

TITLE PAGE

Title: Effects of postural taping on pain, function and quality of life following osteoporotic vertebral fractures – a feasibility trial

Running title: Taping for osteoporotic vertebral fractures

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TITLE

Effects of postural taping on pain, function and quality of life following osteoporotic vertebral fractures – a feasibility trial

ABSTRACT

Objective: Osteoporotic vertebral fractures (OVFs) are common and present a significant burden to patients and healthcare services. Poor posture can increase vertebral pressure, pain and the risk of further fractures. This study aimed to investigate the effects of postural taping on pain, function and quality of life when used in addition to usual care.

Design: A randomised controlled feasibility trial.

Participants: Men and women with at least one clinically diagnosed painful OVF.

Intervention: Participants were randomly allocated to use adhesive postural taping devices at home for four weeks or to continue with usual care.

Main Outcome Measures: Outcomes assessed at baseline and four weeks included pain at rest and on movement (visual analogue scales - VAS), and function and quality of life (Quality of Life Questionnaire of the European Foundation for Osteoporosis - QUALEFFO). Health resource use and acceptability were explored using a specifically designed questionnaire.

Results: 24 participants completed the trial (taping n=13, control n=11). Groups were comparable in age, although the control group contained more men (n=3 versus n=0) and scored slightly lower on most outcome measures at baseline. Descriptive analysis favoured the taping group for most outcome measures. Effect sizes were small to medium (0.37, 0.45 and 0.66 for VAS rest, VAS movement and QUALEFFO respectively).

Conclusions: The taping device demonstrated potential to improve pain and function. However the findings need to be replicated in an appropriately powered study. The study procedures were largely acceptable. A more extensive pilot trial is recommended prior to a definitive trial.

KEYWORDS

Orthotic tape; Osteoporosis; Pain; Spinal fractures

MANUSCRIPT

INTRODUCTION

Osteoporotic vertebral fracture (OVF) is common, accounting for 27% of all fragility fractures (Kondo, 2008). Vertebral deformity, used as a marker for OVF, has a mean prevalence across Europe of 12% in women and men aged 50-79 years (O'Neill et al., 1996). In Canada 23.5% of women and 21.5% of men over 50 years had evidence of vertebral deformity (Jackson et al., 2000). OVF prevalence increases with age and most commonly affects the sixth thoracic to first lumbar vertebrae (Waterloo et al., 2012). Thoracic kyphosis increases vertebral forces in people with vertebral fracture (Briggs et al., 2007) and is a key risk factor for further vertebral fracture (Huang et al., 2006).

OVBs cause significant pain and impact on function and quality of life (QoL) (Sanf elix-Genov es et al., 2011; Yoon et al., 2014). A recent systematic review and meta-analysis showed reduced QoL with OVF, with greater effects on physical than mental components (Al-Sari et al., 2016). Pain following vertebral fracture is one of the most important determinants of QoL (Nevitt et al., 1998). Vertebral fracture impacts on sleep, emotional health and mobility (Francis et al., 2004) and thus presents a major challenge to patients and healthcare services.

In addition to medication for pain relief and underlying osteoporosis, non-pharmacological interventions such as physiotherapy to improve pain and mobility, and to reduce falls and future fractures are advocated (Francis et al., 2004; Sinaki, 2012). A Cochrane review exploring the effects of exercise for OVF (Giangregorio et al., 2013) identified some limited support for effects on pain, physical function and QoL but the small number of low quality trials was highlighted. Other systematic reviews have explored the effects of spinal orthoses and taping (Goodwin et al., 2016; Newman et al., 2016), identifying a lack of evidence for effectiveness and low quality of existing research. All reviews recommended further high quality studies.

Taping to correct posture is a potentially useful addition to rehabilitation following OVF. Posture correction may reduce spinal loading, pain and, in the longer term, risk of further fractures. Postural taping might also improve proprioceptive input, reduce pain and assist engagement in functional activity. Taping has been shown to be effective when used as part of a complex rehabilitation package including other techniques such as manual therapy and exercise, reducing thoracic kyphosis (Bautmans et al., 2010) and improving pain and function

(Bennell et al., 2010). Postural taping is also part of a ‘manual therapy’ intervention in an ongoing large trial (n=600) of rehabilitation for patients with OVF (Barker et al., 2014). The only study of postural taping used in isolation for osteoporosis was a small (n=15) cross-over study by Greig et al. (2008) which found that taping reduced thoracic kyphosis, although it did not alter balance or muscle activity. In that study the effects of tape were assessed during a single session and longer-term effects are therefore unknown. Pain or other clinical outcomes were not included and a potential drawback with the taping technique used (Greig et al., 2008) is the need for trained therapists to apply it on an ongoing basis. Arguably, therefore, it represents an unlikely long-term treatment solution. Novel postural taping devices, for example Posture Pals® (www.posturepals.com.au) and PosturePlast (www.postureplast.co.uk) negate the need for skilled application and could be a more accessible and cost-effective alternative. Of course, such devices could also prove to be ineffective, a finding that could equally help to inform practice. The intervention used in the present investigation, PosturePlast, has previously only been evaluated in a small unpublished cohort study (n=92) of patients with low back pain (<http://www.postureplast.co.uk/healthcare-professionals/clinical-trials.aspx>, accessed 23/2/18). After one week, 83% reported that it was useful for improving posture, 90% that it prevented poor posture and 78% that it improved pain. Rigorous independent evaluations have yet to be conducted.

This feasibility randomised controlled trial (RCT) therefore aimed to undertake a preliminary investigation of the effects of a novel postural taping device on pain, function and QoL following OVF when used for a four-week period in addition to usual care. A primary intention was to inform development of a future definitive RCT.

METHODS

The study was approved by the West Midlands South Birmingham National Research Ethics Service Committee (13/WM/0357).

Recruitment

Men and women diagnosed with OVF from two secondary care organisations in South West England were invited.

Inclusion criteria: 1. Back pain concurrent with a diagnosis of OVF. OVF was confirmed by a Rheumatologist trained in the algorithm-based qualitative (ABQ) method of identifying OVF from spinal radiographs (Ferrari et al., 2008). The ABQ method is the most specific and reproducible method of OVF identification for research purposes, with a low false-positive rate; 2. Fracture not immobilised; 3. Independently mobile (with or without an aid); 4. Able to apply the postural taping device to the low back independently or with assistance.

Exclusion criteria: 1. Osteoporosis secondary to metabolic bone disorders or other disease (steroid-induced osteoporosis was not an exclusion criterion); 2. Fragile or broken skin; 3. Known allergy to adhesive plasters; 4. Vertebroplasty or kyphoplasty.

Potential participants were identified prospectively by physiotherapy, osteoporosis and spinal services and sent study information. Interested participants returned a reply slip to the research team who then telephoned to check eligibility and answer any questions. If potential participants gave verbal consent a mutually convenient appointment was agreed for baseline assessment. On attendance, further opportunity was given for questions before formal written informed consent and completion of study outcomes.

Outcome measures

Outcomes were assessed at baseline and at four weeks. The exploratory nature of the trial and limited resources meant that longer-term follow-up was not possible. Pain at rest and on movement were assessed using two 10cm Visual Analogue Scales (VAS), with anchors of “*No pain*” and “*Pain as bad as it could be*”. Participants were asked to “*Place a vertical mark on each line below to indicate how bad you feel your back pain is today...*” “... **at rest**” and “... **on movement**”. Function and QoL were assessed using the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO-41) (Lips et al., 1999). The QUALEFFO contains 41 questions with Likert scale responses which produce a total score and separate subscales for pain, physical function, social function, general health perception and mental function. The total score and each subscale give a maximum score of 100, with higher scores representing increased severity. The QUALEFFO-41 has been well validated (Lips et al., 1999; de Oliveira Ferreira et al., 2009; Tadic et al., 2012). Demographics (at baseline), healthcare resource use (at baseline and week four) and acceptability of the taping device and outcome measures (at week four) were assessed using specifically designed questionnaires. The wording of questions is reported in the results section.

Interventions

Following baseline assessment participants were randomly allocated to receive the taping device for home use or to continue with usual care. Those receiving taping received full instruction and a supply of devices. An instruction booklet, including information on skin care and research team contact details, was issued. The taping device is a large adhesive plaster with a built-in flexible plastic 'X' (see Figure 1). According to the manufacturer, it is designed to control back movement, reduce pain and improve posture (www.postureplast.co.uk, accessed 23/2/18). The device is designed for the lumbar spine and was applied as per the manufacturer's guidelines but with the aim of influencing posture throughout the spinal column. This rationale was supported by previous evidence that a soft lumbar orthosis reduced thoracic kyphosis in a sub-sample of patients with OVF (Li et al., 2015). Participants were advised to wear the device as often as they felt they needed to or wanted to. Although each device could only be used once, participants could wear each for up to 48 hours and could sleep and shower with it on. Participants were supplied free of charge with sufficient devices so that they could use a new one every day if they wished. When purchased as a pack of 10, the devices normally cost approximately £2.50 each (cost correct at time of publication).

Participants randomised to the control condition simply continued with 'usual care'. The resource use questionnaire collected information about what that constituted. The research team did not provide any additional advice or intervention.

All participants were given a follow-up appointment four weeks later.

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Randomisation

An independent monitor prepared sealed opaque envelopes containing random treatment allocations. The sequence was generated using an online randomisation tool (www.random.org, accessed 3/2/14). Block randomisation (1:1 allocation) was used (block size was four but the research associate was blinded to block size). Randomisation was not stratified. Envelopes were sequentially numbered. Following consent participants were allocated a sequential study number and, following baseline assessment, the corresponding envelope was opened to reveal their treatment allocation.

Blinding

Due to the nature of the interventions, it was not possible to blind patients or the research associate to treatment allocations. However data analysis was conducted blind to treatment allocations. Clinical outcomes were patient self-reported, so the potential impact of lack of researcher blinding was moderated, although it cannot be discounted.

The experimental procedure is summarised in Figure 2.

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Sample size

As this was a feasibility study, a sample size calculation was not performed. Recommendations for such studies vary. Julious (2005) recommended at least 12 per group for a parallel group trial and Hertzog (2008) recommended 10-20 per group for estimating variance to inform power analysis. The maximum sample size was set at 20 per group, although 10-12 per group was anticipated to be sufficient for effect size estimates.

Data analysis

As this was a feasibility study, inferential analysis was inappropriate. Descriptive statistics (mean, standard deviation, standardised effect size and 95% Confidence Intervals (CI)) estimated outcome variability and between-group differences and informed sample size calculations for a future RCT.

RESULTS

Recruitment

A CONSORT flow diagram is presented in Figure 3. 74 potentially eligible patients were sent recruitment packs and 25 of these (34%) consented and were randomised to the control (n=12) and taping (n=13) arms. One control group participant failed to attend follow-up (4% attrition) and was excluded. 24 patients were therefore included in data analysis (n=11 control and n=13 taping).

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Participant characteristics and baseline outcomes are presented in Table 1. Working status and ethnicity are not tabulated but one person in each group worked part time. All others (n=22) were retired. All described their ethnicity as ‘white’ (n=24). Fourteen participants (58%) had a history of more than one fracture, with the proportions of fractures by spinal region as follows: lumbar 47%, lumbar and thoracic 18%, thoracic 35%. The history of OVFs ranged from 3 months to 8 years.

The sex distribution varied between groups, with all three men randomly allocated to control. The control group scored slightly lower on most outcomes, suggesting slightly lower severity.

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Due to slight group differences at baseline, analysis was conducted on change scores (week 4 values minus baseline values). Table 2 presents change scores, mean difference in change scores between groups and standardised effect sizes.

PLACE TABLE 2 HERE

Table 2 demonstrates fairly consistent improvements in both groups. The mean difference favours taping in most outcomes, the only exception being the QUALEFFO-41 general health perception subscale. Generally, point estimates for standardised effect sizes were small to medium. The largest effect sizes were for pain and physical function outcomes. As expected in such a small study, group differences and effect sizes were associated with relatively large confidence intervals, all of which crossed zero.

Resource use

Table 3 illustrates the health resource use reported over the previous four weeks at baseline, giving insight into ‘usual care’. Healthcare consultations were most frequent for physiotherapists (approaching an average of one consultation per person). Two thirds of patients used medications prescribed for their OVF, with an average of two prescriptions for those who used them. Although not reported separately, there were no obvious differences

at baseline between groups in potential confounders related to healthcare consultations or medication. Health care resource data was successfully collected at week four but is not presented due to lack of obvious trends.

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Adverse events

Three participants allocated to taping (23%) reported a mild skin reaction and were advised to discontinue using it. All events were reported to the study sponsor. No other adverse events were reported. In all cases the skin reaction settled within a few days without further medical intervention. All three participants completed follow-up and were retained as part of an intention to treat analysis.

Use and acceptability of the taping device

On average participants used 17 of the 28 devices supplied. The median reported usage was '21-24' days and, when worn, the median duration was '16-18 hours'. 9/13 (69%) wore the device in bed at night although four reported it as 'uncomfortable' when they did so (4/9, 44%). 9/13 (69%) required assistance to put the device on. Of those who required help 5/9 then reported it was 'easy' to apply, but 2/9 still reported it as 'difficult' and 2/9 as 'neither easy or difficult'. Of those who did not require help to apply the device 1/4 found it 'easy', 1/4 found it 'neither easy nor difficult' and 2/4 found it 'difficult'. Specific difficulties reported included removing the device from the packaging, parts of the device sticking together, and having to twist to view the application in a mirror.

Acceptability of the outcome measures

All participants (n=24) rated acceptability of study questionnaires at a median of 2 ('acceptable').

Sample size calculation

A minimum clinically relevant difference is not available for the QUALEFFO-41. A prospective sample size calculation for a definitive RCT was therefore made using VAS pain on movement as this was considered more functionally relevant than pain at rest. Dworkin et al. (2008) concluded that $\geq 30\%$ reduction in pain intensity would be a moderate clinically important difference. This equates to approximately 15mm from the baseline mean of 50.2mm for all participants in the current investigation (n=24). On the basis of an independent t-test,

alpha 0.05, 80% power, SD 31.6mm (the control group SD at the end of week four), a minimum of 71 participants in each group was calculated. A more extensive pilot RCT would confirm the estimates used for this calculation and patient consultation is recommended to inform selection of the primary outcome.

DISCUSSION

There were clear trends evident to support potential beneficial effects of the postural taping device on pain, function and QoL in people with OVF. The standardised effect sizes were generally small to medium which is notable for such a simple device. The mean reduction in VAS pain on movement with taping was approximately 41%, exceeding the 30% considered clinically important (Dworkin et al., 2008). A much smaller reduction of 16% was observed in the control group. The largest standardised effect size was for the physical function subscale of the QUALEFFO-41 scale (Cohen's $d = 0.77$), followed by the total QUALEFFO-41 score (0.67). The potential effects therefore extend across pain, function and QoL. However caution is warranted due to the large confidence intervals around these estimates and these preliminary findings need to be replicated in a definitive RCT.

A relatively high proportion of participants (23%) developed a mild skin reaction when using taping. Smith and Zirwas (2015) reported that, although 0.347% of patients reported an allergy to medical tape, true allergies were estimated to be much lower at 0.033%. Non-allergic tape reactions are therefore likely to be much more common than allergic ones. Non-allergic reactions may be caused by skin inflammation due to factors such as previous skin damage, skin softening, physical distortion, hair removal, tape preventing the removal of skin irritants, and repeated removal of the uppermost layer of skin (Smith and Zirwas, 2015). The high prevalence of such reactions in the present investigation may relate to the older population investigated, who might be expected to have more fragile skin. Other factors may include the large surface area covered by the device, and high forces transferred from the device to the skin surface by the large lumbar spine range of motion. The prevalence of skin reactions is an important consideration for future use of such devices for OVF and for future research into their potential effectiveness. It may be difficult to effectively identify and screen out people who may develop non-allergic reactions and therefore it should be made clear to participants as part of informed consent that such reactions are possible. A per protocol analysis should be considered in future research to

estimate the true effectiveness of the devices in those patients who are able to use them without adverse reactions.

Despite the relatively high prevalence of skin reactions, there was a high level of engagement with and use of the taping devices. The median usage was '21-24' days across the four week period and for '16-18 hours' per day. Although one of the proposed benefits of the devices is they can be self-applied, it was clear that the majority of participants (69%) required assistance. Of the four participants who self-applied the devices, only one reported that this was 'easy'. Such knowledge is important to inform patient information.

Greig et al. (2008) demonstrated that therapist-applied taping reduced thoracic kyphosis so there is clear potential for taping to alter posture and movement. However, it is not clear whether the trends in self-reported clinical outcomes observed in the present investigation are underpinned by biomechanical effects of the taping device.

A more extensive pilot RCT would seem appropriate before progressing to a full RCT. This would allow the assessment of longer-term outcomes and provide additional information about potential adverse events. Inclusion of a third group receiving therapist-applied tape would provide a useful additional comparison to inform clinical practice.

Strengths and limitations

The present investigation was a feasibility study so definitive statements related to effectiveness cannot be made. Randomisation was not stratified by gender and all men were allocated by chance to the control group. Future research should address this. The sample lacked diversity with regards ethnicity, which ideally should be addressed in future research. There are no accepted cut-off scores for severity for the QUALEFFO questionnaire. However, it should be noted that participants in the present investigation generally had higher QUALEFFO scores than previous cohorts reported in the literature. For example the sample included in the initial validation of the QUALEFFO questionnaire (Lips et al., 1999) had a mean total QUALEFFO score of 35.3. The present sample was also older than that reported by Lips et al. (1999) (whose mean age was 66.3 years). Again, future work should aim to recruit a representative sample in relation to condition severity and age.

The study outcome measures were largely acceptable. Information on recruitment rates and estimates of variability have been obtained and have informed a sample size calculation for a definitive trial. The study has also demonstrated the feasibility of collecting health resource use data to inform future economic evaluation. A major limitation was the very brief follow-up (4 weeks) and a future trial should evaluate longer-term effects of the device. Similarly, researcher blinding should be addressed in future work.

CONCLUSION

The postural taping device has demonstrated the potential to improve pain, function and QoL, which is notable for such a simple device. The study procedures were largely acceptable to participants. A more extensive pilot RCT with longer follow-up is recommended prior to a definitive trial.

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TABLES

Characteristic		Taping (n=13)	Control (n=11)
Age, years		73.6±5.9	74.6±7.0
Sex, women:men, n		13:0	8:3
Relationship status, n	Single	0	1
	Married/partner	9	9
	Divorced/separated	2	0
	Widowed	2	1
	Other	0	0
Living arrangements, n	Alone	3	1
	With husband/wife/partner	9	10
	With somebody else	1	0
Baseline outcome measure		Taping (n=13)	Control (n=11)
VAS pain at rest (max 100mm)		35.2±24.1	27.8±23.0
VAS pain on movement (max 100mm)		51.4±15.9	48.8±25.1
QUALEFFO-41 total score (max 100)		55.2±8.2	51.6±9.7
QUALEFFO-41	Pain	66.3±14.9	68.4±11.5
Subscales (all max 100)	Physical function	48.5±11.4	42.5±12.3
	Social function	58.8±16.7	53.6±12.9
	General health perception	71.3±14.3	69.7±15.6
	Mental function	53.1±11.7	49.4±12.4

Table 1. Baseline characteristics and baseline outcome scores in the two groups. All figures are mean±standard deviation except where otherwise stated.

Outcome measure	Taping (n=13)	Control (n=11)	Mean difference (Taping - Control) (95% CI)	Standardised effect size, Cohen's <i>d</i> (95% CI)
VAS pain at rest (max 100mm)	-10.8±19.3	-0.9±33.1	-9.9 (-32.4, 12.7)	0.37 (-0.45, 1.17)
VAS pain on movement (max 100mm)	-20.9±29.8	-7.6±29.4	-13.3 (-38.4, 11.9)	0.45 (-0.38, 1.25)
QUALEFFO-41 total score (max 100)	-4.1±3.2	-1.6±4.3	-2.5 (-5.7, 0.7)	0.67 (-0.18, 1.47)
QUALEFFO-41 Subscales (all max 100)				
Pain	-10.3±12.8	-4.4±8.8	-5.9 (-15.4, 3.6)	0.53 (-0.31, 1.33)
Physical function	-3.8±5.0	-0.1±4.5	-3.7 (-7.7, 0.4)	0.77 (-0.08, 1.58)
Social function	-2.0±5.8	-1.6±8.0	-0.4 (-6.3, 5.4)	0.06 (-0.75, 0.86)
General health perception	-1.0±10.5	-3.6±6.9	+2.6 (-5.1, 10.3)	-0.29 (-1.08, 0.53)
Mental function	-4.6±5.7	-2.1±8.5	-2.5 (-8.5, 3.6)	0.35 (-0.47, 1.15)

Table 2. Difference in patient reported outcome measures from baseline to week 4. A reduction in all figures represents a self-reported improvement. All figures are mean±standard deviation except where otherwise stated.

Health and care service used over the previous four weeks	Combined Groups (n=24)
Total health professional consultations, mean per person (n/sample size)	1.58 (38/24)
Physiotherapist consultations, mean per person (n/sample size)	0.79 (19/24)
Occupational therapist consultations, mean per person (n/sample size)	0.04 (1/24)
Other therapy services consultations, mean per person (n/sample size)	0.00 (0/24)
GP consultations, mean per person (n/sample size)	0.21 (5/24)
Practice nurse consultations, mean per person (n/sample size)	0.54 (13/24)
Got a repeat prescription (without seeing doctor), mean per person (n/sample size)	0.63 (15/24)
Telephoned NHS Direct/NHS 111, mean per person (n/sample size)	0.00 (0/24)
Accessed other GP-based services, mean per person (n/sample size)	0.00 (0/24)
Hospital outpatient clinic appointment, % 'Yes' (n/sample size)	16.67% (4/24)
Admitted to hospital or visited A&E, % 'Yes' (n/sample size)	0.00% (0/24)
Required medications or preparations prescribed by a doctor, % 'Yes' (n/sample size)	66.67% (16/24)
If 'Yes' how many prescriptions, mean per person (n/sample size)	2.00 (32/16)

Table 3. Health and care service resource use at baseline. All questions specified “...for reasons related to your osteoporotic vertebral fracture”. Except where specified otherwise, figures are expressed as the mean number of times per person that services were accessed in the previous four weeks (with the combined number of times that services were accessed by all group members in brackets). NHS Direct/NHS 111 is a non-emergency medical helpline; A&E = Accident & Emergency department; GP = General Practitioner.

FIGURE LEGENDS

Figure 1. Postural taping device in situ.

Figure 2. Flow diagram illustrating the recruitment and experimental procedure.

Figure 3. CONSORT flow diagram.

FIGURES

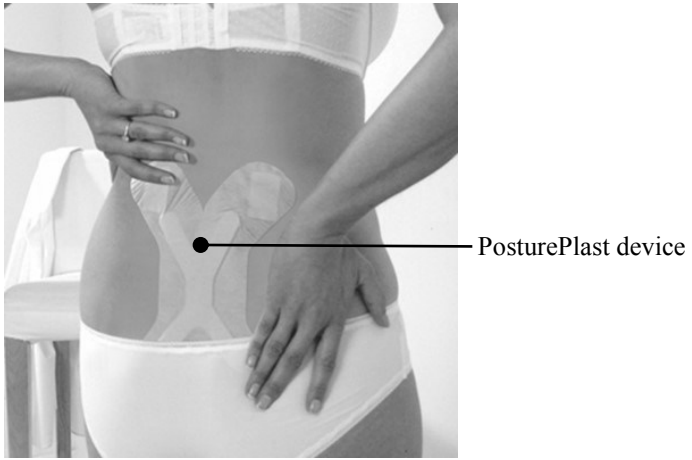


Figure 1. Postural taping device in situ.

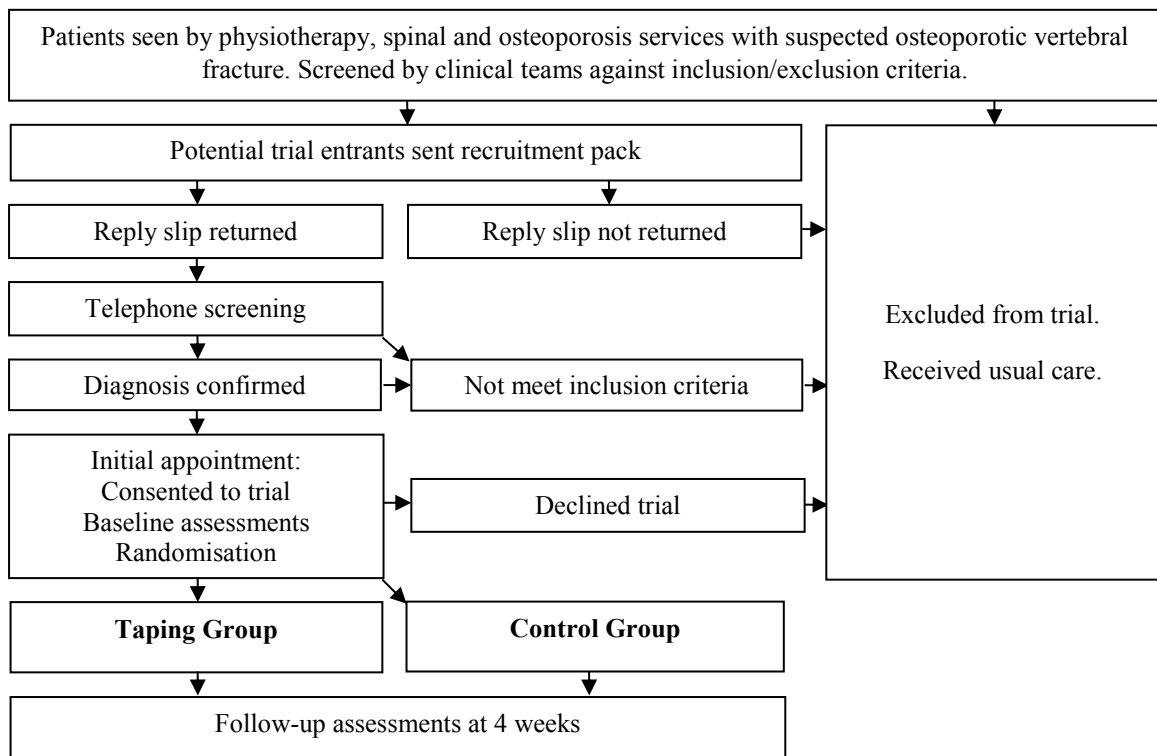


Figure 2. Flow diagram illustrating the recruitment and experimental procedure.

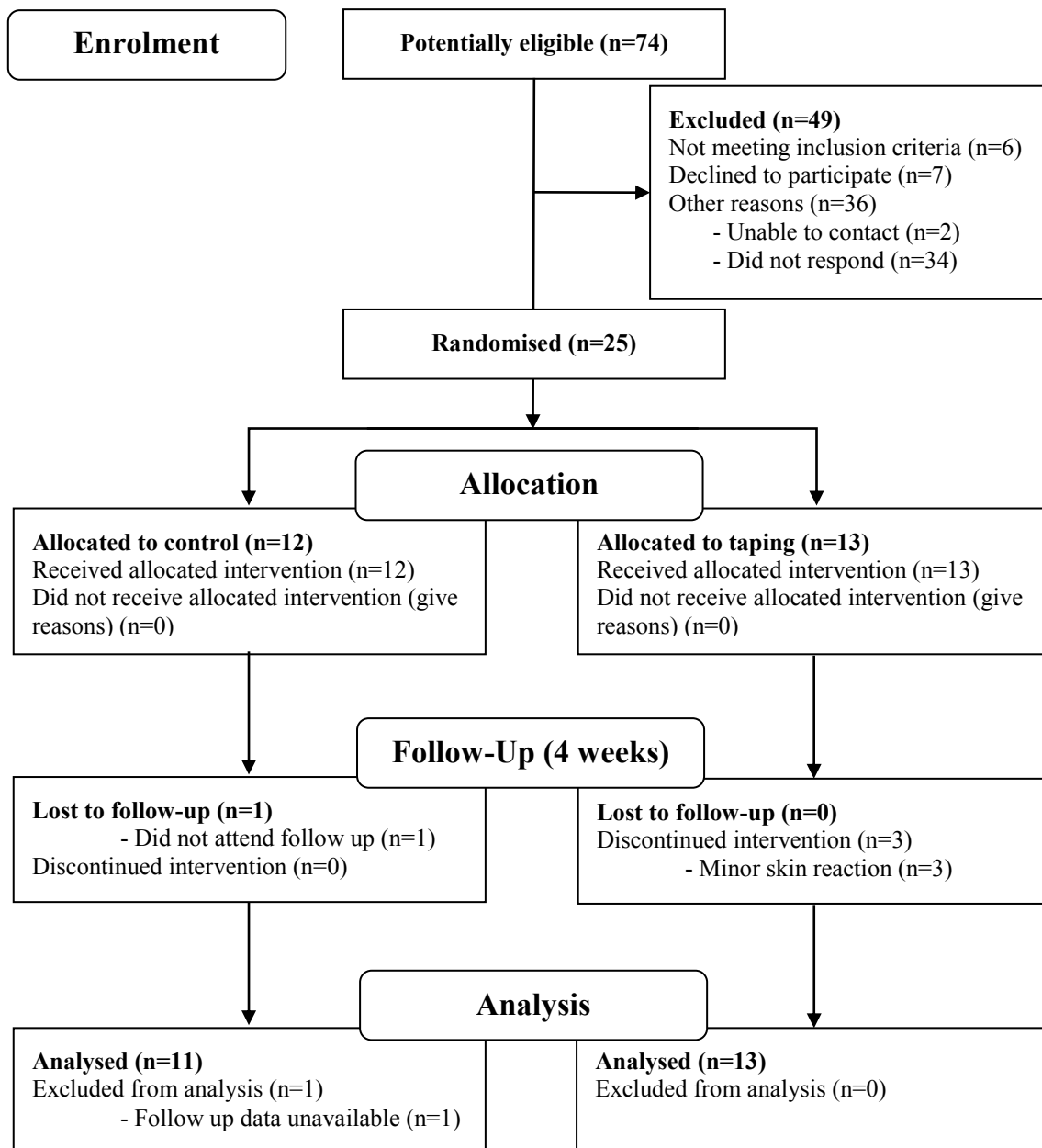


Figure 3. CONSORT flow diagram.