Pain and Rehabilitation
Volume 53 Issue 1 2023

OldPain2Go® a novel intervention for people with chronic low back pain: a feasibility study

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Abstract

Objectives: This feasibility study aimed to inform the development of a protocol for a single-blind randomised controlled trial (RCT) investigating the efficacy of OldPain2Go® for the treatment of chronic low back pain (CLBP).

Design: Single arm feasibility study.

Setting: One private physiotherapy practice.

Participants: Twenty two individuals with CLBP were recruited and 15 completed the study providing full data sets (11 female, 4 male, mean age 49.3, range 18-71 years).

Intervention OldPain2Go®, a novel talking therapy for pain. Participants received up to two individual treatment sessions with one therapist.

Main Outcome Measures: Pain (0-10 pain Numerical Rating Scale) and function (Roland Morris Disability Questionnaire, 0-24, higher score indicates poorer levels of function), measured before and after all sessions and at 3-week follow-up.

Results: The study recruited to target, only one participant withdrew from the study (unrelated to the study) and there were no adverse events/reactions attributed to the intervention. Of 15 participants, five received one treatment session and 10 received two sessions. Improvements in pain and function were seen in all those who completed the study with average improvements above the pre-set minimal clinically important change.

Conclusions: Important methodological information was obtained, which will inform a future large-scale RCT of this intervention. As this was a feasibility study no claims about efficacy can be made. Future research to investigate the efficacy of this intervention is warranted.

Trial registration: ClinicalTrials.gov Identifier: NCT03804567

Contribution of paper

- OldPain2Go® is a new treatment for chronic pain which is growing in popularity but there is no scientific literature on its safety or efficacy.
- A large scale RCT of the efficacy and effectiveness of OldPain2Go® as an intervention for people with CLBP is warranted

Keywords
Chronic Pain; Pain Perception; Complementary Therapies; Low back pain; Feasibility Study

Introduction

Low Back pain is a common condition and prevalence has been estimated to be as high as 20% in the adult population [1]. Chronic Low Back pain (CLBP) can be defined as pain, primarily between the ribs and the buttock, with or without leg pain, which has lasted for three months or more [2]. The individual, societal and economic impact of CLBP is considerable [3] [4] [5]. It is the leading cause of years lived with disability worldwide [6] and a major contributor to work absence [2] [7]. The costs of managing the condition in the UK alone were estimated, in 2009, to be £2.8 billion per annum [5].

OldPain2Go® is a new non-medical intervention for the treatment of chronic pain conditions including, but not

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limited to, CLBP [8]. OldPain2Go® is an (as yet) untested intervention and the mechanism of action is unknown. The underlying premise, however, is rooted in the biopsychosocial model of pain, where the cause of ongoing pain and the development of chronicity, is believed to lie beyond simple tissue damage, injury or malfunction. The intervention draws upon subconscious communication as a means to help patients to reframe their pain as less threatening and remove old, out of date, pain messages that no longer serve a purpose. In that sense there are similarities to other interventions that seek to help patients reframe their pain through educational approaches [9]. However, OldPain2Go® takes the reframing and re-education concept and proposes to apply this directly to both the conscious and the unconscious mind. This is an unusual approach, but is by no means unique. Re-education of the conscious and unconscious mind and individuals' perceptions of themselves and their circumstances has been proposed in approaches such as Neuro-linguistic Programming [10] and hypnotherapy [11] but unlike hypnosis no trance state is needed.

Despite a lack of clinical trial evidence, or a clear mechanism of action, as of August 2022, there were 1,550 people trained in the delivery of OldPain2Go®, including registered healthcare professionals such as physiotherapists and nurses. Approximately 70% of those trained are based in the UK, with the remainder predominately from, Australia, USA, Canada, Netherlands, Norway and Belgium. This popularity can only be based upon positive anecdotal evidence [8] as to date, there are no published scientific studies investigating this novel treatment. Given the popularity and rapid growth of OldPain2Go® there is a pressing need for robust investigation of safety and efficacy, to inform clinical decision making and facilitate patient choice. In accord with accepted practice and MRC guidance [12] we undertook this Feasibility Study to gather information to inform the development of a protocol for a single-blind randomised controlled trial (RCT) investigating the safety and efficacy of OldPain2Go® for the treatment of pain and function, in people with CLBP.

Methods

Study overview

This single-group pretest–posttest feasibility study aimed to recruit 15 participants to receive a novel intervention (OldPain2Go®) to inform the development of a robust protocol for a larger RCT. Key methodological issues that were explored were recruitment processes, participant drop out, intervention delivery, safety, outcome measurement and effect size calculation for future sample size estimation.

Ethics and Governance

Ethical approval was granted by Teesside University (Ref 163/18) and all participants provided written informed consent. The study was registered at ClinicalTrials.gov (Identifier: NCT03804567) prior to commencement.

Setting and participants

The study was undertaken in a single UK private physiotherapy practice (referred to as the Centre). The study was advertised on the Centre's Facebook page, website and on a poster in the waiting room. Forty two individuals contacted the Centre to enquire about participation, or were identified by the receptionist as potentially eligible, and all were sent the Participant Information Sheet. Twenty-three (17 female, 6 male) subsequently contacted the Centre and were invited to attend the Centre for an initial meeting. Twenty-two were assessed for inclusion by one of the authors (DC). Individuals were eligible for inclusion if they were currently suffering from non-specific CLBP for ≥3 months, were aged over 18 years, and for whom OldPain2Go® was indicated as a treatment option after the standard clinical screening process for the OldPain2Go® treatment. Individuals were excluded if they had any red flags indicative of a serious or sinister pathology, or if they lacked the capacity to give informed consent. Additionally, after formal consent was obtained, participants were withdrawn from the study if a 'yes' signal was not exhibited at screening after two requests (see intervention section for details).

Outcome measures

A 0-10 Numeric Rating Scale (NRS) with verbal anchors of 0 = *No Pain* and 10 = *Worst imaginable Pain* was used to measure back pain intensity. Function was assessed using the Roland Morris Disability Questionnaire (RMDQ) [13]; a 24 item, closed question, self-completed questionnaire. Higher scores indicate poorer levels of function. Both the pain NRS and the RMDQ are valid and reliable measures in this population [14] [15].

Procedure

On first attendance, participants were allocated a unique study code number. The intervention was delivered and data collected, by one of the authors (DC) who has been using OldPain2Go® in clinical practice since Sep 2017. Demographic details, standard medical history and a standard physiotherapy examination were recorded/undertaken. Both outcome measures (Pain NRS and RMDQ) were recorded and the standard OldPain2Go® specific screening was undertaken. Participants were asked why they think their pain is ongoing. They were then offered a brief individualised re-conceptualisation of their pain; re-framing their pain from a biomedical tissue injury based understanding towards a more contemporary biopsychosocial understanding in keeping with a pain neuroscience education [16] [17]. Included within the reframing was an explanation that *new pain* (acute pain) can be a good thing, as it alerts us to potential danger or problems, but, that *old pain* (chronic pain), is the persistence of a now redundant message, that no longer serves a useful purpose. Participants were informed that the OldPain2Go® intervention is not designed to cause numbness, or analgesia (like a painkiller) but the "*removal of the old pain messages"*. Participants were told that they did not need to believe in the technique for it to work, but they simply had to want to let go of their pain and be happy to receive the intervention.

It was explained to participants that the intervention aims to establish a connection with their unconscious mind, through setting up a *'Yes'* signal, with the use of an ideomotor response. The signal being an unconscious tilt/lean forward, while standing. This was demonstrated and participants were guided through the same movement by gentle touch on both shoulders. Participants were then asked to close their eyes and mentally ask their unconscious to give them a signal for a 'yes.' If the sway forward (the 'yes' signal) occurred, the participant progressed to receive the OldPain2Go® intervention. If there was hesitancy, or no signal occurred, DC provided re-assurance and asked again for the 'yes' signal. If the yes signal came, within 10sec, the participant was eligible to progress, as per the study protocol. If it did not come the participant was ineligible for the study and withdrawn at this point from the study and offered the option to receive usual physiotherapy care. Treatment sessions lasted for one hour.

Upon completion of the first OldPain2Go® treatment session, participants immediately completed the Pain NRS and an appointment was made for one week later. At the second appointment the previous week's history and a standard physical examination was recorded/undertaken and both outcome measures were recorded. Those participants who were no longer experiencing any pain, or whose pain was reduced and no longer an issue for them, were thanked for attending, no intervention was applied and one week later they completed both outcome measures, online, for a final third time (their 3-week follow-up measures). For those participants who were still experiencing pain, at session two, the OldPain2Go® intervention was applied again. Those participants then completed the Pain NRS immediately after the second intervention and a third appointment was made for one week later. At the third appointment the previous week's history and a standard physical examination was recorded/undertaken and both outcome measures were recorded. One week later those participants completed both outcome measures, online, for a final fourth time (their 3-week follow-up measure).

Statistical analysis

Participant characteristics were described using descriptive statistics. All outcome measure data was analysed to produce point estimates and measures of variance. The effect size (change in measure/baseline SD) was calculated as Cohen's d with 0.2, 0.5 and 0.8 considered as a small, medium and large effect size [18]. A minimally clinically important difference (MCID) was pre-set at a 10% change from baseline for both pain and function, based upon the values used within the NICE guidelines for lower back pain [19].

Results

Recruitment methods proved successful and the study was completed within a five month period. Twenty-three people expressed an interest in participating (17 female, 6 male). Twenty-two attended (one did not attend and there was no reason provided), were recruited, and received a first treatment (17 female, 5 male, mean age 49.7, range 18-76 years). Nine participants received only one treatment (6 female, 3 male, mean age 45.1, range 18-76 years) - one withdrew due to an acute exacerbation (not study related) and the others did not require a second treatment under the protocol. The remaining thirteen participants received a second treatment (11 female, 2

male, mean age 52.9, range 28-71 years). Final data was collected from 16 participants of whom fifteen had completed data collection at all points (completers) (11 female, 4 male, mean age 49.3, range 18-71 years). Of those 15, five received only one treatment and ten received two. No adverse events, or reactions, associated with the intervention, were reported, or observed. Figure 1, the CONSORT Flow Diagram, illustrates recruitment and participant progression throughout the study.

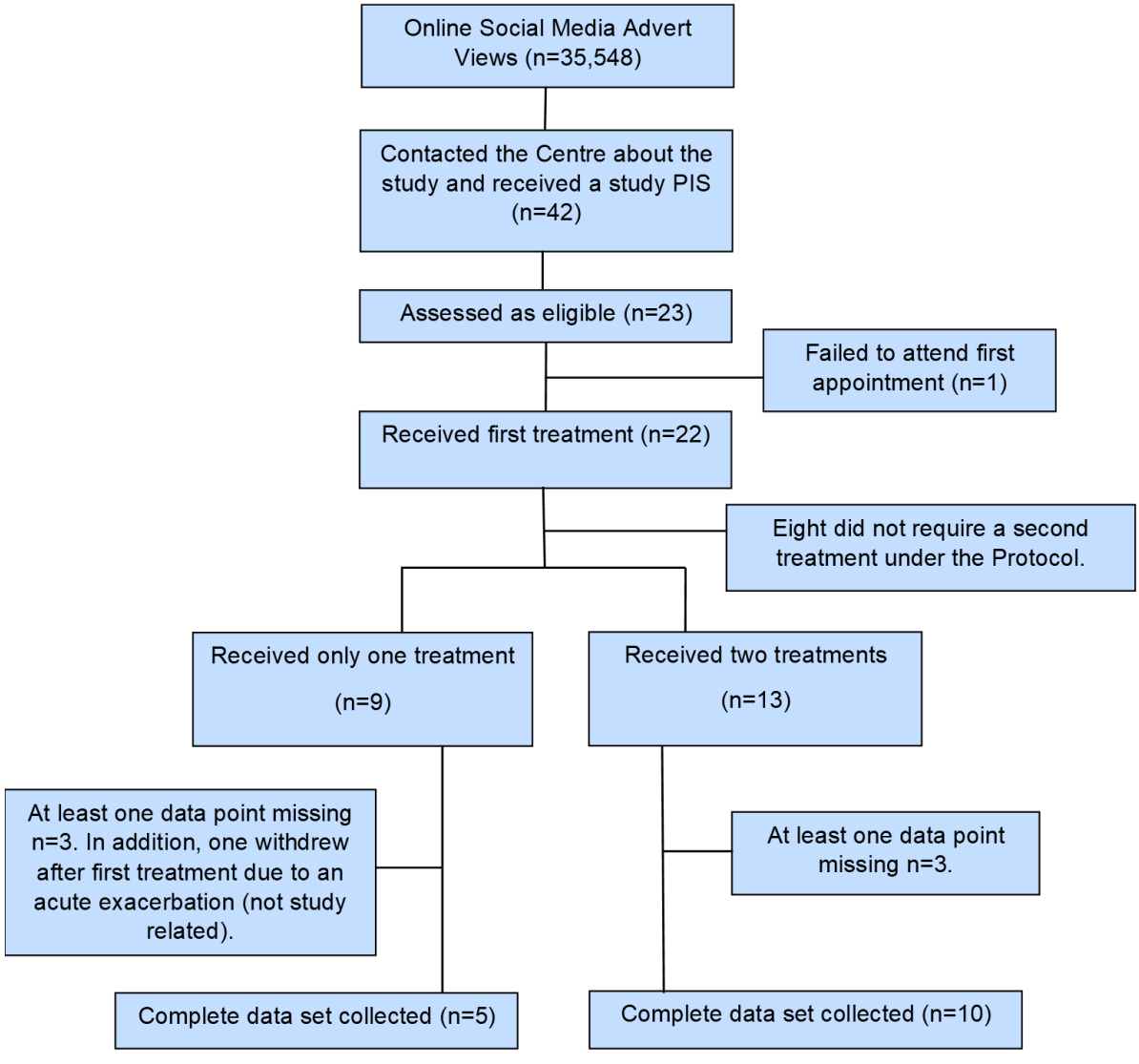

Figure. 1: CONSORT Flow Diagram illustrating recruitment and allocation of participants over the course of the study.

Table 1 shows the demographic information for all completers as a group and then for those who received only one, or two, interventions separately.

The mean (±1 Standard Deviation [SD]) values for pain (NRS) and function (RMDQ), at each data point, are shown in Figures 2 and 3, respectively.

Data was normally distributed. With reference to baseline value, pain was reduced by 4.0 points (3.2, 4.8) (mean, 95% CI) and 4.4 (3.3, 5.5) immediately after session 1 and at 3-weeks follow-up (final data collection), respectively. These reductions both exceeded the *a-priori* MCID of 10%, being 65.4% of mean baseline values, after session 1 and 71.0% of mean baseline values at the 3 week follow up. A large effect size for pain was found at both time points, d=2.67 one week after session 1 and d=2.93 at the 3 week follow-up.

A similar pattern was seen for function, where the RMDQ reduced by 8.1 points (5.1, 11.1) and 8.9 (5.9, 11.9) one week after session 1 and at 3-weeks follow-up (after session 1 and at the 3 week follow up point, respectively). Again, these reductions both exceeded the a-priori MCID of 10% being 64.9% of mean baseline

values, after session one and 71.3% of mean baseline values at the three week follow up. The effect sizes were again large, d=1.62 one week after session 1 and d=1.78 at the three week follow-up.

Table 1: Demographic information for All Completers as a group, and for those who only received one and those who received two, treatments separately

	All completers (n=15)	**Received one treatment (n=5)**	**Received two treatments (n=10)**
Male	4	3	1
Female	11	2	9
Mean Age (1SD)	49.3 (18.0)	44.8 (25.3)	49.3 (18.0)
Age Range	18-71	18-71	28-68
Working Sedentary	5	1	4
Working Manual	2	1	1
Not working	3	1	2
Retired	5	2	3
Patient identified with a causative initial physical event (e.g. Road traffic accident)	6	1	5
Patient did not identify with a causative initial physical event	9	4	5
Additional pain sites other than the lower back	1	0	1
Previous surgery related to present complaint	3	2	1
Not taking Medication	3	1	2
Prescription Medication	6	2	4
Non-prescription Medication	6	2	4

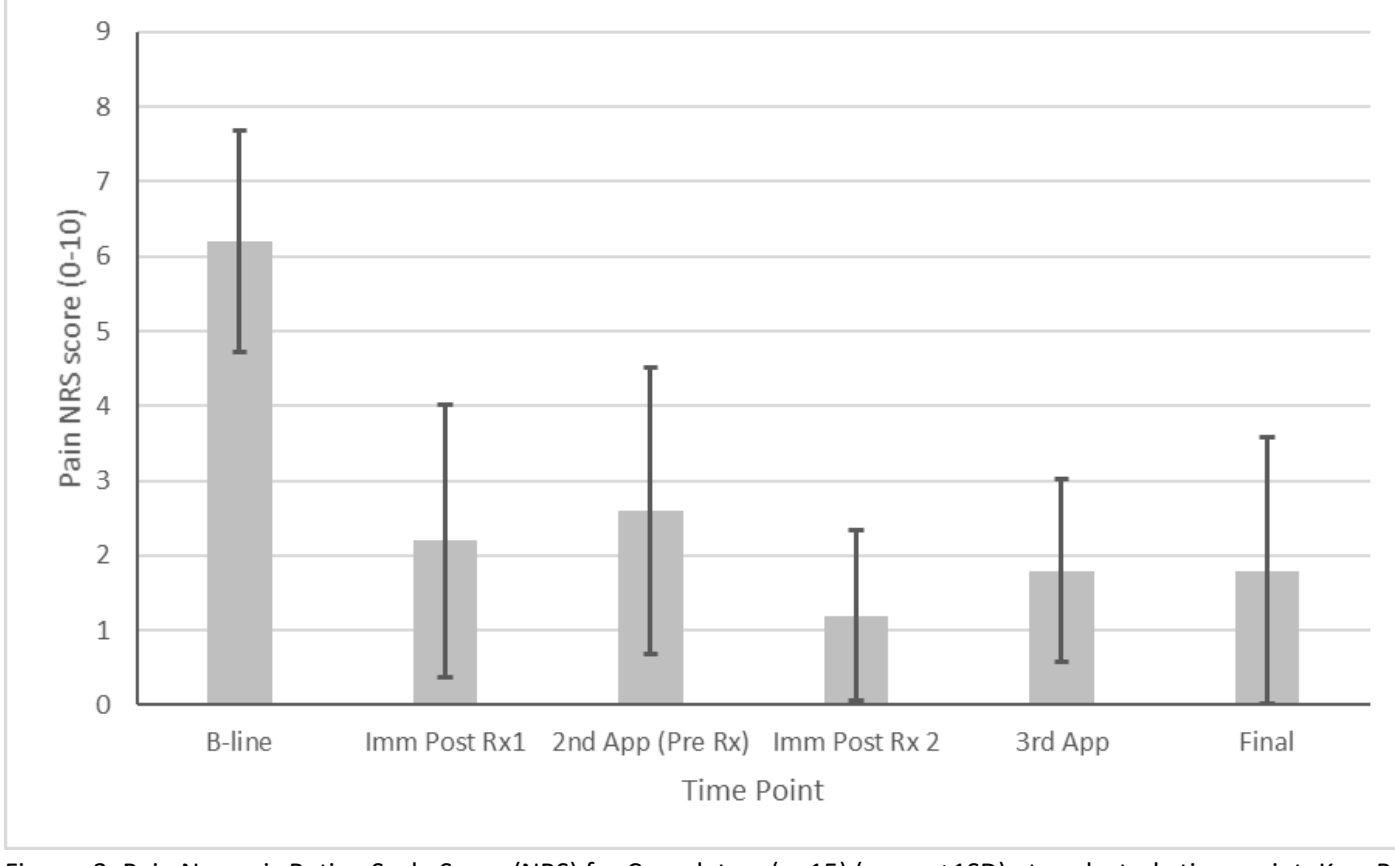

Figure. 2: Pain Numeric Rating Scale Score (NRS) for Completers (n=15) (mean ±1SD) at each study time point. Key: B-line = Baseline; Imm = Immediately; App = Appointment; Rx = Treatment

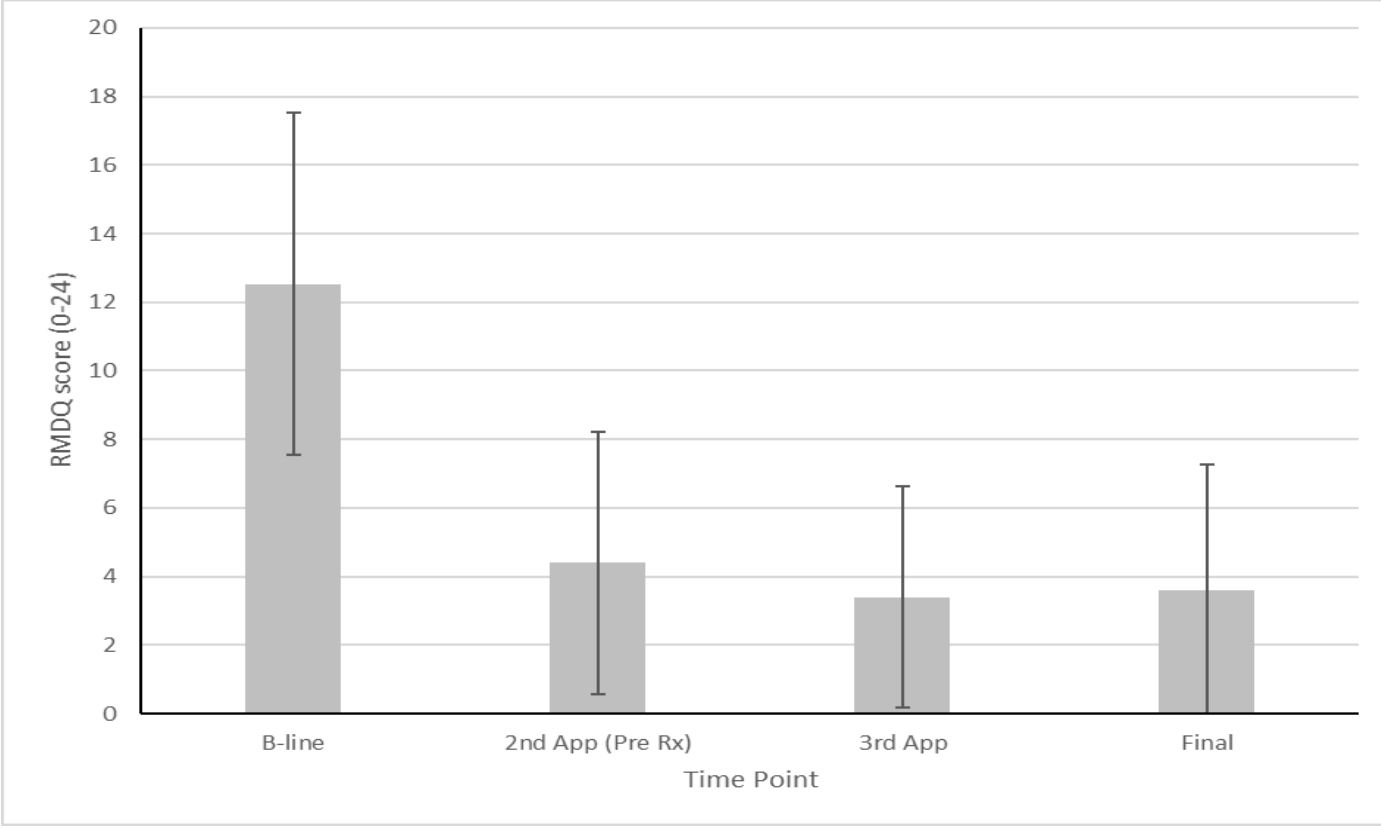

Figure. 3: Roland Morris Disability Questionnaire (RMDQ) for Completers (n=15) (mean ±1SD) at each study time point. Key: B-line = Baseline; Imm = Immediately; App = Appointment; Rx = Treatment

Discussion

The aim of this feasibility study was to gather information to inform the development of a protocol for a single-blind randomised controlled trial (RCT) investigating the safety and efficacy of OldPain2Go® for the treatment of pain and function, in people with CLBP. Key methodological issues that were explored were recruitment processes, participant drop out, intervention delivery, safety, outcome measurement, and effect size calculation to inform future sample size estimation.

Recruitment processes worked well within this single site feasibility study. The time taken, from initial advertising of the study to final data collection, was under five months. The study was advertised on the social media site (35,548 views) of the private physiotherapy practice where the study was delivered, and through a poster in the waiting room for 41 days. One third (n=5) of those who completed the study were indicated to receive only one treatment, under the protocol, with the other participants (n=10), receiving two.

Given that this was a feasibility study no inferential analysis was conducted. There was, however, no discernible difference in the baseline outcome values, between those providing a complete data set and those who did not. Recruitment and retention strategies were considered to be successful. How *dropout* is defined and whether the reasons for dropout are reported varies considerably in intervention trials [20]. If dropout is defined as, *withdrawal from treatment*, the rate observed here was 4.5%; if defined as, *non-completion and treatment dropout*, the rate was 31.8%. Identifying the reasons for and implications of this dropout rate were beyond the scope of this study but would benefit from further exploration.

All participants who completed the study reported improvements in both pain and function. The magnitude of the improvement, both immediately post treatment and at the 3 week follow up point, were well above the MCID and the effect sizes reported were large for both measures. Given the tendency for small studies to demonstrate overly inflated effect sizes these findings should be interpreted cautiously [21] [22]. It is particularly promising to see these improvements occur within a relatively brief period of time and relatively short duration patient contact time of one hour per treatment session. This has potential implications for service provision where resources are

continually over stretched and provides justification for further exploration of this novel intervention.

These results demonstrate the feasibility and safety of recruiting to and delivering OldPain2Go®, for the treatment of pain and function, in people with CLBP within a research setting. While no adverse events, or reactions, associated with the intervention were reported or observed here, it is possible very rare events or reactions may not have occurred in this small sample.

Study limitations

It is important to interpret these findings in the context of a feasibility study, rather than a study of efficacy. Thus, no claims of efficacy are made and the effects observed here could be attributed to non-intervention, methodological constraints, for example, placebo effects or regression to the mean. In addition, the sample size is small (compared to that required in a definitive RCT) and recruitment occurred from a single site, private physiotherapy practice. The non-completion and treatment drop-out rate of 31.8% also warrants further qualitative exploration given potential implications for intervention efficacy. The intervention was delivered by a physiotherapist with over 20 years of experience treating patients with CLBP, who is a registered trainer of the OldPain2Go® technique. The possibility of a positive *halo effect* must therefore be acknowledged [23].

The findings support further preparatory work and an expanded feasibility study with a control group prior to undertaking an adequately powered RCT, to comprehensively investigate the safety and efficacy of this intervention. Future work should consider using multiple sites and multiple clinicians, with blinded outcome assessment, and long-term outcomes. Furthermore, the question of what the most suitable comparison group would be should be explored whether usual care, or some form of placebo control (the latter to confound any effect from patient/therapist contact time, and the potential bias associated with the therapeutic alliance between the patient and the therapist) remains to be determined. In addition, a nested qualitative study would help gain insight into the patient's experiences and perceptions of the intervention and obtain feedback on how the intervention might be enhanced from the patient perspective and to inform the design of an RCT.

Conclusion

The aim of this feasibility study was to gather information to inform the development of a protocol for randomised controlled trial (RCT) investigating the safety and efficacy of OldPain2Go® for the treatment of pain and function, in people with CLBP. The recruitment process was robust, recruiting to target within a short space of time. Only one participant withdrew from the study and there were no adverse events/reactions attributed to the intervention. Improvements in pain and function were seen in all those who completed the study with average improvements well above what is considered clinically relevant and which could be expected due to natural variance. As such, there is sufficient evidence that a fully powered RCT is warranted. However, further feasibility/pilot work should be undertaken to further assess the protocol prior to undertaking a definitive trial.

Ethical Approval Teesside University School of Health and Life Sciences Research Ethics Committee, Ref 163/18

Funding No funding required.

Conflict of Interest The authors listed below are full time academics and declare that they have no conflicts of interest: AMcS, KS, and DM.

The authors listed below report that they have received training in the OldPain2Go® treatment and use the intervention in clinical practice: DC and CR.

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