Title: Effect of taping as part of an exercise and advice physiotherapy programme on pain and function in patients with knee osteoarthritis.

Project Lay Summary:

Osteoarthritis is a common condition that tends to affect the weight bearing joints of the body especially the knees. It is caused by damage in the joints and usually develops in people over the age of 45. It is a type of arthritis that causes pain and stiffness in the joints. Pain can be difficult to manage and can make day to day activities difficult. Treatment of osteoarthritis of the knees includes advice on managing symptoms and exercises to strengthen the leg muscles. Exercise can sometimes be difficult due to high levels of pain, but physiotherapists can help this by applying tape on the knee to support the joint. However, there is inconclusive evidence about the effects of tape alongside an exercise programme for knee osteoarthritis.

This randomised controlled trial aims to look at the effect that taping the knee has on pain levels during a physiotherapy programme of advice and exercise. Patients will be recruited from a physiotherapy department after being diagnosed by their GP with knee osteoarthritis. The study will involve patients attending an education session and then a 6 week exercise programme with some of the patients having their knees taped during the exercises. To assess the results of wearing the tape, pain levels, difficulties with day to day activities and walking will be assessed before and after the 6 week programme. If taping is found to be successful, it could suggest a way to improve the management of osteoarthritis and help patients cope with their symptoms.

Background of study:

Osteoarthritis (OA) is a condition characterised by joint pain and stiffness that can cause difficulties with activities of daily living and affect quality of life (Page et al, 2011). It is the most common cause of knee pain in people over 50 years of age (Warden et al, 2008) and places a considerable burden on the health care system (Chandra et al, 2012). The National Institute for Health and Care Excellence (NICE) (2014) have advised a holistic management approach including interventions such as education, advice and exercise highlighting an important role for physiotherapy. Page et al (2011) have recommended the use of knee taping as a physiotherapy intervention for knee OA. It is suggested that knee taping can reduce the stress on the patellofemoral joint and offload soft tissues to help reduce knee pain associated with OA. Also, Chandra et al (2012) report that knee taping can increase proprioception and improve neuromuscular control.

Performing a literature search highlighted a number of studies related to taping and knee OA. Hinman et al (2003), Hinman et al (2002), Cushnaghan et al (1994) and Crossley et al (2009) looked at taping for patients with knee OA and found beneficial effects in terms of pain relief. However, they used taping as a single intervention which does not relate to typical clinical practice (Bennell et al, 2005). There are other limitations including small sample sizes and no long term follow up which reduced the validity and generalisability of the results. Bennell et al (2005) and Quilty et al (2003) compared taping as part of a physiotherapy programme against sham or no intervention with knee OA patients. They found non-significant improvements in pain scores which

Bennell et al (2005) suggest could be explained by patients self-applying tape and that this was not monitored throughout the study. In comparison, Chandra et al (2012) found that a physiotherapy programme with taping was more effective in pain relief and function than physiotherapy alone. Although the physiotherapy programme consisted of ultrasound and exercise which does not relate to current clinical practice and lacked an education element which is vital in the NICE (2014) guidelines for knee OA management.

Overall there is contrasting and inconclusive research regarding the use of taping with knee OA. There is also a need to further investigate the effect of taping alongside a physiotherapy programme that complies with the current clinical guidelines patients with knee OA.

Purpose of study:

It has been suggested that due to the aging of the population and increasing levels of obesity, there will be an increased demand for the treatment of knee OA (Cross et al, 2013). This means that is highly important to have effective interventions to help patients manage their condition. The aim of this study is to investigate the effectiveness of knee taping as part of a physiotherapy programme on patients with knee OA. This project could have important implications for the future management of knee OA and can provide patients with an intervention to help self-manage pain associated with their condition (Warden et al, 2008).

This study will look at knee taping alongside a physiotherapy programme consisting of advice, education and exercise to comply with the NICE (2014) guidelines on knee OA management. Pain levels will be the primary outcome measure with secondary outcome measures including physical function and quality of life.

Null Hypothesis:

Taping as part of a physiotherapy programme will have no effect on pain levels, physical function and quality of life with knee OA patients.

Research design and methods:

This project is designed as a randomised controlled trial with two intervention arms (tape and no tape) alongside a 6 week physiotherapy programme. Blinding is not possible due to only one researcher completing the work.

Subjects will be recruited when attending a physiotherapy department with a diagnosis of knee OA. They will be invited to participate in the study, provided with an information sheet and will sign a consent form (see appendix 2). Inclusion criteria is based on the American College of Rheumatology criteria (Altman et al, 1986), which consists of: aged 45 or over, complaints of activity related knee joint pain and OA changes confirmed on knee x-ray. Subjects will be excluded if they have additional knee injuries or previous knee surgery, allergic to tape, poor skin condition or if they are unable to take part in exercise due to pre-existing health conditions. Subjects will be randomly allocated to either tape or no tape intervention by opening an opaque sealed envelope.

The primary outcome measure is the Visual Analog Scale (VAS) for pain which consists of a 10cm horizontal line with no pain and worst imaginable pain at opposite ends. It has shown good test-retest reliability and sensitivity in patients with degenerative joint pain (Hawker et al, 2011). Subjects will be asked to record their average pain level over the previous week and the score will be calculated by measuring the distance on the line. The Western Ontario and McMaster Universities OA Index (WOMAC) and Timed Up and Go (TUG) will be secondary outcome measures. The WOMAC looks at 3 dimensions including pain, stiffness and physical function. It is designed to be used with knee OA and reliability, validity and responsiveness has been demonstrated (McConnell et al, 2001). The TUG is also a validated and reliable test of physical function in older people (Chandra et al, 2012). Outcome measures will be collected by the same physiotherapist at baseline and 6 weeks.

Subjects will attend an OA education session consisting of a presentation which complies with the NICE (2014) guidelines and aims to enhance the understanding and management of the condition. They will be provided with an OA knee information booklet from the Arthritis Research UK (2011). Subjects will then attend 6 weekly physiotherapy sessions and take part in an exercise group with each session lasting 45 minutes. The exercises that will be performed are shown in appendix 2.

The subjects in the taping group will be taped prior to starting the exercises, it will be worn for 24 hours and then be reapplied by the same physiotherapist each session. Subjects will be asked to shave removing the hair from the knee prior to tape application if required. A strip of 5cm Fixomull undertape will be placed beneath the rigid 3.8cm Leukotape P Zinc Oxide tape to protect the skin. Taping will be based on McConnell (1996) to provide a medial glide and tilt to the patella. Tape will also be applied to offload the infrapatellar fat pad. These taping techniques have also been used in similar studies (Chandra et al, 2012, Hinman et al, 2003, Hinman et al, 2003). Taping techniques will be piloted before the study to ensure a standardised method and screen the tape.

Sample size has been calculated as 21 subjects per group using a standard significance level of 0.05 and an acceptable power level of 80% as suggested by Hicks (2009). A change in pain of 1.75cm on the VAS has been recommended as the minimum clinically important difference (Bellamy et al, 1992) and standard deviation has been assumed at 2cm.

Data collected will be presented using boxplot graphs and will be tested for normal distribution. Depending on the results either the t test or the Mann-Whitney U test will be used to compare the data. Statistical calculations will be calculated using SPSS20 software and a 95% significance level will be used (Hicks, 2009).

Location of study and access arrangements:

The study will be carried out in the gym of the physiotherapy outpatient department of a Community Hospital where the researcher is currently a member of staff. Approval and written permission to carry out the project in the department will be sought from the head of physiotherapy and the manager of the Hospital. Local General Practitioners

refer patients to the physiotherapy department for assessment and treatment. Subjects that are referred with a diagnosis of knee OA and fit the criteria will be recruited following assessment. Subjects that agree to participate in the study will be provided with an information sheet and consent form before starting the project. An email will be sent internally to all physiotherapists in the department containing the information sheet, inclusion and exclusion criteria to help subject recruitment.

Resource implications:

The physiotherapy department runs a knee OA education session and patients are then encouraged to attend a 6 week exercise programme. As the researcher is involved in running these sessions as part of normal commitments, the project will be carried out alongside normal daily work. The researcher will complete data processing, statistical testing and the writing up in their own time. Gym equipment, questionnaires, photocopying facilities and patient information will be available in the outpatient physiotherapy department. The researcher will supply the Leukotape P Combi Pack which costs £12 and it is estimated that 3 packs will be needed.

Ethical considerations:

Ethical approval will be pursued from Cardiff University research review ethics committee and the specific community hospitals ethics board. Subjects will be invited to voluntary participate in the study and given an information sheet highlighting the purpose of the study and the procedures involved. The information sheet will be provided at least 48 hours before the study begins to allow enough time for the subjects to decide whether to complete and sign the consent form (see appendix 1). If subjects are unable to read the document then it will be read to them and subjects will be encouraged to ask any questions or express any concerns. This will mean that subjects will give their full informed consent to participate in the study and it has been described as the most important component of ethics in human studies (Portney and Watkins, 2013). It will be explained to subjects that they have the right to withdraw from the study at any point and they will not have to provide a reason.

To abide with the Data Protection Act (1998) subject's information and data will be recorded anonymous and confidential by using identification numbers. This will be kept on an electronic patient record system on a password protected computer in the physiotherapy department which has swipe card access. Risk assessments will be carried out according to the Management of Health and Safety at Work Regulations (1999) with regards to the researcher carrying out lone working and subjects using the gym equipment. Page et al (2011) suggest that there are practical elements to consider when using taping including minimising the risk of adverse effects on subject's skin condition. This will be done by screening subjects to check appropriateness for taping and using undertape. If subjects are identified to have skin irritation or concerns then taping will stop immediately. This is the only potential side effect to subjects as the study uses rehabilitation that is commonly used and fits with current practice guidelines.

Project Timetable:

Activity	Start Date	Completion Date
Literature Review	January 2016	March 2016
Proposal Development	March 2016	April 2016
Submit proposal to ethical committee.	May 2016	May 2016
Submit to Community Hospital ethics committee	June 2016	June 2016
Recruit subjects	August 2016	September 2016
Piloting method	September 2016	September 2016
Data collection	September 2016	January 2017
Analyse data	February 2016	March 2017
Write up dissertation	March 2017	June 2017
Final submission	June 2017	June 2017

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Exercise programme:

Subjects will vary frequency and repetitions individually according to ability level and severity of symptoms.

Exercises will include:

- Static bike
- Walking on treadmill
- Cross trainer
- Leg press weight machine
- Sit to stands
- Step ups
- Bridging
- Straight leg raise with or without ankle weight
- Knee extension with or without theraband
- Knee flexion with or without theraband
- Single leg stand
- Wobble board
- Hamstring curls with or without ankle weight
- Squats