



K E E L E
UNIVERSITY

Primary Care Musculoskeletal Research Centre

What have we learned from high quality randomized controlled trials?

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Background

- Value of RCTs
- Evidence based practice
 - hierarchy of evidence

one large RCT

=

60-80% systematic review

Study design

- Issues in designing RCTs
- Study aims
- Ask an important question
- Phases of clinical trials
 - I, II, III and IV
 - efficacy, effectiveness, pragmatic studies

“Is this treatment helpful on average for a wide range of patients?”

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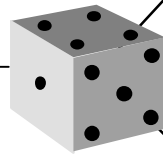
*Assignment
Randomization*

Intervention

Group 1 → Outcome

Group 2 → Outcome

No intervention; placebo; best available



Large simple megatrials

- Recruiting patients from many centres - simple design
- Collect 10 times *less* data and recruit 10 times *more* patients
- Recruit in uncertainty (collective)

Study population

- Eligibility criteria
- Case definition
 - non-specific musculoskeletal pain
 - recruit participants who qualify
 - large numbers enrolled in fastest possible time
- Generalizability

Interventions

- Development of intervention
- Treatment definition
 - multiplicity of approaches ‘black box’
 - therapist part of the intervention
 - real world environment
- Comparator

Analysis

- Intention-to-treat
- Collection of data and statistical analysis performed blind to treatment group
- Data Monitoring and Ethics Committee

A PRAGMATIC APPROACH: an example in primary care

The effectiveness of manual therapy or pulsed short-wave diathermy in addition to exercise and advice for neck disorders; a pragmatic randomized controlled trial in physiotherapy clinics.

Dziedzic et al, Arthritis Rheum 2005;53:214-222



Aim of the study

Primary objective

to compare at 6 months the effect of adding:

1. Manual Therapy
2. PSWD

to Advice and Exercise alone

Secondary objectives

- to compare clinical outcomes at 6 weeks
- to compare cost consequences at 6 months

Eligibility

- **Inclusion**

- 18 years and over
- Clinical diagnosis neck pain and/or stiffness (including unilateral arm pain)
- Referred from primary care
- No treatment previous 6 months

- **Exclusion**

- ‘Red flags’
- Serious pathology, inflammatory arthritides, progressive neurological signs, contraindication to treatment, injury awaiting claim, pregnancy

Study intervention

All patients received :

- home exercise sheet (Physio Tools)
- one to one advice on managing their neck problem
- an information leaflet (**arc**) to take home

Study intervention

Interventions:

- no additional treatment to advice & exercise
- manual therapy; defined as hands-on mobilisation/ manipulations
- PSWD

maximum of 8 twenty-minute treatments in 6 weeks

Outcome measures

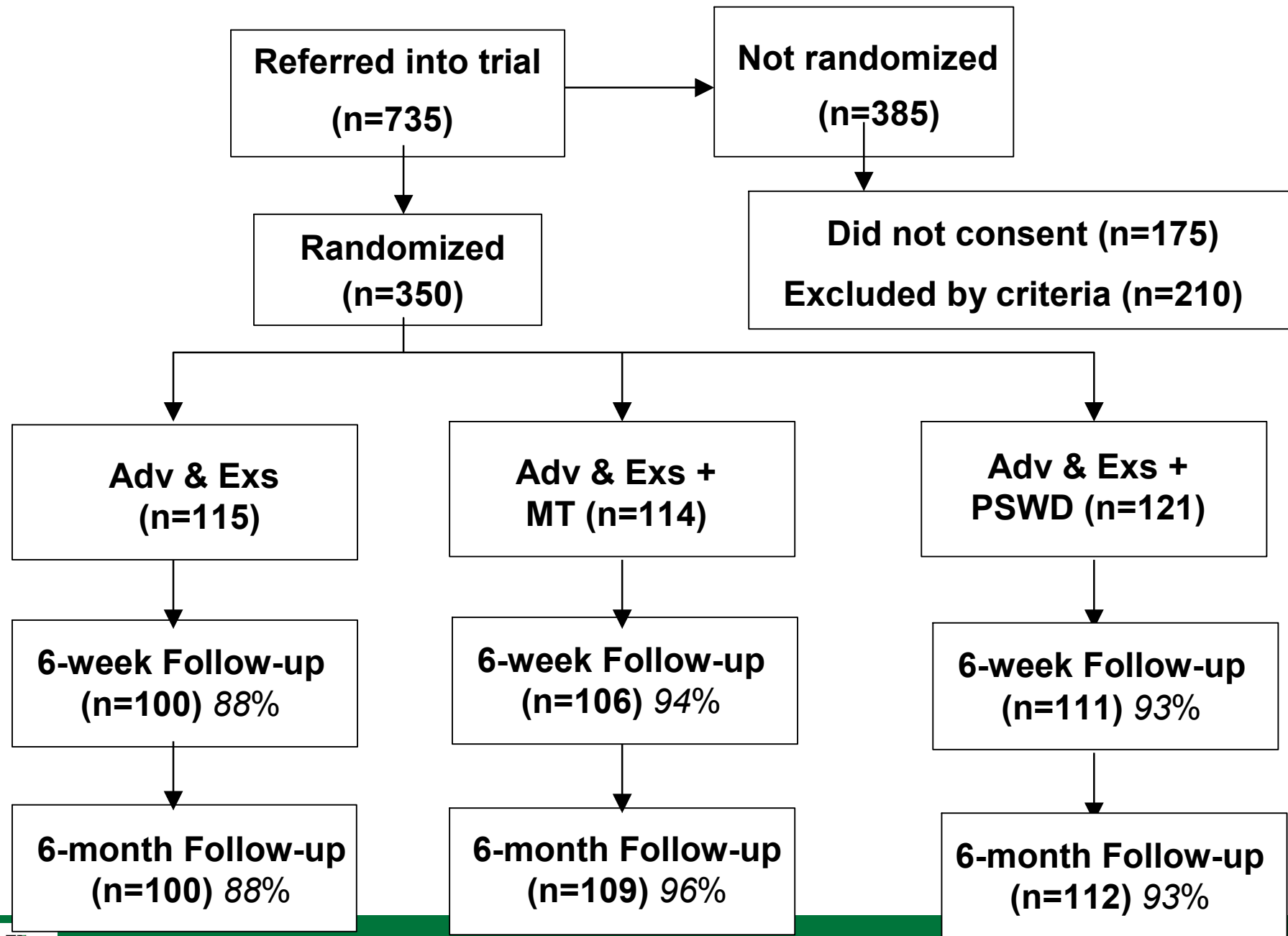
- Primary outcome measure
 - Northwick Park Neck Pain Questionnaire
 - pain disability measure (Leak et al, 1994)
 - 9 Questions 100-point scale
 - Baseline, six weeks, six months

Secondary outcome measures

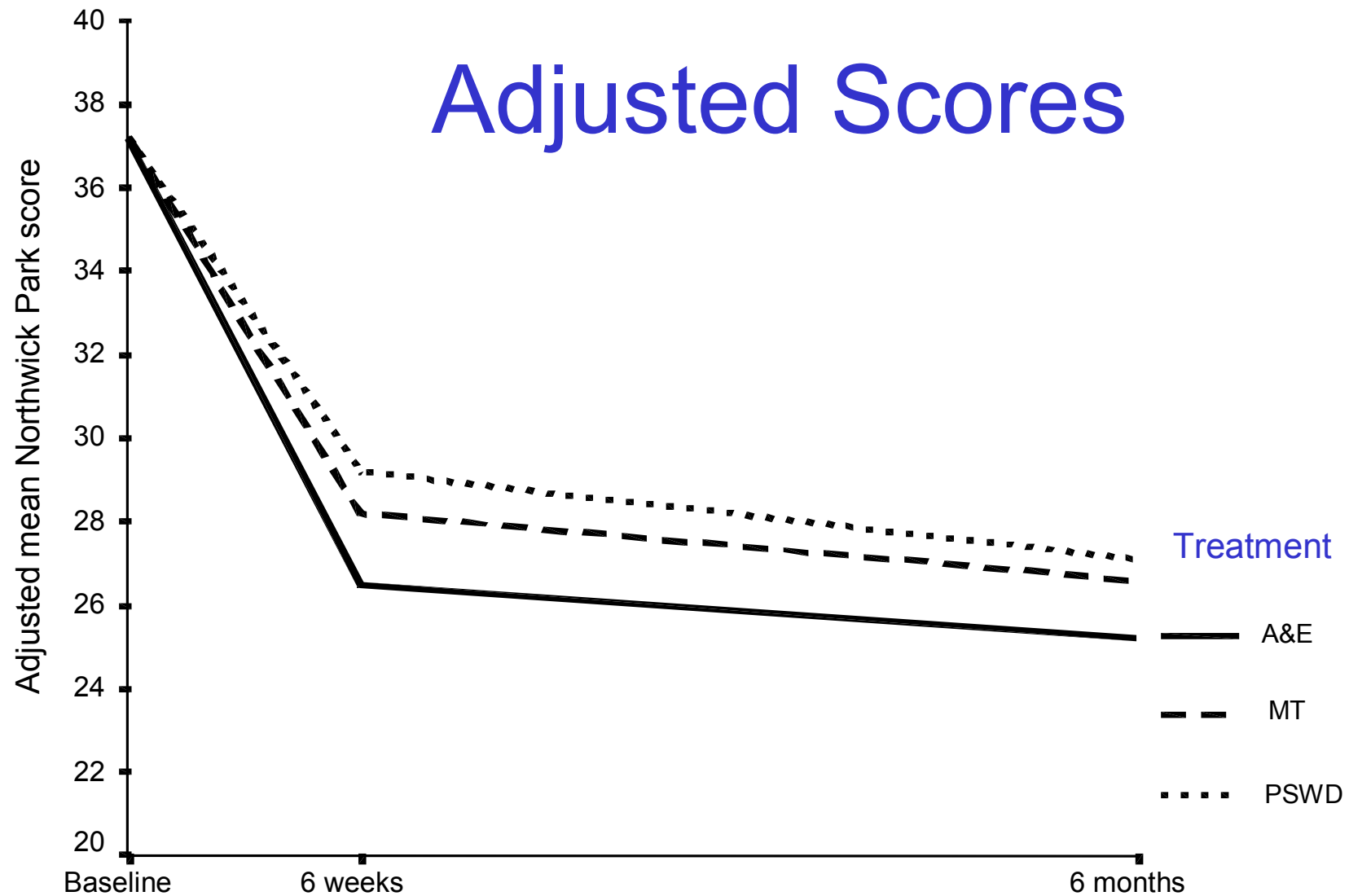
1. Patient's global assessment of improvement
2. Average pain severity over the past 3 days
3. Severity rating of patient-nominated main problem over the past 3 days
4. Employment days lost since last assessment
5. Side effects in the first 6 weeks
6. Co-interventions
7. Patient-related costs
8. Quality of life: Euroqol EQ-5D and SF-12
9. Patient satisfaction

Results

- 735 patients were screened
- Target recruitment 350 in 22 months
- Mean age 51 years
- 63% Female



Adjusted Scores



Summary of results

- No differences in primary outcome at 6 m
- Patient satisfaction was in favour of MT
- Treatment course was shorter in the advice and exercise alone group
- 350 patients randomized, 15 centres, 70 physiotherapists
 - 92% f/u at 6 months
 - 98% received their allocated treatment

Conclusion

The addition of manual therapy or PSWD to exercise and advice alone does not provide any better clinical improvement in the physiotherapy treatment of non-specific neck disorders

“In an attempt to find out what really works, British physiotherapists conducted a rigorous clinical trial..... These findings are important. They show that the best options for neck pain are fairly simple and inexpensive.”

Professor Ernst The Guardian 9th August 2005.

Acknowledgements



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