Derek Tobin

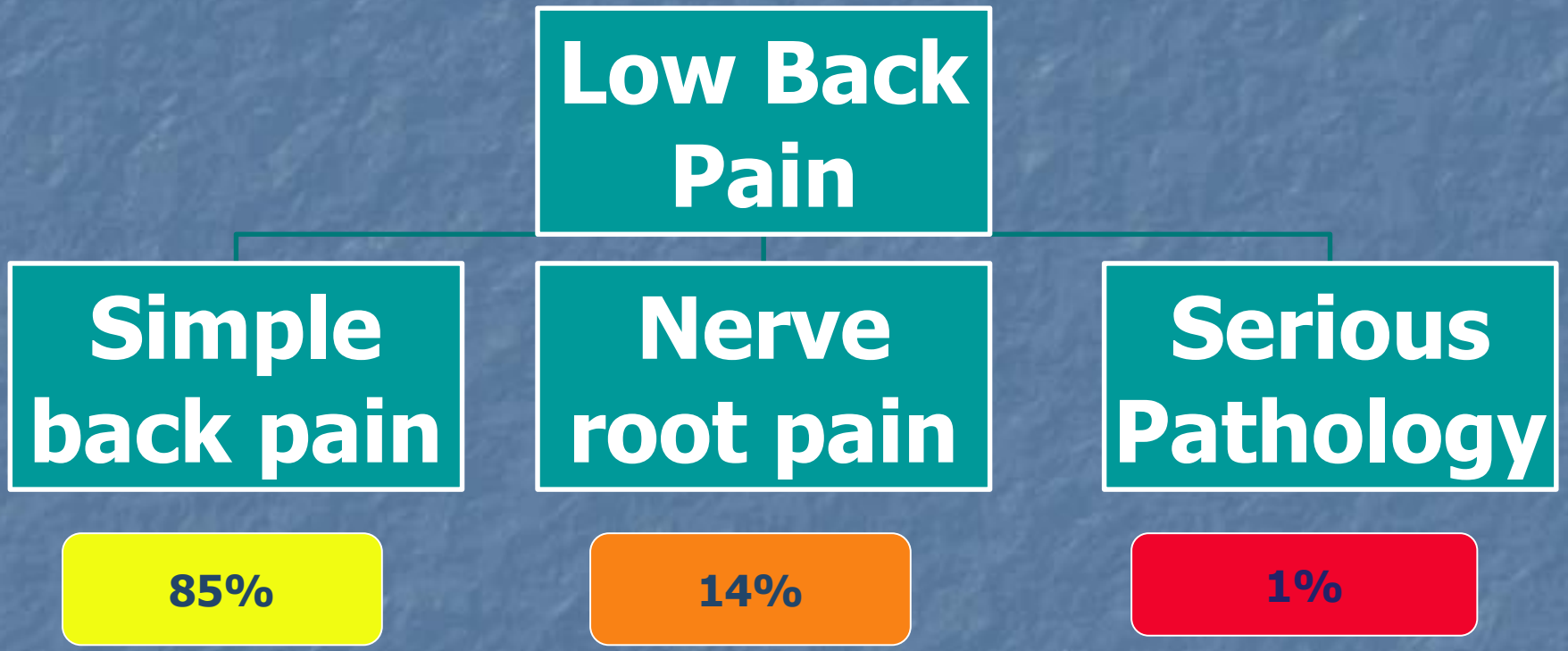
An Single-Blind, RCT Comparison of Discharge with Advice versus Usual Physiotherapy Care in Low Back Pain patients in GG&C classified as Low Risk with the Start-Back Tool.

September 2016

Aims

- Raise awareness of the Start Back Tool.
- Outline what was done in trial.
- Discuss results of trial for our demographic.
- Implications for future service provision.

The Challenge – Sub-classification of Low Back Pain



Sub-classification of the Simple Back Pain Group is the goal.

Sub-classification in Low Back Pain

- Sub-classification in LBP: Called the "Holy Grail" of LBP by the Cochrane Back Review Group.
- Prognostic assessment - highlighted in the European Guidelines for LBP in primary care. Heterogeneity stated as main research priority by International Forum on Primary Care Research on LBP in 1995 and remains so today.
- Targeted treatment may follow from these – better outcomes.
- The Start Back tool is the first instrument specifically developed and validated for use in primary care in the UK to purposely targets these identified research priorities.
- By defining these subgroups and providing a targeted treatment approach for each; the treatment of back pain now stands on the threshold of significant progress. Finally it may be possible to answer the fundamental yet elusive question of - who will do best with which treatment? (Enter the Start Back Tool – stage left)

The Start Back Tool

- 9 Item Scale
- Sub-classifies LBP to allow targeted treatment approach.
- Low, Medium & High Risk – in terms of ongoing disability due to LBP.

Thinking about the **last 2 weeks** tick your response to the following questions:

		Disagree	Agree
		0	1
1	My back pain has **spread down my leg(s)** at some time in the last 2 weeks	☐	☐
2	I have had pain in the **shoulder** or **neck** at some time in the last 2 weeks	☐	☐
3	I have only **walked short distances** because of my back pain	☐	☐
4	In the last 2 weeks, I have **dressed more slowly** than usual because of back pain	☐	☐
5	It's not really safe for a person with a condition like mine to be physically active	☐	☐
6	**Worrying thoughts** have been going through my mind a lot of the time	☐	☐
7	I feel that **my back pain is terrible** and **it's never going to get any better**	☐	☐
8	In general I have **not enjoyed** all the things I used to enjoy	☐	☐

9. Overall, how **bothersome** has your back pain been in the **last 2 weeks**?

Not at all	Slightly	Moderately	Very much	Extremely
☐	☐	☐	☐	☐
0	0	0	1	1

Total score (all 9): _____ Sub Score (Q5-9):_____

Items include:

Referred leg pain

Comorbid pain

Disability

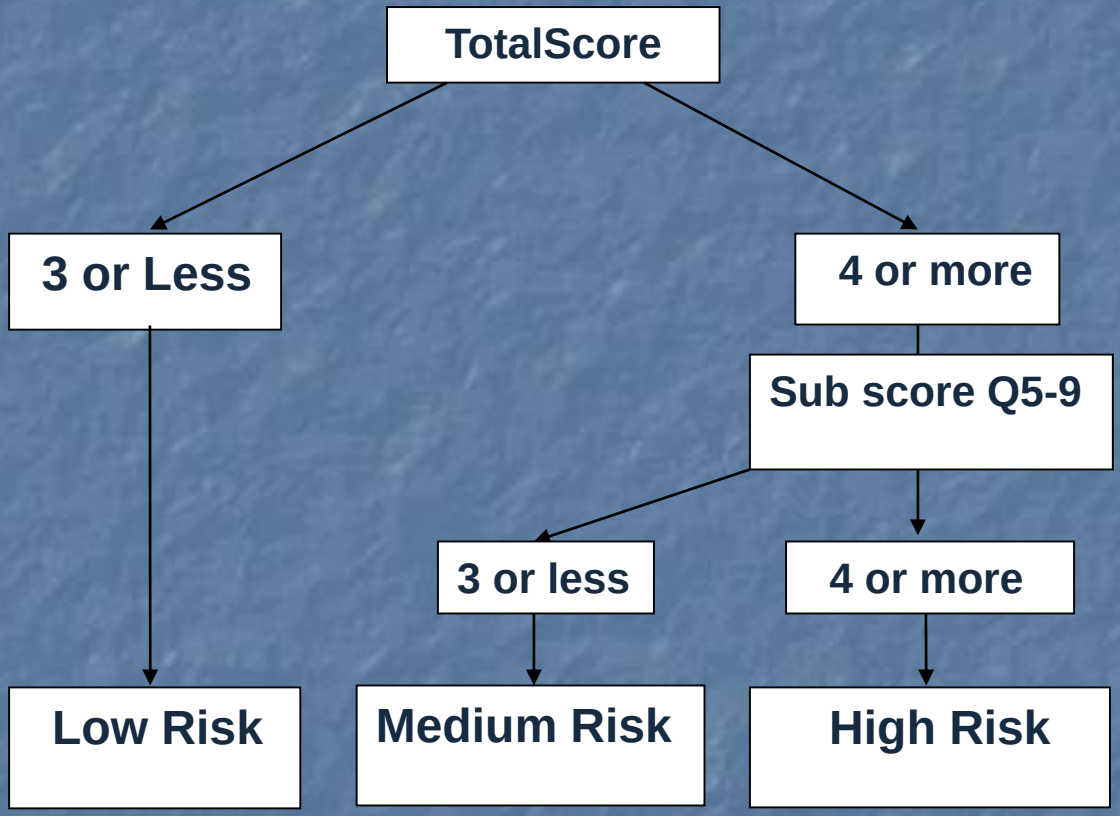
Fear avoidance

Anxiety

Catastrophising
Depression

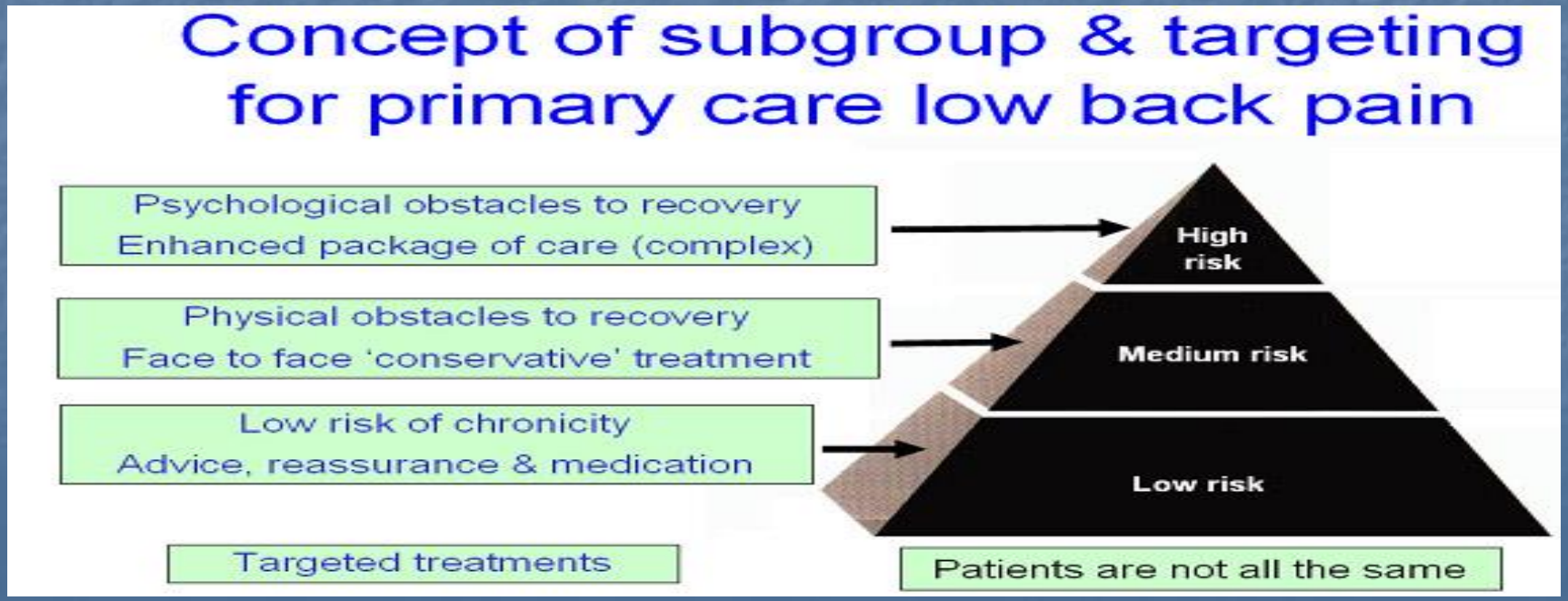
Overall impact

The STarT Back Tool Scoring System



Keele STarT Back / MSK Screening Tool

- Identify patient's level of risk for chronicity (using prognostic screening tool)
- One complexity scale that integrates key *modifiable* physical & psychosocial factors
- Seeks to improve assessment & treatment efficiency



Main Aims for Current Trial

Investigate the effects of two interventions (Usual Care or Discharge with Advice) in the Low Risk (as classified by the Start-Back Tool) population of Low Back Pain patients.

A single-blind Randomised Controlled Trial was developed to investigate the research question:

“How do patients self-referring to physiotherapy with LBP who are classified as “Low Risk” on the Start Back tool and Discharged with Advice, compare with those who receive Usual Care in terms of clinical outcomes, patient satisfaction and healthcare consumption?”

Objectives: Compare Usual Care versus Discharge with Advice in Low Risk Group using Scottish patients.

- Back-pain-related disability (RMDQ)
- Pain (4 measures NPRS)
- Global Measures of overall recovery (2 Measures).
- Patient Satisfaction (7 Measures)
- Health care consumption up to 1 year (5 Measures)

What was done?

- A single-blinded RCT was conducted at 9 physiotherapy sites in Glasgow's North East Quadrant.
- Ethical approval was obtained from NHS Research Ethics Committee (REC Approval No: 13/WM/0087 - IRAS Project ID - 99760) and Glasgow Caledonian University's School of Health & Life Science Ethics Committee.
- R&D Approval from GG&C NHS Board (R&D Approval No: GN12PY487).

- **Inclusion Criteria**

  Patients aged 18 years and over who self-refer for physiotherapy treatment for an episode of non-specific low back pain, with or without referred leg pain.

- **Exclusion Criteria**

  Patients with Red Flags for potential Serious Spinal Pathology.

  Patients with any of the following: not fluent in English, cognitively impaired, unable to read and write or who have functional illiteracy or blindness.

  Patients with a past medical history of previous spinal surgery.

Recruitment / Setting

MSK physiotherapy departments (7 Primary Care & 2 Acute sites) within the North East quadrant of Greater Glasgow & Clyde NHS.

MSK physiotherapists within the North East Quadrant of Greater Glasgow and Clyde NHS attended a 2 hour training session ran by the primary researcher. At this training they were given a presentation on the Start-Back Tool and taught the research protocol.

Recruitment: Procedure

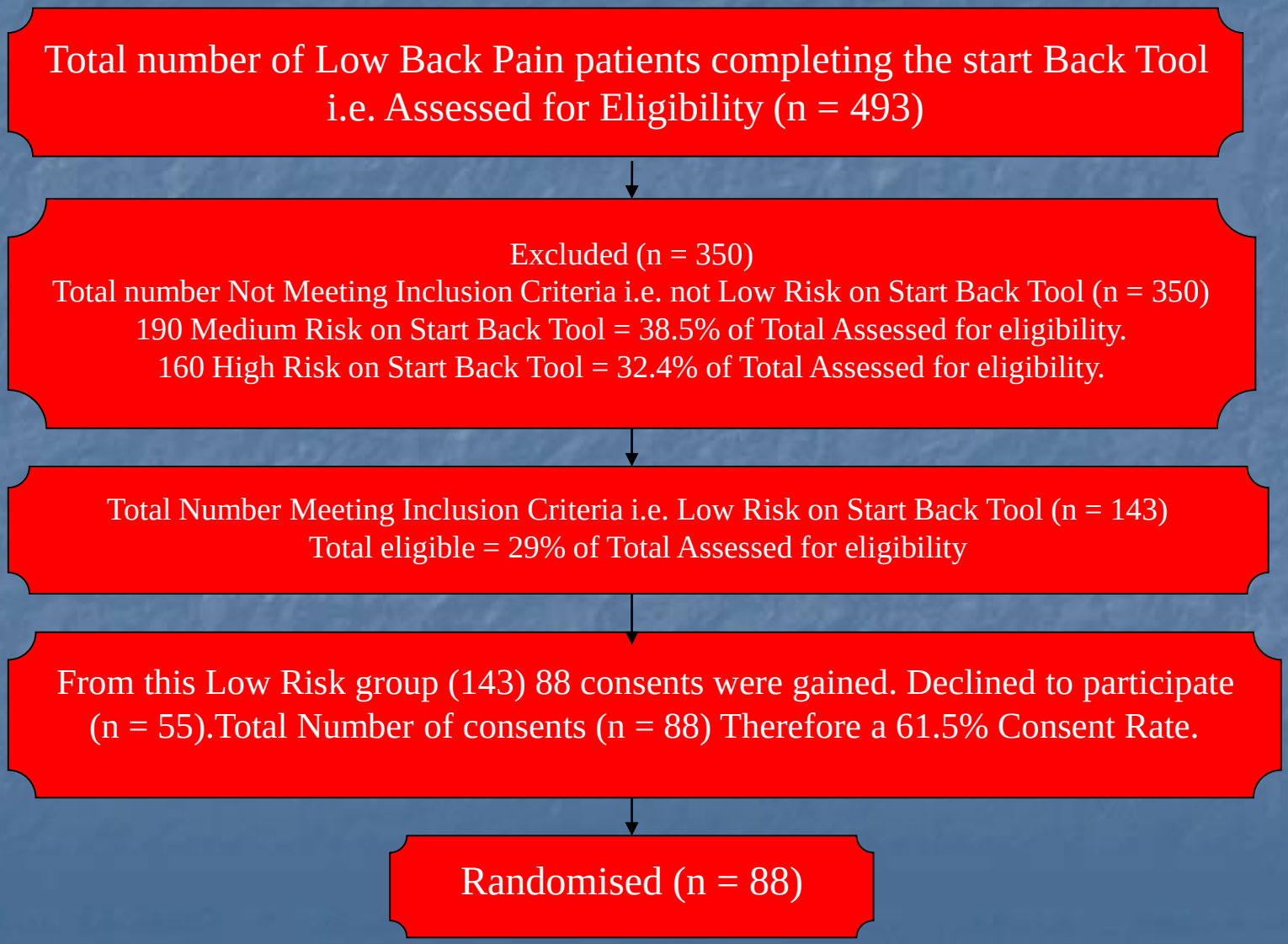
The trial lasted 22 months for both recruitment and follow-up. This comprised an initial 10 month recruitment period and since the trial includes a 1 year outcome, a further 12 months of subsequent data collection.

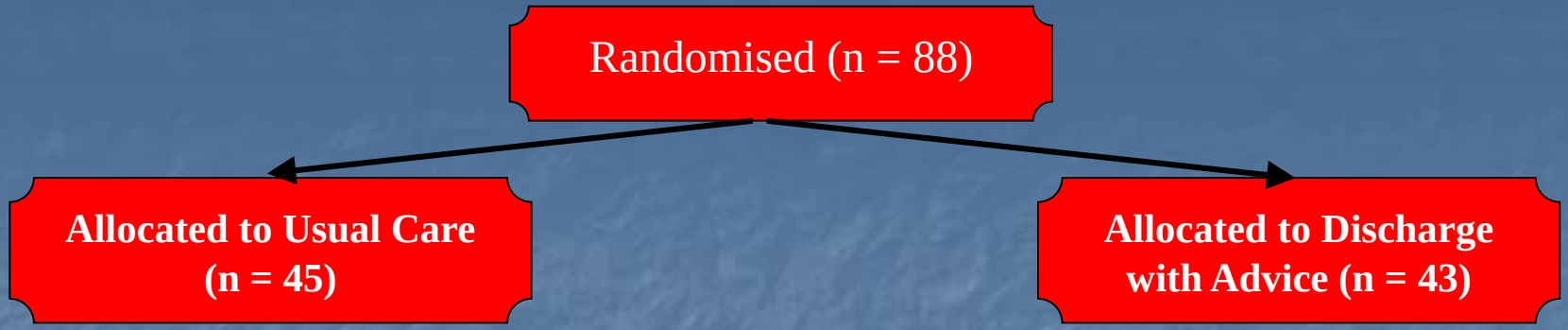
Patients were identified through their self-report of their primary condition as being LBP at the point of self-referral.

All consecutive male and female patients with LBP as a primary condition (with or without leg pain) accessing physiotherapy via self-referral and meeting the inclusion criteria were asked to complete The Start Back Tool as part of their initial triage.

- If they met the criteria for Low Risk – a score of 3 or less - they were informed by the physiotherapist about the trial and given a patient information pack.
- If having read pack they were willing – written consent was gained for entry to trial.
- Pt then randomised into one of two groups i.e. Usual Care or Discharge with advice.

Flow Diagram of the process employed through the different phases of the research including: recruitment, intervention allocation, follow-up and data analysis, as per the CONSORT 2010 Statement (Schulz *et al* 2010).





Usual Care

If participants were randomised into the "Usual Care" group they received whatever care the treating physiotherapist felt was appropriate irrespective of them being in a trial. The aim here is not to compare Discharge with Advice with any one modality but rather to gauge it against physiotherapy as a general approach.

Discharge with Advice

Participants received a 45 minute physiotherapy session comprising subjective and objective physical assessment, reassurance and advice. Key messages were reinforced by supplying "The Back Book" (RCGP 2002) patient information booklet before they were then discharged to self care.

Blinding Procedure

The treating physiotherapists could not be masked to randomisation because they were administering the active intervention, i.e. Discharge with Advice. Patients were made aware that they would be treated according to one of two already established primary care management models.

Further Treatment or Consultations

Irrespective of the treatment group they were randomised into, participants were not restricted from using health care elsewhere (either via the NHS or Private routes) or seeing their GP during the follow-up period regarding this condition.

The demographic data of all 88 patients who consented and were randomised was used as per intention to treat to establish the robustness of the randomisation process.

Baseline Demographic Data

Age: The sample population comprised an age range from 22 years to 87 years with a mean age of 50.8 years

Gender

Within this sample population there were 35 males (39.8 %) and 53 females (60.2%).

Results confirmed that the distribution by age and gender to each group was random.

SIMD

A check of the Postal Code distribution within both groups found no significant differences between these groups (P = 0.56) in terms of the Scottish Index of Multiple Deprivation (SIMD) scores.

Baseline Patient Characteristics

Tests were performed for baseline levels of Pain (4 items), RMDQ Scores, Start Back Scores and a Global Measure for overall "Bothersomeness" of the condition.

All baseline characteristics demonstrated random distributions in both groups and no significant differences were found between the Usual Care and the Discharge with Advice Groups for any item.

Between Group Differences in Outcome

The data were analysed to see if there were any significant between-group differences for any outcomes at 3, 6 and 12 months. This analysis showed that for 17 of the 19 outcomes studied (including the Primary Outcome Measure of Back-Pain-Related Disability) within the trial there were no between-group differences in outcomes at any time-point.

The 2 outcomes in which statistically significant between-group differences were found are outlined.

Primary Outcome Measure: Back-Pain-Related Disability RMDQ

The primary clinical outcome - effect of treatment on the level of back-pain-related disability - RMDQ. Jordan *et al* (2006) established that significant clinical improvement is present if RMDQ score is reduced by 30% from baseline.

3 months - 24% difference (Mean) not statistically significant and as below the 30% threshold did not reach Clinical Significance.

6 months -statistically significant difference (P = 0.01). This represented a 40% (Mean) reduction in score from baseline to 6 months and therefore reached clinical significance

1 year remained both statistically (P = 0.012) and clinically significant at a 39% reduction

This shows that the clinically significant improvements gained by the patients at the 6 months were maintained at 1 year.

Dichotomize outcome RMDQ. Poor outcome = 7 or over on the RMDQ post-intervention. 6 or under is regarded as a “Good Outcome” (Hill et al 2008).

Usual Care group; at 3 months 53%, 6 months 76% and at 1 year 71% = good outcome.

Discharge with Advice at 3 months 83%, 6 months 71% and at 1 year 76% of patients = good outcome.

The between-group difference - 3 month figure (53% UC versus 83% DWA) suggests that those in the DWA group achieve a good outcome quicker than those who attended for a full course of physiotherapy.

Reason?

Majority of those in the UC group were still attending physiotherapy at the 3 month time-point (mean time to discharge was 94 days).

Secondary Outcome Measures: Pain

•Both groups demonstrated **statistically significant reductions** in all pain measures.

•**Average Low Back Pain** (Last 2 weeks) at all time-points (3 months, 6 months and 1 year) No diff by group.

• **Least Painful LBP** (Last 2 weeks) at both 3 months and 6 months. No diff by group.

•**Present Pain** level at the 1 year time-point. No diff by group.

•**Average Leg Pain (Last 2 weeks)** at both 3 months and 6 months. No diff by group.

Secondary Outcome Measures: Global Change

Global Measures for Recovery

Bothersomeness

Back pain “bothersomeness" measured using a single validated question (Dunn et al, 2005). Rate on a 5 point ordinal scale how "Bothersome" their back pain had been in the last 2 weeks.

Both groups - statistically significant reduction in how “bothersome” back pain was at all time-points (3 months, 6 months and 1 year).

No between-group difference, same outcomes achieved irrespective of intervention group.

Patient Satisfaction

Information Received: No significant difference between groups.

Care Received: No significant difference between groups. At 3 months 74% of all Usual Care and 78% of all Discharge with Advice patients described themselves as either "Very Satisfied" or "Quite Satisfied."

Would you receive the same care again? No significant difference between groups "At 3 months 87% of all Usual Care and 88% of all Discharge with Advice patients stated they would either "Definitely" or "Probably" have the same care again.

Overall Results of Care: No significant difference by group. Average 7/10 on NRS both groups.

Expectation for Back Pain Relief: No significant difference between groups at any time-point for this item.

Would you recommend care received to friends and family? No significant difference between groups. 79% of all Usual Care and 66% of all Discharge with Advice patients stated they were either "Definitely" or "Probably" recommend this care to friends or family.

Secondary Outcome Measures: Healthcare Consumption.

- Low levels of ongoing **GP attendance** and no between-group difference - 80% of Usual Care and 82% of Discharge with Advice patients had not been back to their GP on any occasion for their back condition since attending physiotherapy
- **No GP Home visits** – at 1 year outcome in any patient in any group.
- 1 Year time-point 90% of Usual Care and 94% of Discharge with Advice patients had not seen their **Practice Nurse** on any occasion for their back condition since attending physiotherapy. No between-group difference.
- **Sick Certification –** only one patient in each group had any sick certificates related to their back pain. No between-group difference.
- Very little **Further Self Referral**: 95% of patients in the Usual Care and 82% of patients in the Discharge with Advice made no attempts to self refer for further treatment for this condition. No between-group difference.

Outcomes which demonstrated a between-group difference.

• **Patient Satisfaction Measure**: Patients were asked to rate on a 5 point ordinal scale - how satisfied they would be if they had to live the rest of their lives with the pain as they were experiencing it right now?

•No significant difference in patient satisfaction between both groups at either the 3 month or the 6 month time-point. By 1 year however, the difference was significant (P = 0.04) with those in the Discharge with Advice group showing statistically significantly higher satisfaction for this question.

Global Measure: Change in LBP

This global measure asked the patient to rate on a 6 point ordinal scale how they think their back pain has changed over time as relates to improvement or worsening.

Significant difference in patient-perceived change between both groups for this item at the 3 month time-point (P = 0.041) but not at 6 months (P = 0.292) nor at 1 year (P = 0.810). The **Discharge with Advice Group** demonstrated a statistically significantly greater **Global Reduction in low back pain** (How has it changed?) at 3 months compared to **Usual Care Group.**

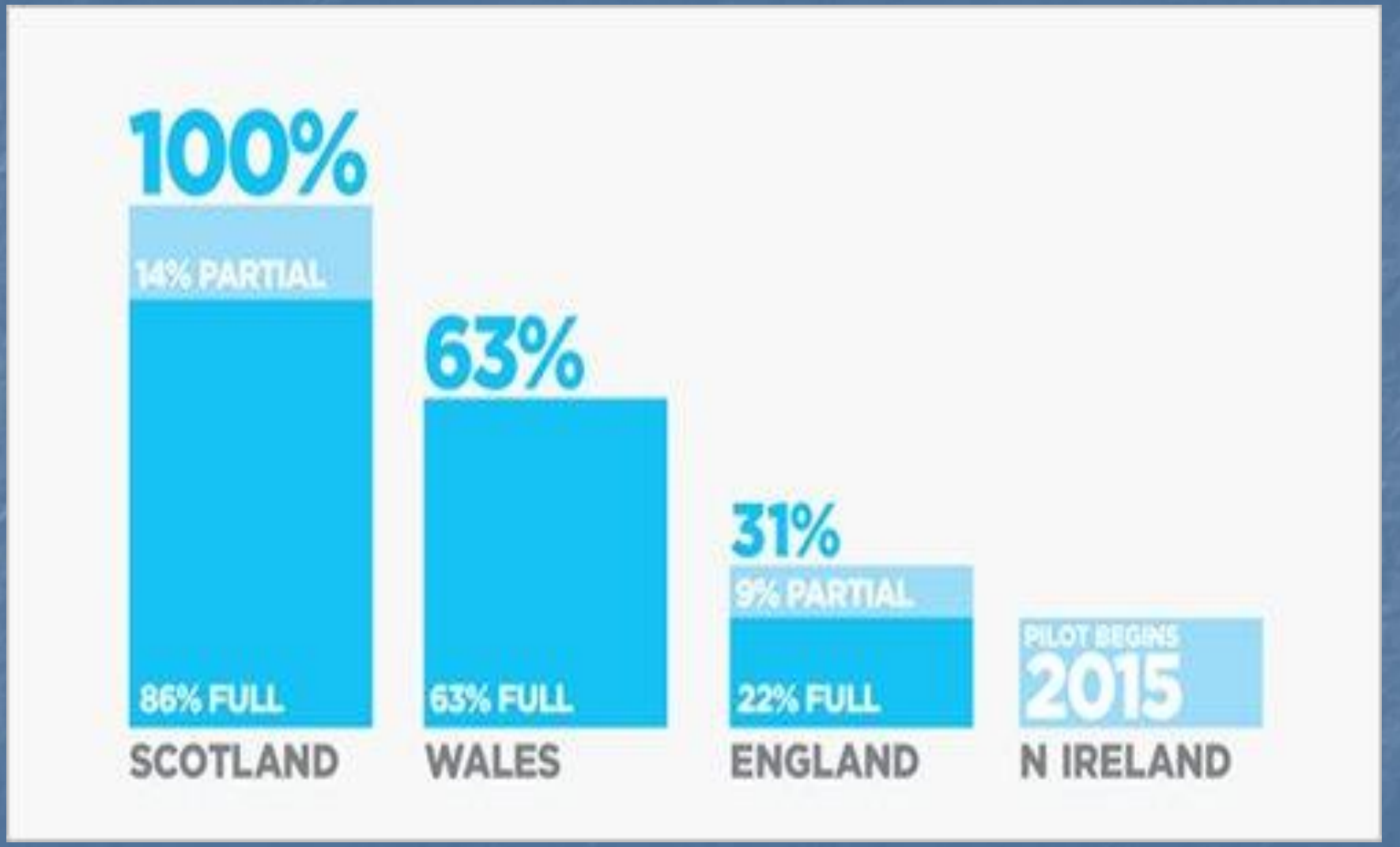
Self Referral versus GP Referral

Age and gender profiles are the same, but self-referral group has significant differences in terms of their presenting condition and its severity, the duration of their symptoms is less and they're absent from work in lower proportions and absent for only half the mean time of those referred by GPs.

Self-referral patients also completed their treatment at physiotherapy in greater proportions than GP-based referrals (9).

National work has suggested that those who self-refer are more proactive, autonomous and compliant (10). The population studied within this trial may therefore be more autonomous in their health-seeking behaviour and this may prove to be an important characteristic for outcomes, although further research is needed to investigate this theory.

UK Self Referral Profile 2015 (CSP Frontline 2015).



Challenges

- Getting GPs in Scotland to use tool.
- GP decision making for referral to physiotherapy is currently inconsistent. The start back tool may help to provide a more systematic approach by reassuring GPs that important modifiable risk factors have not been missed and patients should fare well with self care.
- Low Risk group might represent as many as 56% of all back pain consultations with the family doctor. With such a prevalence, the adoption of this model within GP practice in Scotland (even for the Low Risk recommendations alone) could have a significant impact upon resources whilst still fostering equally favourable outcomes.
- Whilst this would reduce the burden on physiotherapy services in respect to the Low Risk patients, it must be remembered that the adoption of the start back approach (with targeted treatment for Medium and High risk patients) could also improve primary care for such LBP patients and subsequently reduce demands on secondary care services for further investigations and management.

Challenges - Getting Physios to use the tool.

Low Back Pain at least 25% of all patients receiving outpatient physiotherapy have a chief complaint of Low Back Pain. Although common condition the outcomes of physiotherapy care for patients with LBP are variable and sub-optimal, with many patients failing to experience significant reductions in pain and disability.

Physiotherapists may be reticent to change practice. (H. Frost 2004).

- **Usual Care Group: Number of Physiotherapy Appointments**
- Usual Care group received a mean number of 4.26 review appointments (range = 1-13, Standard Deviation 3.588). Each review = 30 minutes. Therefore - Usual Care group received a mean of 2 hours and 8 minutes extra care per patient than the Discharge with Advice group.

- 1 year (Trakcare) = total of 20, 408 back pain patients per year. If 29% of these (as per the current trial) = Low Risk this equals 5, 918. If we consider that each of these is currently receiving an average of 4.26 return appointments this equals 25, 212 return appointments each of which is of 30 minute duration. This is 12, 606 hours of physiotherapy treatment per year which may be saved or better used to reduce waiting lists if we adopt a stratified management approach.

- This Usual Care group also had a mean of 1.21 Failed to Attends (Range 0-5, Standard Deviation 1.618).

- The mean duration of treatment for Usual Care was 94.5 days (i.e. between initial assessment and final attendance/discharge (Range 14-243 days, Standard Deviation of 55.07). This 94.5 day figure roughly equates to the three month time-point at which it has been noted that no patients in the Usual Care group considered themselves as "completely recovered".

Usual Care in Low Risk – Wasted Resources?

- National trials in Scotland - LBP is the reason for presenting to physiotherapy in 30% of all cases of true self-referral and in 33% of all cases of GP-suggested self referral (9).

- If we apply the results from this trial (i.e. 29% of those presenting with LBP are Low Risk) then between 8.7-9.6% (average 9.2%) of all MSK physiotherapy referrals (i.e. total figures not just LBP) could be managed by the discharge with advice intervention outlined herein. The converse would be to consider that in those 9.2% of all MSK physiotherapy contacts, patients receive 4.25 reviews (over 2 hours of physiotherapy) which yield no improvement in clinical, patient satisfaction or healthcare-use outcomes.

- This equates to a cost of £217 for each of those Low Risk patients currently attending physiotherapy and receiving 4.25 reviews. Outcomes in the Low Risk DWA group were non-inferior despite having an average of 4.25 less physiotherapy sessions.

- This is in keeping with the theory that a substantial proportion of physiotherapy referrals based on clinical judgment alone might be unnecessary and that many Low Risk patients are receiving unnecessary treatments in current practice. This has significant resource implications for those managing such services and the current trial supports the notion that a stratified management approach could provide value for money.

Key Findings

- This research has answered the call from other research (Frist *et al* 2011) to investigate whether physiotherapy can effectively alter the already favourable prognosis of patients in the Low Risk category enough to warrant the additional costs of care. The results of this trial suggest that it does not.

- In line with previous Start Back Research the current study's use of stratified care did not adversely affect pain or disability outcomes for patients in the low risk group and indeed the low risk patients fared well with self management.

- This research supports the clinical effectiveness and cost-effectiveness of a stratified management approach in this Low Risk population of back pain patients.

Key Findings

- Low Risk - good prognosis and therefore should not be routinely referred for physiotherapy (Fritz et al 2011) since such referral is unlikely to be cost effective (Hay et al 2012). The current trial's findings are certainly congruent with this position.
- If they are GP-referred or self-refer – DWA is a good option.

Recommendations

- The latest NICE (2016) recommends the use of the Start Back Tool as follows: "*Consider using risk stratification (for example, the STarT Back risk assessment tool) at first point of contact with a healthcare professional for each new episode of non-specific low back pain with or without sciatica to inform shared decision-making about stratified management.*"
- *Based on many trials showing consistent results.*

Future

- Implement the Start-Back Approach for GGC MSK – already in use in East, South & Clyde Quadrants should be in all quads by end September 2016.

- Potential for better management of not just Low but also Medium and High Risk categories.

Questions?