, P=0.05]. Participants in the scanning laser group reported longer pain duration (M=10.84 months, SD=9.63) than the control (M=5.44 months, SD=5.59) or hand held laser (M=5.28 months, SD=7.00) groups. Given evidence of significant associations between pain duration

Table 2. Wound and pain characteristics by treatment group.

		Control	Hand-held laser	Scanning laser	Total	Sig.
		(n=17)	(n=18)	(n=19)	(n=54)	
Wound duration (months, M ± SD) *		6.59 ± 5.68	8.00 ± 12.57	13.61 ± 18.27	9.48 ± 13.43	P=0.26
Wound size (cm^2) (M ± SD)*		12.81 ± 13.98	10.67 ± 24.31	14.24 ± 17.86	12.60 ± 18.95	P=0.85
Wound depth (mm) (M ± SD)*		1.40 ± 1.44	1.27 ± 2.04	0.98 ± 1.81	1.20 ± 1.74	P=0.79
Number of signs of infection/critical colonisation (M ± SD)		3.59 ± 1.23	3.17 ± 1.45	3.16 ± 1.86	3.30 ± 1.48	P=0.62
Wound type (%)	Venous leg ulcer	29.4 (n=5)	50.0 (n=9)	26.3 (n=5)	35.2 (n=19)	n/a ^
	Mixed venous/arterial leg ulcer	47.1 (n=8)	33.3 (n=6)	26.3 (n=5)	35.2 (n=19)	
	Arterial leg ulcer	17.6 (n=3)	5.6 (n=1)	21.1 (n=4)	14.8 (n=8)	
	Other diagnosis	5.9 (n=1)	11.1 (n=2)	26.3 (n=5)	14.8 (n=8)	
Pain duration (months, M ± SD)		5.44 ± 5.59	5.28 ± 7.00	10.84 ± 9.63	7.29 ± 7.98	P=0.05
Pain medication used (% yes)*		82.4 (n=14)	76.5 (n=13)	73.7 (n=14)	77.4 (n=41)	n/a ^

* Sample size variations due to missing data

^ Insufficient sample to conduct statistical analysis

Table 3. Pain interference scores by treatment group.*

Study period	Assessment point		Control	Hand-held laser	Scanning laser	ANCOVA
	Baseline	(M ± SE)	3.88 ± 0.56	4.28 ± 0.55	3.89 ± 0.55	F(2,51)=1.74, P=0.19
LILT Treatment Period		(n=)	(n=17)	(n=18)	(n=19)	
	FN 1	(M ± SE)	3.86 ± 0.58	2.56 ± 0.56	3.18 ± 0.57	F(2,46)=0.15, P=0.86
		(n=)	(n=16)	(n=17)	(n=16)	
	FN 2	(M ± SE)	2.57 ± 0.60	2.30 ± 0.58	2.87 ± 0.57	F(2,42)=0.65, P=0.53
		(n=)	(n=13)	(n=15)	(n=17)	
	FN 3	(M ± SE)	2.48 ± 0.62	1.98 ± 0.63	2.48 ± 0.59	F(2,37)=1.81, P=0.18
		(n=)	(n=13)	(n=12)	(n=15)	
Monitoring Period (no LILT)	FN 4	(M ± SE)	1.55 ± 0.70	2.17 ± 0.67	2.75 ± 0.65	F(2,26)=0.57, P=0.57
		(n=)	(n=8)	(n=10)	(n=11)	
	FN 5	(M ± SE)	0.94 ± 0.71	2.36 ± 0.66	3.14 ± 0.71	F(2,28)=1.78, P=0.19
		(n=)	(n=10)	(n=12)	(n=9)	
	FN 6	(M ± SE)	2.02 ± 0.77	1.49 ± 0.70	2.16 ± 0.75	F(2,24)=1.69, P=0.21
		(n=)	(n=8)	(n=10)	(n=9)	

* The reported mean and standard errors were generated using linear mixed model analysis.

and both primary and secondary outcome variables, and the theoretical relevance of pain duration to the study aim, this variable was controlled for where possible in the main statistical analyses.

Pain interference with ADL

Linear Mixed Model (LMM) analysis, including pain duration as a covariate [F(1,53.35)=5.00, P=0.03], showed a significant overall decline in pain interference throughout the study period [F(6,193.91)=5.08, P<0.00] and a significant treatment group by fortnight interaction [F(12,194.34)=1.99, P=0.03]. However, no overall difference between treatment groups was observed [F(2,59.12)=0.32, P=0.73]. ANCOVA tests, controlling for pain duration, conducted at each fortnightly assessment identified no significant differences between the study groups for BPI interference (Table 3).

Pain severity

LMM analysis, with pain duration as a covariate [F(1,53.69)=0.63, P=0.43], showed a significant reduction in pain severity over the study period [F(3,104.52)=7.55, P<0.00]; however, there was no significant main effect for treatment group [F(2,55.41)=0.99, P=0.38] or treatment group by time interaction [F(6,104.47)=1.23, P=0.30]. ANCOVA tests, controlling for pain duration, identified no significant differences between the study groups for BPI severity at any of the fortnightly assessments during the LILT Treatment Phase (Table 4).

Effect and sample size estimates

Effect sizes were determined using means and standard deviations generated by the ANCOVA analyses (Table 5). These data were used to conduct power analyses for both BPI interference and BPI severity scores computing the size of the sample required to find a significant difference between the treatment groups. Power estimates were calculated using G*Power Version 3.0.10 software (Franz Faul, Universitat Kiel, Germany) using an ANOVA fixed effects, omnibus, one-way test, alpha=0.05, power=0.90. Effect sizes were calculated from baseline to the third fortnight (representing the LILT Treatment Phase), baseline to the sixth fortnight (inclusive of the LILT Treatment and Monitoring Phases), and also from baseline to the first fortnight given that the differences in pain scores for the groups appeared largest at this initial assessment point. Due to missing data for the BPI severity outcome measure, effect and sample size estimates were only possible for the LILT Treatment Phase.

Effects were calculated for two models: 1) three trial groups (control, hand-held laser, and scanning laser), and 2) two trial groups (control and hand-held laser). This second model was pursued because the direction of clinical effects observed in this study favoured the hand-held laser. Future clinical trials may also wish to consolidate efforts to establish clinical effectiveness for just one laser application in comparison to a control group. Effect sizes were interpreted using Cohen's (1988) description of small (0.2–0.3), medium (0.5), and large (>0.8) effects[26].

Table 4. Pain severity scores for the treatment groups.*

Study period	Assessment point		Control	Hand-held laser	Scanning laser	ANCOVA
	Baseline	(M + SE)	3.94 + 0.51	4.19 + 0.47	3.93 + 0.52	F(2,38)=1.05, P=0.36
LILT Treatment Period		(n=)	(n=13)	(n=17)	(n=14)	
	FN 1	(M + SE)	3.42 + 0.49	2.20 + 0.51	3.40 + 0.50	F(2,41)=0.01, P=0.99
		(n=)	(n=16)	(n=13)	(n=15)	
	FN 2	(M + SE)	2.78 + 0.52	2.29 + 0.51	3.09 + 0.51	F(2,37)=0.50, P=0.61
		(n=)	(n=13)	(n=14)	(n=14)	
	FN 3	(M + SE)	2.30 + 0.59	1.65 + 0.55	2.91 + 0.59	F(2,29)=1.24, P=0.31
		(n=)	(n=10)	(n=12)	(n=10)	

* The reported mean and standard errors were generated using linear mixed model analysis.

The power analyses revealed medium effect sizes in the first fortnight, favouring a greater reduction in pain on both interference and severity scales for the hand-held laser group. The required sample sizes estimates are small; between 20 and 34 participants per group depending on the model and pain measure considered. The effect sizes applicable for the LILT Treatment Phase (0–3rd fortnight) were small, suggesting per group sample sizes of approximately 90 participants for BPI interference and 50 participants for BPI severity. A very small effect size was observed for the pain interference measure after 12 weeks of follow-up. This finding implies an effect with limited clinical relevance for which an excessive sample size renders further clinical trials less practical.

Discussion

This study sought to appraise the feasibility of conducting an RCT examining the effects of LILT on unresolved chronic wound pain. The generation of more accurate effect sizes upon which power analyses could be based would indicate, firstly, the clinical significance of the effect of LILT, and secondly, the viability of conducting clinical trials given the sample size required. The fact that no analysis identified significant differences between the treatment groups for pain reduction was not unexpected given the intent was to conduct a proof of concept study which involved a small sample.

Eligibility to participate in the trial was unresolved pain, the duration of which was in excess of seven months on average at baseline. Nonetheless, pain appeared to resolve and a third of study wounds progressed to healing during the study regardless of the randomised treatment. Quite possibly, this finding could be explained by changes brought about by a subject's awareness that they are a participant under study (the Hawthorne Effect)[27], although another plausible explanation is that greater access and regular treatment by a WMCNC during the study resulted in enhanced care and client outcomes. The provision of wound dressings at no cost might be another reason that pain reduced during the study, if cost had been a barrier to the use of best practice wound treatments.

A medium effect in the initial fortnight was observed favouring a pain reduction for the hand-held laser group. The effect is sufficiently large to suggest some clinical significance for this treatment compared to the control or scanning laser group, and a small sample per group would be required to find a significant difference based on this effect size.

A smaller effect was observed during the LILT Treatment Phase (0-6 weeks) with correspondingly larger but not excessive sample sizes in contrast to that required for the first fortnight. The only pain measure for which there was a 12-week follow-up was the pain interference score for which a small effect was observed and an impractical sample size requirement of 484 per group estimated. Given that evidence of LILT's efficacy coincides with the LILT Treatment Phase, exploration of the impact of longer treatment courses on pain modulation has merit.

Pain resolution was observed in all groups and although there were no meaningful, significant differences detected between groups, participants randomised to the scanning laser had the least impressive results in this trial compared to the control and hand-held laser groups. The treatment protocol was standardised in this study for transparency regarding the

Table 5. Effect and sample size estimates.

		Effect size	Per group n=	Total n=
BPI interference				
3 groups	0–1 fortnight	0.36	34	102
	0–3rd fortnight (treatment)	0.22	89	267
	0–6th fortnight (total)	0.16	168	504
2 groups	0–2 weeks	0.44	29	58
	0–3rd fortnight (treatment)	0.24	93	186
	0–6th fortnight (total)	0.10	484	968
BPI Severity				
3 groups	0–1 fortnight	0.43	24	72
	0–3rd fortnight (treatment)	0.29	51	153
2 groups	0–1 fortnight	0.53	20	40
	0–3rd fortnight (treatment)	0.34	48	96

treatment intervention, an approach which limited the extent to which the full functionality of the scanning laser could be employed. However, the scanning laser also presents perhaps the lowest applicability to a mobile community health care workforce because it is clinic-bound, in contrast to the portability of the hand-held laser.

The threshold for pain for the trial was ≥1 on an 11-point scale. This level recognises the clinical imperative of alleviating all pain and that older age is associated with greater acceptance of pain[28]. The average level of pain experienced in this study was low, possibly reflecting these age-related factors, and increased the risk of a statistical "floor effect". The inclusion of clients with a higher level of unresolved pain for future trials is recommended.

This study was conducted in a clinic setting to ensure the safety of clients and clinicians. As such, the effect sizes generated may differ to those that would have been found if the participants had been treated at home. It is recommended that the effect sizes determined in this study are confirmed by comparing a hand-held laser group to a control group in the home setting to further refine the safety, feasibility, merit and sample size targets as a preamble to a large RCT.

Study limitations

As participants were recruited from one Australian community nursing service, the generalisability of the results to people with chronic wound pain more broadly is limited. A small and quite heterogeneous sample was included in this proof of concept study, limiting the potential to examine the effectiveness of LILT for subgroups, for instance by wound aetiology. This also limited the capacity to conduct statistical tests that would detect significant differences in wound aetiology between the study groups and identify a potentially confounding variable. The exclusion of participants with arterial disease or ensuring sufficient and equivalent presence of individuals with diabetes mellitus in the study groups given the effect of diabetes mellitus on the effectiveness of LILT[29,30] is recommended for future studies.

Details regarding the size of the population, eligibility of participants, and willingness to participate in the study were not gathered and would have been helpful information for researchers planning subsequent LILT trials. Further streamlined measures monitoring the care provided to the groups would have enabled greater comparison of the groups to eliminate differences in wound management and pain medication use as potentially confounding variables. Finally, this study was conducted as an open label trial. Future studies might explore the viability of utilising a placebo "laser" treatment to enhance the design rigour and mitigate potential placebo effects.

Conclusion and summary

This study provides evidence on the effect of LILT on resolving chronic wound pain. A small, short-term benefit of the hand-held laser treatment to resolve wound pain was found. In preparation for a large RCT, it is suggested that the safe use of the hand-held laser in-home is assessed, whilst simultaneously confirming the effect size when

comparing the hand-held laser group to a blinded control group. The prospect that LILT can offer older people a non-pharmacological means of reducing wound pain requires substantiation in a larger clinical trial.

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