Physiotherapy for Hypermobility Trial (PHyT): The Intervention Package

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Agenda

10:30-11:15 Hypermobility & physiotherapy
11:15-11:45 **Practical:** diagnosis & assessment
11:45-12:30 Development of the physiotherapy package & guiding principles
LUNCH
1:15-2:15 The physiotherapy package
BREAK
2:30-3:00 **Practical:** posture & movement control
3:00-3:30 The feasibility RCT

Hypermobility & Physiotherapy (45 min)

Overview

- Definition, diagnosis, prevalence of JHS
- Impact and management of JHS
- Systematic review of exercise for joint hypermobility (Palmer et al 2013)
- UK-wide survey of physiotherapy practice (Palmer et al, in preparation)

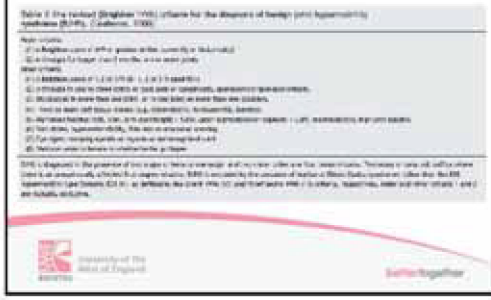
Joint Hypermobility Syndrome (JHS)

"...heritable disorder of the connective tissues characterised by hypermobility, often affecting multiple joints, and musculoskeletal pains in the absence of systemic inflammatory joint disease such as rheumatoid arthritis"

Ferrell et al (2004)

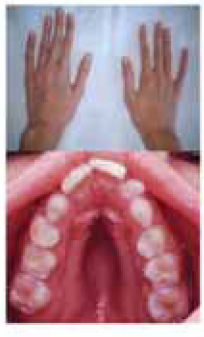
The Beighton Score

Revised Criteria (Brighton 1998)



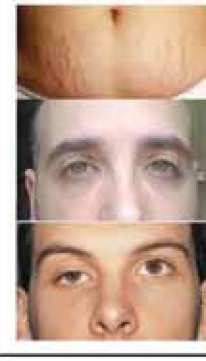
(5) Marfanoid habitus

- Tall
- Slim
- Arm span:height >1.03
- Upper segment:lower segment < 0.89



(5) Marfanoid habitus

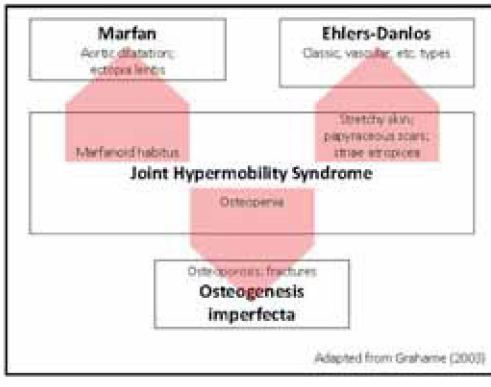
- Arachnodactily ('spider fingers')
- High arch palate



(6) Skin striae

(7) Eye signs

- Antimongoloid slant
- Drooping eyelids



Adapted from Grahame (2003)

Prevalence of JHS

- Difficult to estimate due to:
  - Different diagnostic criteria/cut-offs
  - Generalised Joint Laxity (GJL) versus JHS
- More common in children, females and some ethnic groups (e.g. Asian, African and Middle Eastern populations)
- Approx 5% women and 0.6% men have symptomatic JH (Simpson 2006)

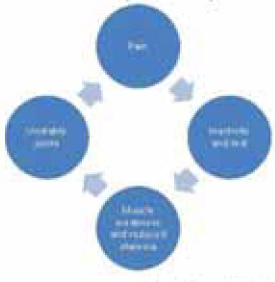
Prevalence of GJL

- GJL in 6,022 children (mean age 13.8 years) (Clinch et al 2011)
  - Beighton ≥ 4 = 19.2% (27.5% girls, 10.6% boys)
  - Beighton ≥ 6 = 4.2% (7.0% girls, 1.3% boys)

Pain Generation

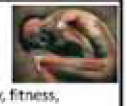
- Excessive movement → ↑ stress on joint surfaces, ligaments and other structures → joint pain (Simpson 2006)
- Pain → muscle inhibition → atrophy and reduced joint control (Keer and Simmonds 2011)
- Mechanoreceptor damage (Frontera 2003) → ↓ proprioception (Hall et al 1995, Fatoye et al 2009)
- Inability to acknowledge extreme joint range → ↑ stretching → ↑ instability

Vicious cycle of pain



Adapted from Mallard and Murray (2003)

Impact of JHS

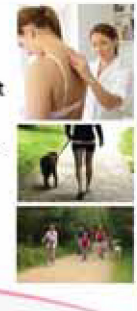


- Anecdotally, many issues (Grahame 2003): anxiety, fitness, gait, pain, proprioception, QoL, strength
- Impaired gait, pain, proprioception, QoL, ROM, strength identified in children (Fatoye et al 2009, 2011, 2012)
- Fatigue, anxiety and depression → ↓ social function (Bravo et al 2010)
- True impact of JHS in adults to be established. Ongoing work at UWE Bristol includes:
  - Qualitative focus groups with patients
  - Development of an outcome measure
  - PhD studentship investigating impairment, activity and participation in JHS v healthy controls
  - Systematic review of the impact of JHS

Management of JHS

- Acute management:
  - Taping, bracing or splinting (Keer and Simmonds 2011)
  - Non-steroidal anti-inflammatory drugs (Simpson 2006)
- Long term management:
  - Education (to increase knowledge and understanding) (Russek 1999, Russek 2000)
  - Therapeutic exercise (to enhance muscle strength and balance) (Keer et al 2006)

Therapeutic exercise



- Control of posture and movement is key – movement 'quality'
- Small number of research studies on the effectiveness of exercise
- Systematic review conducted to underpin research (Palmer et al 2013)

Systematic Review of Exercise for JHS

(Palmer et al 2013)

Aim: "To establish the effectiveness of therapeutic exercise for the management of JHS"

- Scoping identified small number of studies so did not prescribe exercise type or outcomes
- 9 online databases, snowballing, hand search
- Conducted in November 2012
- CASP quality appraisal – individual appraisal, group discussion, consensus

Studies included

- 1 randomised controlled trial in adults (Sahin et al 2008 – knee specific, n=70)
- 1 randomised comparative trial in children (Kemp et al 2010 – 'whole body', n=57)
- 2 cohort studies in adults (Barton and Bird 1996 – 'whole body', n=25; Ferrell et al 2004 – knee specific, n=18)

Findings

- Patients who exercised improved over time
- Large standardised effect size: 0.75 (pain at rest) to 1.72 (pain on movement) [NSAIDs for OA knee pain ~0.30]
- Generalised exercise no better than joint-specific exercise (Kemp et al 2010)
- No convincing evidence that knee exercises better than control (Sahin et al 2008) – no direct statistical comparison
- No clear cause-effect relationships demonstrated
- No adverse effects reported
- Methodological quality lacking (particularly statistical power and adequate control intervention)
- Further robust studies required

UK-Wide Physiotherapy Survey

(Palmer et al, in preparation)

- Aim: *"To identify 'usual' physiotherapy practice in terms of the diagnosis, management and assessment of adults with JHS across the UK"*
- Survey designed on basis of previous MSK surveys - 5 drafts
- Participant information; service description; diagnosis; management aims; management interventions; assessment
- n=201 paper copies to randomly selected NHS Trusts (England=168, Scotland=17, Wales=10, Northern Ireland=6)
- Online version developed (www.surveymonkey.com)
- Advertised on ICSP

Findings

- N=64 responses
- Assessment ≤60min (98%); Treatment ≤30min (95%); Treatment ≤6 (81%); Treatment ≤4 months (73%)
- Brighton criteria not used much (31%) - reliance on Beighton score, pain and family history
- Aims of treatment and interventions used seem well aligned – focus on education, exercise and self management
- Pain relief is not a main aim of treatment …but pain is most often assessed – obvious mismatch

Overall Summary

- Brighton criteria used for JHS diagnosis (main criteria are joint laxity + pain)
- JHS likely to have a significant impact
- Beliefs, behaviours and exercise likely to be key to effective management – reflected in current physiotherapy practice
- More evidence required for the effects of exercise

Practical: diagnosis & assessment
(30 min)

Development of the physiotherapy package & guiding principles
(45 min)

Overview

- What patients and clinicians say about physiotherapy for JHS
- Guiding principles
- Development of the physiotherapy package

What patients and clinicians say about physiotherapy for JHS

What patients and clinicians say about physiotherapy

- NIHR HTA funded study
- Focus groups with patients (x4, n=25, 3 men) and clinicians (x3, n=16, 3 men)
- Bath, Bournemouth, Bristol, Hertfordshire
- Explored perspectives on physiotherapy – exercise, education, advice, support……
- Aim was to use findings to help design intervention and supporting materials

Patient findings - negative ×

- Delay in being diagnosed – then lack of information
- Problems accessing treatment, waiting lists
- Physios lack understanding – JHS unpredictable, pain moves
- Unable to treat joints not specified on referral
- Only 6 treatments – frustrating, slow progress
- Different physios – conflicting information, no continuity
- Need help managing 'flare-ups'
- Focus on acute and not long-term problems
- Focus on one joint rather than whole body
- Curtain cubicles – lack of privacy

Patient findings - negative ×

- No time to address questions/concerns – process driven
- Patients don't know what 'normal' movement is
- Sessions very short
- Given 'random exercises' that made pain worse
- Didn't know what exercises were for
- Didn't know how to progress exercises
- Told to give up running/allotment – things they enjoyed
- Need more supervision for exercises
- Exercises didn't fit in with lifestyle (e.g. at school)
- Difficult to get motivated
- Made to feel guilty for lack of progress

Patient findings - positive ✓

- Private physio – able to see when want
- Range of techniques and exercises
- Variety of exercises
- 'Hands on' approach to demonstrate exercises
- Group exercises
- Pilates and 'core' strength rather than specific muscle exercises
- Keeping active during a 'flare-up'
- Hydrotherapy and sauna

Patient findings - positive ✓

- Quality of movement important, not repetitions
- Pacing
- 'If it hurts don't do it' – best advice
- One hour sessions
- Ergonomics advice – OT
- Specialist physiotherapy good
- Space out treatments – progress can be slow
- Info on footwear

Patients want…

- Understanding and reassurance
- Continuity of care
- Physios to understand JHS and impact on life
- Physios to understand the pain with JHS
- Physios to 'expect the unexpected'
- An 'all body approach'
- To be treated as an individual
- Physios to listen – people with JHS know a lot
- Outcome-focussed treatment rather than number of sessions

Patients want…

- Exercises that fit in with lifestyle
- Advice on fatigue
- Advice on how to cope emotionally
- To be 'hands-on' when demonstrating exercises
- A range of exercises to keep it interesting
- What exercises to do on a good or bad day
- To know what their 'bad habits' are
- Information about pacing
- To see a physio every 6 months/year
- Set realistic targets for you as an individual

Patients want…

- Information
- Advice on day to day activities
- What is the future?
- Be understanding
- Provide support and motivation
- Make feel at ease, it's not your fault, empower
- Tailor activities that are important to you
- Supervised exercise
- Reduce risk of 'flare-ups'

Clinician findings

Interestingly, very similar to patients…

- JHS patients are a 'challenge'
- Treat as individuals
- Whole body approach
- Advice, education, posture, self management
- Need to 'educate the masses'
- Psychological/mental health issues important
- Pacing
- Realistic goals
- 'Quick wins' important

Clinician findings

- Teaching self management
- Staying active – 'as active as they can be'
- Teach how to move
- Listen, collect information about whole body
- Symptom modification tests
- Difficult managing expectations
- Treatment time-consuming – difficult to fit into 6 sessions
- Do not fit acute model

Clinician findings

- Some patients reluctant to exercise due to fear of movement
- Exercise doesn't work for all – get demotivated if doesn't help
- Teach position, posture, neutral joint position
- Myofascial release can be useful
- Fatigue management important
- Heat and ice, dealing with a 'flare-up'
- Exercises that fit into daily life

Summary

- People with JHS and clinicians with a special interest in JHS agree on many things
- Some very clear messages to guide development of the intervention…
- … but need to be realistic about resources

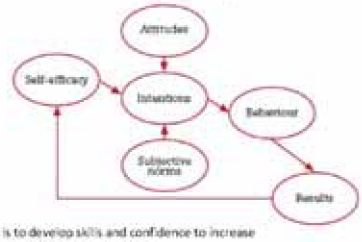
Guiding principles

Guiding principles

- Resource 'envelope' (1:1, x6 30min sessions, 4 months)
- Easy to implement across the UK
- Flexibility to tailor to individual patients
- Include:
  - Posture and movement quality
  - Exercise and physical activity (to include progression)
  - Goal setting and pacing
  - Dealing with set-backs
  - Dealing with psychosocial issues ("taking control")
  - Long-term management and staying active

Bandura's Self-Efficacy Theory

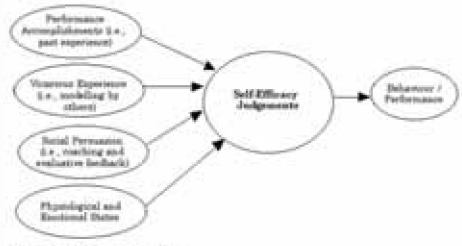
(Bandura 1977)



Aim is to develop skills and confidence to increase physical activity and self-manage

Bandura's Self-Efficacy Theory

(Bandura 1977)



Sources of Self-efficacy Information

Development of the physiotherapy package

Process of development

- Based on previous knee OA intervention, adapted from ESCAPE-knee pain (Hurley et al 2007)
- Made specific to JHS and added additional issues raised by focus groups
- Developed with patient research partners and 'clinical' members of the research team (clinical psychology, physiotherapy and rheumatology)
- Piloted with 8 patients (in two NHS Trusts) and evaluated (6 patients, 4 physiotherapists) - feedback generally very positive
- Minor amendments (e.g. A4 with more space for notes; removed session numbers to encourage flexibility; added some additional figures)

LUNCH
(45 min)

The physiotherapy package
(1 hour)

Assessment

- Do not intend to be prescriptive, but……
- Posture and quality of movement likely to be more useful than joint-specific or joint-by-joint assessment:
  - Sitting and standing posture
  - Reaching
  - Gait
  - Specific patient-reported function

Assessment

- Identify areas requiring specific posture and movement re-education
- Identify 'tight' muscle groups requiring lengthening
- Identify potentially unhelpful beliefs
- All can be individually addressed as part of the intervention

Advice Session

- Based on ARUK and HMSA booklets
- Should include:
  - What is hypermobility (ARUK, p5)
  - How is hypermobility diagnosed (ARUK, p10)
  - Drugs (ARUK, p11-13) – but advise to consult GP
  - Self-help and daily living (ARUK, p14)
- Also discuss anything else that patients specifically ask about…
- …but use information from the booklets rather than personal opinion or experience (as much as possible)

AIMS, BENEFITS OF PHYSICAL ACTIVITY, POSTURE, MOVEMENT QUALITY, PAIN RELIEF

DISCUSSION (~10min):

- Aims – outline aims of the programme and check understanding that the ultimate aim is to enhance self management
- Ideal if patients do 'homework' but important not to feel guilty if can't
- Outline potential benefits of exercise for JHS, difficulties and recommendations (* take home message is that any increase in physical activity is good)

AIMS, BENEFITS OF PHYSICAL ACTIVITY, POSTURE, MOVEMENT QUALITY, PAIN RELIEF

PRACTICAL (~20min):

- Demonstrate and discuss posture and movement quality (based on findings from assessment)
- Give some exercises (from booklet)
- Discuss pain relief
- Discuss homework and agree spacing of sessions

MEDICATION, SLEEP HYGIENE, GOAL SETTING

DISCUSSION (~15min):

- Review reflection from last session and discuss any issues from reading for this session (medication, sleep hygiene and setting goals)
- Discuss short and long-term goals – what they are, how they might go about achieving them
- Discuss cycle of change and where they are
- Introduce the activity action plan and diary

MEDICATION, SLEEP HYGIENE, GOAL SETTING

PRACTICAL (~15min):

- Review exercises and discuss/problem-solve how to integrate into daily activity
- Introduce new exercises/progression (if appropriate)
- Discuss homework, particularly planning and implementing physical activity action plan

PACING OF ACTIVITY

DISCUSSION (~15min):

- Review reflection from last session and discuss any issues from reading for this session (pacing of activity)
- Discuss pacing in some detail
- Discuss/problem-solve physical activity action plan and activity diary (from last session)

PACING OF ACTIVITY

PRACTICAL (~15min):

- Review exercises and discuss/problem-solve how to integrate into daily activity
- Introduce new exercises/progression (if appropriate)
- Discuss homework, particularly integrating pacing into day-to-day activity

DEALING WITH SET-BACKS

DISCUSSION (~15min):

- Review reflection from last session and discuss any issues from reading for this session (dealing with set-backs)
- Discuss dealing with set-backs in some detail
- Discuss/problem-solve physical activity action plan and activity diary and pacing (from previous sessions)

DEALING WITH SET-BACKS

PRACTICAL (~15min):

- Review exercises and discuss/problem-solve how to integrate into daily activity
- Introduce new exercises/progression (if appropriate)
- Discuss homework, particularly personal plan for dealing with set-backs

TAKING CONTROL

DISCUSSION (~15min):

- Review reflection from last session and discuss any issues from reading for this session (taking control)
- Discuss importance of discussing issues with friends, family, colleagues and GP who can refer to psychological therapies (if appropriate)
- Discuss/problem-solve physical activity action plan and activity diary, pacing and dealing with set-backs (from previous sessions)

TAKING CONTROL

PRACTICAL (~15min):

- Review exercises and discuss/problem-solve how to integrate into daily activity
- Introduce new exercises/progression (if appropriate)
- Discuss homework, particularly personal plan for taking control

LONG TERM MANAGEMENT, STAYING ACTIVE

DISCUSSION (~15min):

- Review reflection from last session and discuss any issues from reading for this session (long term management, staying active)
- Discuss plans for remaining active and dealing with relapses in physical activity
- Discuss/problem-solve physical activity action plan and activity diary, pacing, dealing with set-backs and taking control (from previous sessions)

LONG TERM MANAGEMENT, STAYING ACTIVE

PRACTICAL (~15min):

- Review exercises and discuss/problem-solve how to integrate into daily activity
- Introduce new exercises/progression (if appropriate)
- Discuss plans for remaining active in the long term
- Re-iterate main points from programme
- Wish them good luck…

BREAK
(15 min)

Practical: posture & movement control
(30 min)

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Thank You

[redacted]

The feasibility RCT (30 min)

Stage 3 – feasibility RCT

- Screening, assessment and consent process
- Advice session
- Randomisation after advice session (Principal Investigator on site) – online (quickest) or telephone
- Inform patient of allocation and book treatment if randomised to receive physiotherapy
- Chief Investigator to send questionnaires at 4 and 7 months
- Qualitative researcher to arrange interviews

Screening Referrals

- Principal Investigator on site screens referrals for likely JHS
- Send study information packs (record details of who is sent information – proforma)
- Reply slips returned to Department (send reminder after 2 weeks if no reply)
- Book for study assessment/advice session
- Send questionnaires (returned to Chief Investigator)

Exclusion Criteria

- Failure to meet the inclusion criteria;
- Other known musculoskeletal pathology causing pain, particularly multiple joint osteoarthritis and inflammatory musculoskeletal disease such as rheumatoid arthritis (fibromyalgia and Ehlers Danlos Syndrome (hypermobility type) are not to be used as exclusion criteria);
- Other serious pathology including malignancy;
- Conditions affecting ability to exercise e.g. uncontrolled cardiovascular disease;
- Recent physiotherapy for JHS (within the last year);
- Pre-existing significant psychological distress or psychiatric conditions;
- Referred for or currently undergoing psychological treatment, such as Cognitive Behavioural Therapy.

Assessment, Consent & Advice Session (1hr 20min)

- Explain study (SOP)
- Check inclusion/exclusion criteria (proforma)
- Take informed consent
- Conduct full physiotherapy assessment
- Deliver advice session. Issue ARUK and HMSA booklets
- Randomisation

Treatment

- Issue patient handbook
- Deliver 6 sessions over 4 months (from date of consent)
- Shea to send questionnaires at 4 and 7 months
- Qualitative researcher to arrange interviews with patients and physios

Training of additional therapists

- Each team (NBT & RNHRD) to train at least one other therapist to deliver the intervention
- Preferably should then deliver the intervention (but not absolutely necessary)
- Qualitative interviewer will interview trainers and trainees