CHAIN –Cycling Against Hip Pain

Report on Outcomes

Executive Summary

- Around a third of people aged over 45 years in the UK (8.75 million) have sought treatment for osteoarthritis, and 2.12 million for osteoarthritis of the hip.
- The CHAIN programme was conceived by Mr Robert Middleton, a consultant orthopaedic surgeon, and Tom Wainwright, a physiotherapist, as a way of implementing NICE guidelines for patients with hip osteoarthritis.
- The aim of the programme is to reduce pain and encourage mobility through a six week programme of education and static cycling sessions, and to equip participants with the confidence to self-manage the condition.
- CHAIN was developed in partnership with The Royal Bournemouth Hospital, Bournemouth and Christchurch General Practitioner Localities, Dorset Clinical Commissioning Group, BH Live, Active Dorset, Bournemouth Borough Council and Bournemouth University.
- £40,000 was provided by the Dorset Clinical Commissioning Group to set up, deliver and evaluate the intervention.

Participant Outcomes:

Participant outcomes improved. Across the cohort we found:

- significant improvement in function
- significant improvement in strength
- significant improvement in walking
- significant reduction in pain at rest and on weight-bearing
- significant increase in range of motion at the hip
- significant increase in wellbeing measured on the EQ5D Visual Analogue scale

- majority of patients report improved flexibility; reduction in pain, and need to take analgesics; activities of daily living easier; less disturbed sleep; feeling fitter and stronger.

Project Outcomes:

- **National recognition**
    - Finalist in UK Active Flame Award for Health Partnership of the Year Category.
- **Academic Recognition:**
    - Case study published in BMJ Case Reports Feb 2015.
    - Interim results published in 'Osteoarthritis and Cartilage' (highest impact osteoarthritis journal).
    - Paper describing participant involvement submitted to the journal 'Research Involvement and Engagement'.
    - Paper reporting findings submitted to the 'International Journal of Orthopaedic and Trauma Nursing'.
- **Presentations and posters:**
    - London Hip Meeting April 2014
    - Bristol Hip Meeting November 2014
    - OARSI conference (poster), published in 'Osteoarthritis and Cartilage', April 2015
    - Physiotherapy UK 2014 (poster), October 2014
- **Funding applications for future research:**
    - Research for Patient Benefit – £350,000 for a three year randomised controlled study comparing CHAIN with standard care (physiotherapy).
    - Innovation, Excellence and Strategic Development (IESD) funding – a 3 year project to deliver and evaluate CHAIN in West Dorset, Cornwall, South London and Shropshire.
- **Social Media and Communications**
    - Website, local radio interviews, coverage in local press

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1. Background

Around a third of people aged over 45 years in the UK (8.75 million) have sought treatment for osteoarthritis, and 2.12 million for osteoarthritis of the hip[1]. Over 17 million people are expected to be living with osteoarthritis by 2030[2]. Osteoarthritis led to the loss of 36 million working days in 1999-2000 at an estimated cost of £3.2 billion[3]. Hip osteoarthritis is associated with hip pain, stiffness, and dysfunction in activities of daily living and is the most common reason for a total hip replacement. In 2012, there were 76,448 primary hip replacements in England, Wales and Northern Ireland at a cost to the NHS of over £400 million[2]. Ninety-two per cent of hip replacement patients had a diagnosis of osteoarthritis[4].

A recent report by Arthritis Care[5] found that 70% of those with osteoarthritis experience some kind of constant pain even while taking pain medication. Pain has a direct impact on patients' quality of life with 82% finding daily activities difficult. Forty-two per cent of those of working age reported that osteoarthritis had an impact on their or their partner's working life. Only a third of people surveyed (32%) were offered advice or support to help them self-manage their pain. Of those offered advice, 77% found it useful.

Recently published National Institute for Health and Care Excellence guidance[6] for the care and management of osteoarthritis in adults recommends three core treatments; education and self-management, exercise (specifically local muscle strengthening and general aerobic fitness) and interventions to achieve weight loss where necessary. Before hip surgery can be considered, an individual should first be offered these core treatment options. This guidance is supported by a recent systematic review of guidelines for the management of osteoarthritis that recommends exercise and education as core treatments[7].

Regular physiotherapy services offered in the National Health Service encompass some of these core treatments. However, recent research has shown that despite improving hip pain in patients with osteoarthritis of the hip, physiotherapy (including education and advice, manual therapy and home exercise) was no more effective than placebo[8]. Furthermore, overall hip function did not improve, suggesting the dosage of exercise offered in this treatment was not optimal.

There is substantial evidence to support exercise in the treatment of osteoarthritis and research has indicated that exercise (in addition to patient education) could reduce the need for hip surgery by up to 44%[9]. A meta-analysis by Hernandez-Molina et al[10] found that exercise is an effective treatment for pain in osteoarthritis of the hip, particularly programmes with a strengthening element. Exercise has also been shown to improve pain and function in those awaiting hip surgery[11 12] and improve post-operative outcomes[13 14].

The CHAIN programme was conceived by Mr Robert Middleton, a consultant orthopaedic surgeon, and a physiotherapist, Tom Wainwright, as a way of implementing the NICE guidelines.[3] The aim was to reduce pain and encourage mobility, and equip participants with the confidence to self-manage the condition. The programme was developed in partnership with The Royal Bournemouth Hospital, Bournemouth and Christchurch General Practitioner Localities, Dorset Clinical Commissioning Group, BH Live, Active Dorset, Bournemouth Borough Council and Bournemouth University. Dorset Clinical Commissioning Group provided £40,000 to set up, deliver and evaluate the intervention.

Two CHAIN participants enjoying static cycling

2. Intervention

The intervention comprised a six weeks programme (see Appendix 1 for overview)**.** Groups had a maximum of 15 people and took place once a week for six weeks at Littledown and Pelhams Park Leisure Centre.

The programme consisted of a different 30 minute education session each week and a specially designed 30 minute graduated indoor stationary cycling exercise class. Difficulty and intensity of the exercise class was changed by altering the cadence (rate of pedalling) and the resistance of the static bicycle throughout the class. The education component, based on NICE guidelines, was facilitated by a qualified physiotherapist and was aimed at promoting the effective ongoing self-management of osteoarthritis of the hip. It included:

- Education and Advice
- Exercise
- Lifestyle and general health
- Community links and signposting to information where necessary
- Monitoring of symptoms
- Information on diet and supplements

The physiotherapist who had designed the education sessions delivered the education component to the first few groups of participants, and then trained two other physiotherapists to take this role. The cycling exercise class was facilitated by a gym instructor experienced in leading indoor cycling classes.

A home exercise programme including stretches and land-based exercise was developed with each participant. Cycling was encouraged but not mandatory. If participants did not have access to a bicycle, solutions were discussed such as using static bikes and community links (shops, gyms, leisure centres) to enable them access to cycling equipment. Participants were also given an exercise diary to complete outside of the programme to monitor their home exercise activity to act as an additional motivational tool and encourage adherence.

2.1 Evaluation of intervention

Participants were assessed before and after the six week programme. These assessments included:

- Hip Disability and Osteoarthritis Outcome Score (HOOS) function scale – assesses physical function on a scale of 0 – 100 (100 no symptoms, 0 extreme symptoms).

- Oxford Hip Score – assesses function and residual pain in patients. A score of 40+ suggests satisfactory function (scale of 0 – 48).
- EQ-5D-5L and EQ-5D VAS – patients' report of their general health.
- Sit-to-stand score - assesses lower-extremity strength and balance. Score consists of time taken to stand up and sit down five times as quickly as possible.
- Timed Up and Go (TUG) Test - assesses a person's mobility and walking. It comprises rising from a chair, walking 3m, turning, returning to the chair and sitting down again.
- Pain at rest and on weight bearing (scale 0 – 10).
- Range of Motion – assesses degree of flexibility in your hip sockets.
- Tolerance test using Watt Bike ((http://wattbike.com/uk/). The Watt Bike was also used to assess power output and pedalling technique, and results from the initial assessment were explained on a one-to-one basis at a later education session in order to improve power and technique.
- Participants were asked to name three goals they wished to achieve with the programme; the three most useful things about the programme; what they would change; and whether they would recommend the programme to others.

After the final assessment, participants were sent a report of their progress which included the changes in the above assessments, and output charts from the WATT bike from before and after the programme.

3. Participant Outcomes

The CHAIN programme ran from October 2013 to April 2015, and 119 patients were referred onto the programme. 54% of participants were female, and the mean age was 62, with ages ranging from 39 to 81. 78% of participants had a diagnosis of osteoarthritis, whilst 10% were yet to have a diagnosis. 25% of participants had a BMI lower than 25, 35% a BMI between 25.0 and 29.9 and 25% had a BMI of 30 and over.

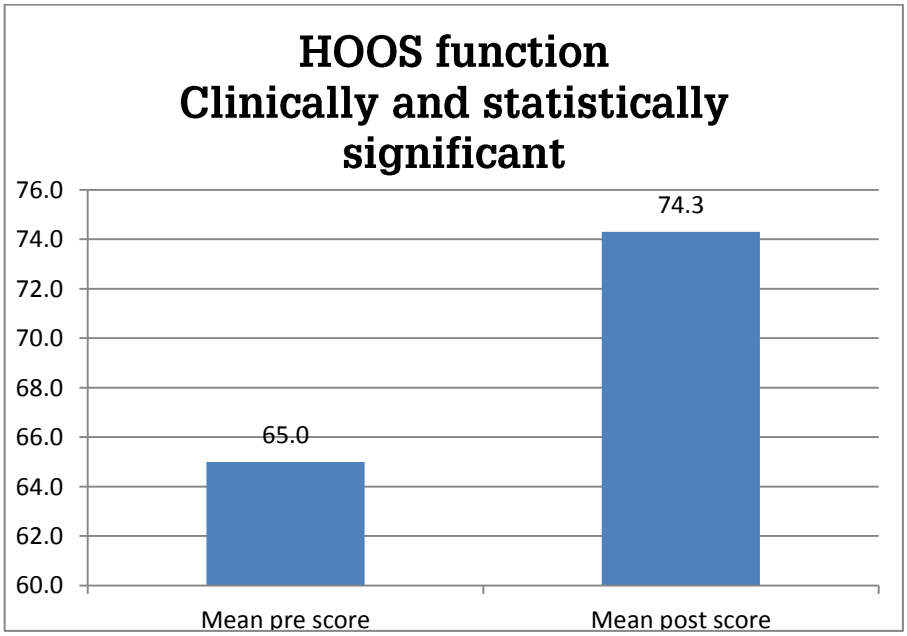
Participants came from 38 GP surgeries with St Albans, Winton and Southbourne each referring six or more patients.

Of the 119 participants who were enrolled on the CHAIN programme, 114 went on to start the intervention. 98 participants completed the intervention and 96 completed the final assessment and had their data analysed as part of the evaluation. Further details can be seen in Appendix 2.

3.1 Function

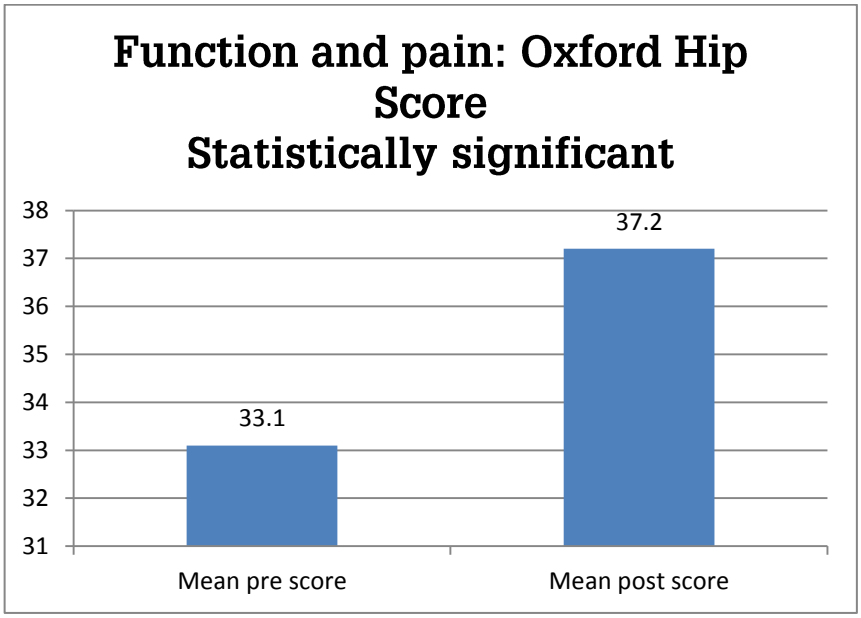
3.1.1 Hip Disability and Osteoarthritis Outcome Score (HOOS) function

The mean HOOS Function score improved from 65.0 to 74.3. This was statistically significant, $p \leq 0.001$. This change of 9.3 is larger than the minimum clinically significant difference found by Angst et al, 2001[15], and so is likely to be clinically significant.



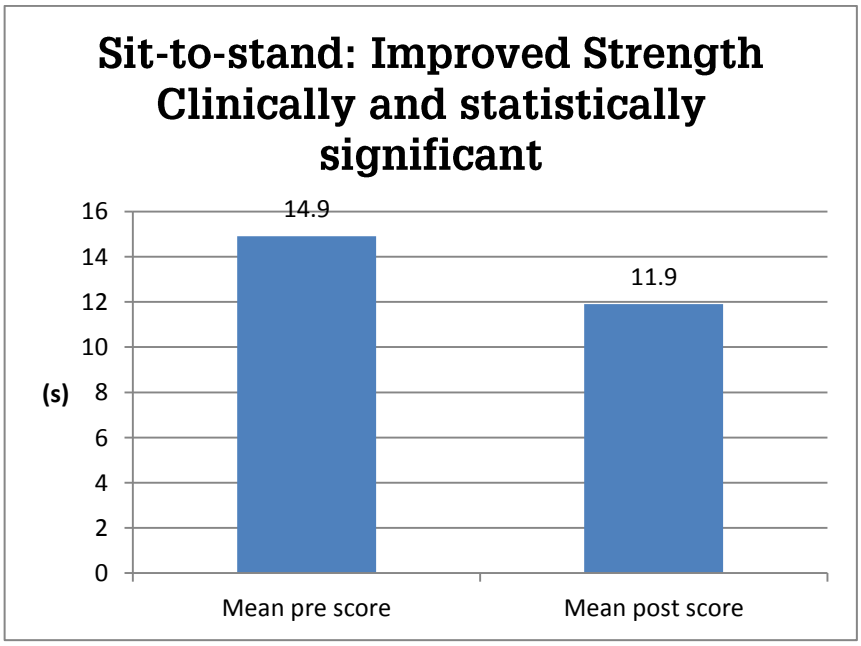
.1.2 Oxford Hip Score

The Oxford Hip Score improved from 33.1 to 37.2, a gain of 4.1. This was statistically significant, ($p \leq 0.001$). Beard et al[16] found a minimal important change of 8 points for the Oxford Hip Score, however this was for comparing scores before and after hip replacement and so is unlikely to be sensitive enough for the CHAIN programme.



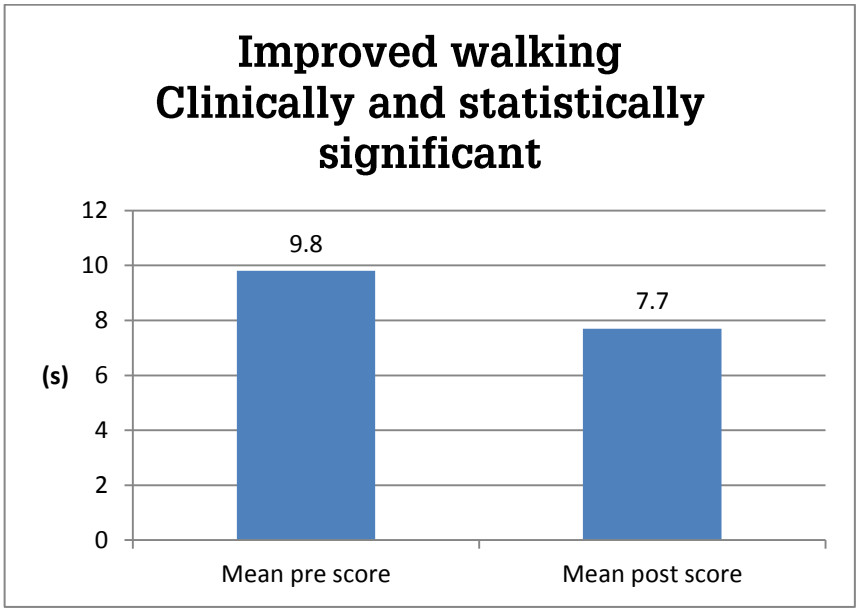
3.2 Strength

The Sit-to-Stand test mean score improved from 14.9s to 11.9s. This was statistically significant ($p \leq 0.001$). This change of 3s is larger than the minimum detectable change of 2.5s found in an elderly female population by Goldberg et al, 2012[17], and so is likely to be clinically significant.



3.3 Walking

The Timed Up and Go (TUG) test mean score improved from 9.8s to 7.7s. This was statistically significant (p≤0.001). Wright et al, 2011[18] found a minimum clinically important improvement of 0.8s – 1.4s for patients with hip osteoarthritis so the change of 2.1s is likely to be clinically significant.



3.4 Wellbeing

The mean EQ-5D-5L score improved from 0.696 to 0.756, a gain of 0.060.

The mean EQ-5D Visual Analogue Score (0-100) improved from 74.6 to 81.6, a gain of 7.0.

The changes for both scores were statistically significant (p≤0.001).

3.5 Pain (measured on a visual analogue scale 0 – 10)

At rest, pain scores lowered from 3.0 to 1.8. This change was statistically significant, p-0.006.

On weight bearing, pain scores lowered from 3.7 to 2.2. This change was statistically significant, p≤0.001.

3.6 Range of Motion (ROM)

Flexion increased from a mean of 93 to 100 degrees.

Extension increased from a mean of 23 to 31 degrees.

Both these changes were statistically significant (p≤0.001).

3.7 Qualitative Feedback

The majority of participants reported improved flexibility; a reduction in pain and the need to take analgesics; easier to carry out activities of daily living; less disturbed sleep; and feeling fitter and stronger.

They reported the following benefits:

- Being introduced to cycling and exercise as a lifestyle;
- Increased confidence in setting up bike and pedalling correctly;
- Social interaction with people in the same position was motivating and supportive;
- Learning about effects of exercise, nutrition and analgesics;
- Motivation to continue exercising;
- Realisation that you do not have to accept the pain and can exercise without pain increasing.

Suggested improvements included longer education sessions; more cycling sessions; daytime sessions; more guidance on bike set up and spinning technique; more on nutrition; advice on stretching and further exercises; and more comfortable saddles. Comments from participants were fed back to programme staff after each group had finished so that they could be taken into consideration for following groups. All participants said they would recommend the programme.

Feedback from participants after the programme:

> “I must say that doing this programme has dramatically reduced my hip pain”.
>
> “Knowledge gained from the programme is significant”.
>
> “I found the CHAIN programme very informative and it was great to meet others with hip problems”.
>
> “I knew I was fitter and had lost weight, but very pleased with the much improved flexibility of hip and pelvis”.
>
> “As a result of the course I did join the 37 mile Sky Ride through The New Forest two weeks ago and thoroughly enjoyed it”.

4. WATT Bike

Participants were asked to do a 12 minutes tolerance test on the WATT bike as part of their pre and post programme assessments. An example of the WATT bike output, pre and post the programme, is included at Appendix 3. The WATT bike showed great potential in assessing power and technique although more extensive testing was beyond the scope and funding of the evaluation. It was also great as a method of keeping all abilities interested in the cycling, particularly high functioning individuals, as it is used by some of the best cyclists in the world.

Trying out the static bikes on the CHAIN programme

5. National Recognition

The CHAIN programme was a finalist in the ukactive and Matrix Flame Awards 2014, a highly coveted accolade in the health and fitness sector. The awards recognise suppliers, operators, educational institute, health practitioners and corporate organisations who have demonstrated exceptional standards across their area of work.

A static cycling session on the CHAIN programme

6. Publications

6.1 Case Study[19]

A case study was published in in BMJ Case Reports in Feb 2015, on a 71-year old man with a complex range of co-morbidities who took part in the CHAIN programme. Following the intervention, significant improvements were seen in the HOOS function score, Oxford Hip Score, Sit-to-Stand test, Timed Up and Go (TUG) test, pain scores and hip flexion. He also lost 2.1kg.

The man reported "amazing difference" in improvement in strength and use of right leg, and in physiological welfare and fitness. Six weeks after the programme he was cycling around town for at least 15 minutes a day, and walking his dogs.

Many clinicians would have questioned the man's suitability for the programme due to the co-existing medical conditions. This case study shows that patients may be much more able than we think to achieve significant improvement with exercise.

The man said:

"The programme made me realise that exercise was the best way to improve my pain and the use of my leg. It has made such a difference to me. I can now turn over in bed at night without having pain. I am determined to keep up with the exercise. Sometimes I don't want to go out and walk the dogs, but once I am halfway through my walk I realise that I am walking more easily."

"I think it is important that you stick with the programme and the exercise. It is tough the first couple of sessions, but you need to see it through to get the benefits, and to acquire the knowledge and advice that will help. It is also really positive that it is done in a local leisure centre. I never realised how much support was on offer at these places, and the enthusiasm for exercise at the centre was really infectious."

6.2 Interim results[20]

Interim results were published as an abstract in 'Osteoarthritis and Cartilage' in April 2015. 'Osteoarthritis and Cartilage' is the highest impact osteoarthritis journal.

6.3 Patient Involvement paper

Participants from the first three courses were invited to attend an evening forum at Littledown to discuss the design of a randomised controlled trial, comparing the CHAIN programme with standard care, to be submitted to NIHR Research for Patient Benefit funding stream. Six people attended with all three courses represented. The forum was very positive about the programme, and suggested that it was extended to 8-10 weeks, with the final two weeks concentrating more on the cycling. As a result the programme was extended to 8 weeks in the funding application.

A paper titled 'More than just ticking a box … how patient and public involvement improved every aspect of the research design and funding application for a project to evaluate a cycling intervention for hip osteoarthritis' is being published in the journal 'Research Involvement and Engagement'.[21]

6.4 Report of final findings

A paper reporting the findings from the CHAIN programme has been submitted to the 'International Journal of Orthopaedic and Trauma Nursing'.

7. Presentations and Posters

7.1 Presentations

Presentations on the CHAIN programme and interim results were presented by Mr Robert Middleton at the Bristol Hip Meeting in April 2014 and the London Hip Meeting in November 2014.

7.2 Posters

7.2.1 Osteoarthritis Research Society International Conference, Seattle, May 2015

A poster entitled “To evaluate a cycling and education programme as a treatment intervention to improve functional outcome measures for patients with osteoarthritis of the hip” was accepted for the Osteoarthritis Research Society International (OARSI) Conference. Unfortunately the poster wasn’t presented at the conference due to illness.

7.2.2 Physiotherapy UK 2014 Conference, Birmingham, October 2014

A poster entitled “A service evaluation of a cycling and education programme for the treatment of hip osteoarthritis” was presented at the Physiotherapy UK conference in October 2014 (see Appendix 4).

8. Funding applications for future research and evaluation (not service provision)

8.1 NIHR Research for Patient Benefit (RfPB)

A funding application for £350,000 was submitted to RfPB in January 2015. The funding is for a randomised controlled trial to compare an eight-week cycling exercise and educational programme (an extended version of CHAIN) with usual physiotherapy care for the treatment of hip osteoarthritis for 158 participants. Participants' ability to complete activities of daily living, pain levels, quality of life, and psychosocial wellbeing will be compared along with cost-effectiveness.

The first submission was not successful, however reviews of the application were favourable and it is planned to resubmit.

More information on RfPB calls and competitions can be found at:
http://www.nihr.ac.uk/funding/RfPB_calls-and-competitions.htm

8.2 Innovation, Excellence and Strategic Development (IESD) funding

Active Dorset submitted an application to IESD in March 2015. The funding is to support a three year project to deliver and evaluate the CHAIN programme in four new regions (West Dorset, Cornwall, South London and Shropshire).

Applicants should hear by the end of the year whether they have received funding.

Further information on IESD funding can be found at:
https://www.gov.uk/government/publications/iesd-voluntary-sector-funding-for-health-and-care-projects

9. Social media and communications

The webpage below was created on the BH website, and updated as the study progressed.

http://www.bhlive.co.uk/news-and-media/latest-news/2013/09/24/study-to-reduce-hip-arthritis-pain-launches-in-bournemouth-and-christchurch/

Two press releases were circulated to the press, one before the start of the programme in autumn 2013, and one at the end of 2014. Coverage was achieved in local papers and magazines, and several participants signed up for the programme as a result of the coverage.

Tom Wainwright was interviewed on Hope Radio about the CHAIN programme on two occasions. On the first occasion at the end of 2013, he was accompanied by a participant who had just finished the first group and so was able to discuss her experience of taking part; on the second in April 2014 he discussed the very encouraging interim results.

10. Next Steps

10.1 Modelling of cost effectiveness

A model of cost effectiveness could be calculated in order to ensure that costs represent good value, and that resources are allocated appropriately.

10.2 Expansion

Pilot work could be done to explore how the CHAIN programme could be expanded to:

- further geographical locations within the UK and globally
- include different types of osteoarthritis such as knee
- use a wider range of providers

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