KEELE 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

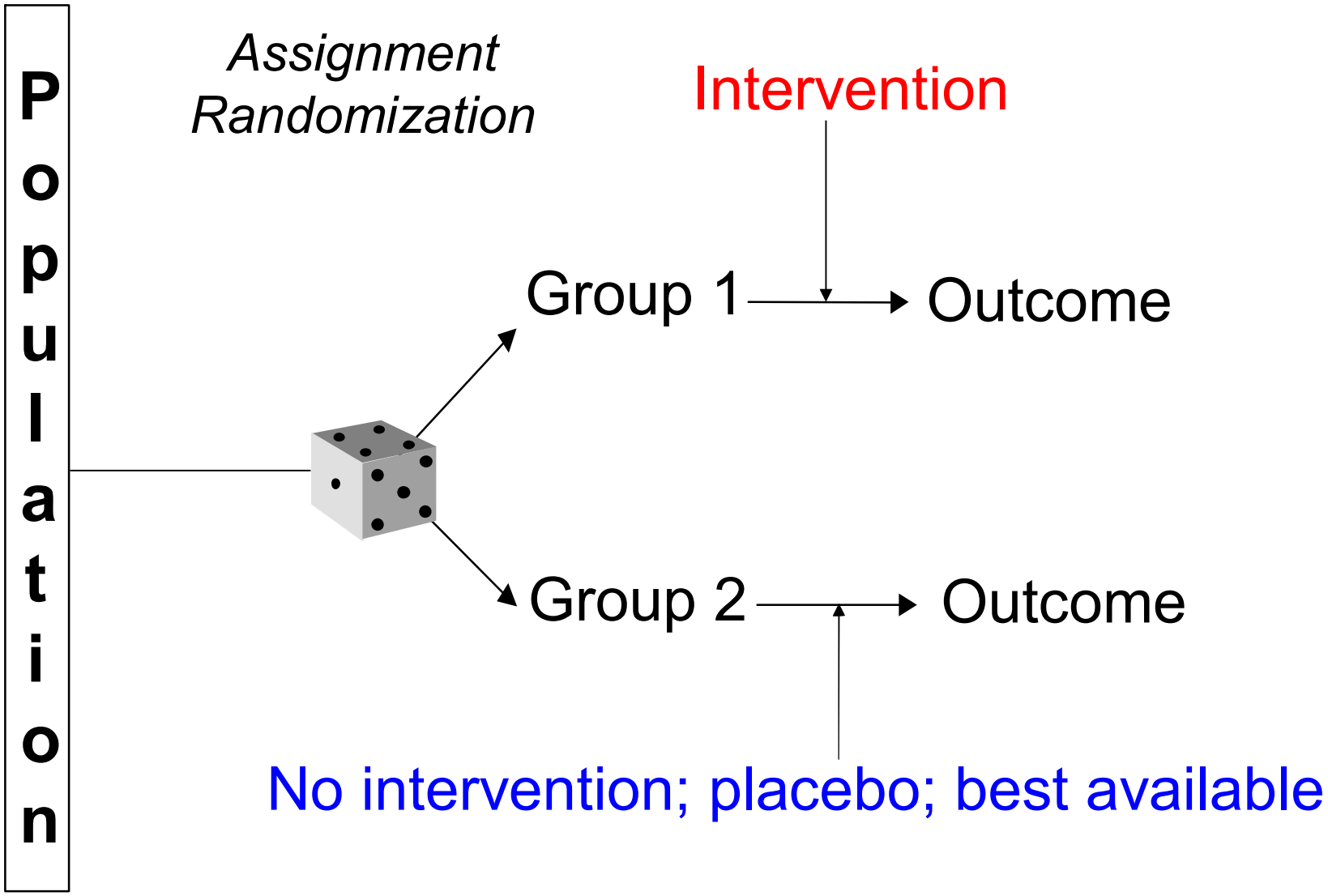
=

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?"


Population
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

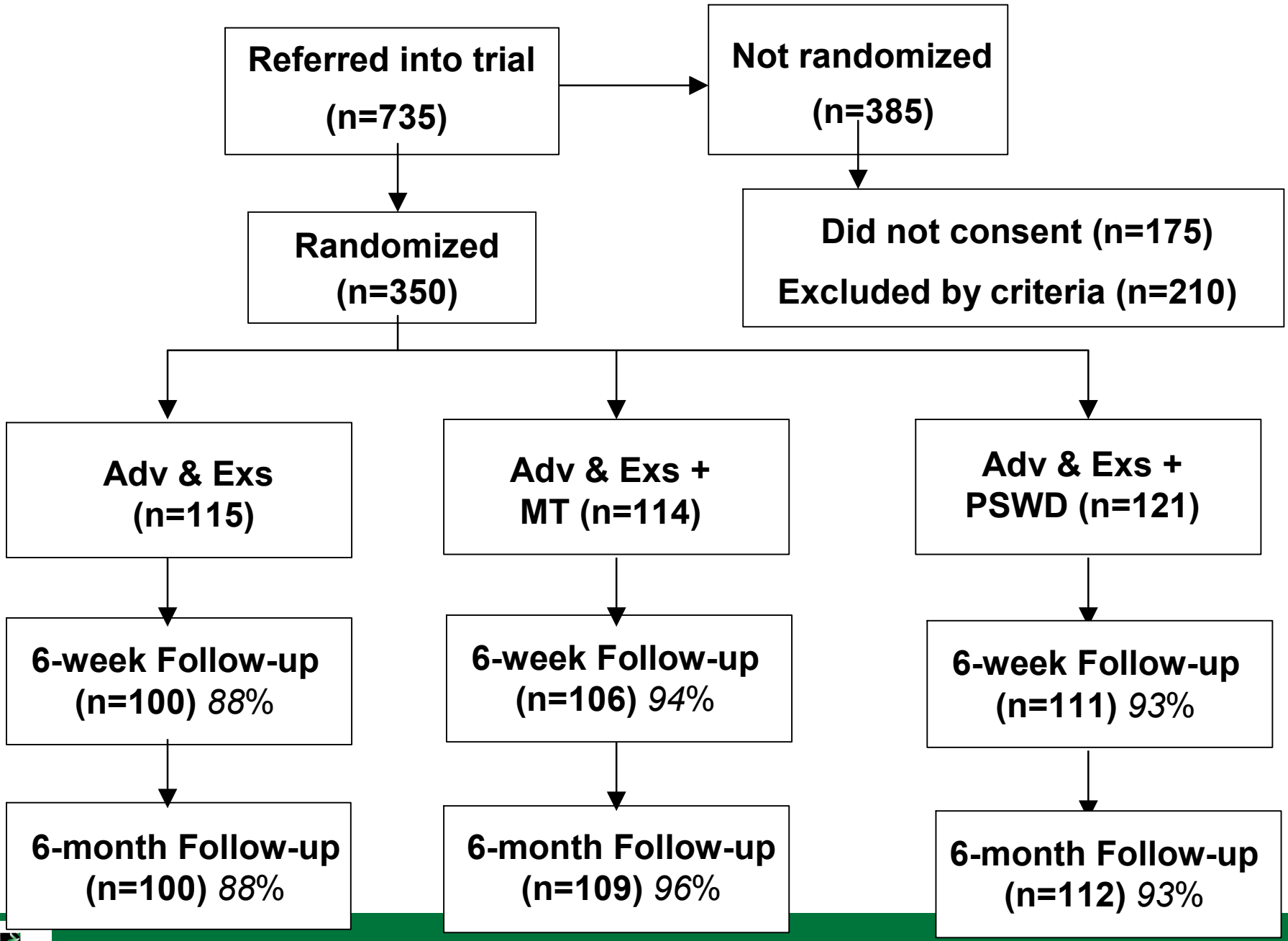
- Primary outcome measure
  - Northwick Park Neck Pain Questionnaire
    - pain disability measure (Leak et al, 1994)
    - 9 Questions 100-point scale
  - Baseline, six weeks, six months

Secondary outcome measures

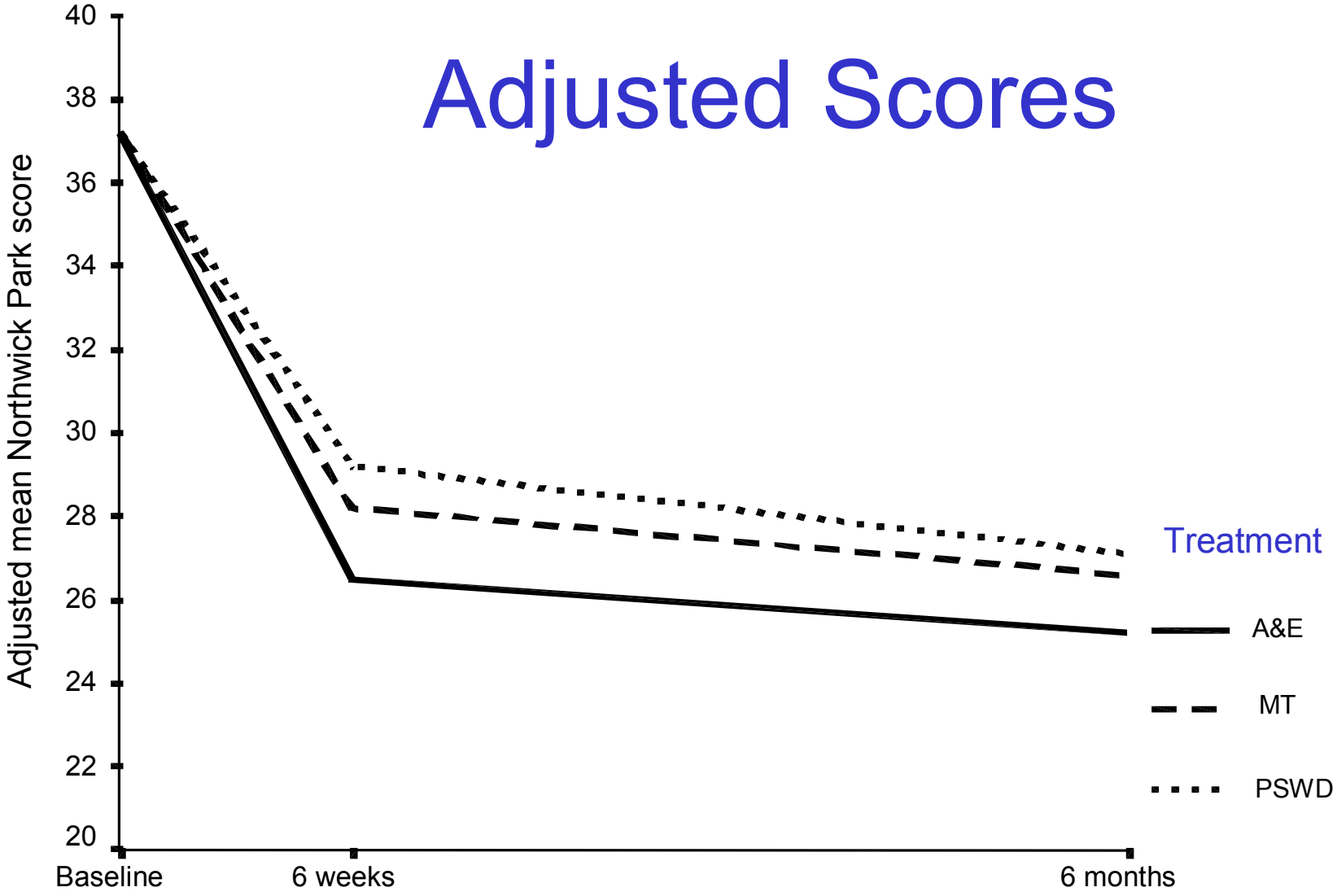
1. Patient's global assessment of improvement
2. Average pain severity over the past 3 days
3. Severity rating of patient-nominated main problem over the past 3 days
4. Employment days lost since last assessment
5. Side effects in the first 6 weeks
6. Co-interventions
7. Patient-related costs
8. Quality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


Referred into trial
(n=735)
Not randomized
(n=385)
Randomized
(n=350)
Did not consent (n=175)
Excluded by criteria (n=210)
Adv & Exs
(n=115)
Adv & Exs +
MT (n=114)
Adv & Exs +
PSWD (n=121)
6-week Follow-up
(n=100) 88%
6-week Follow-up
(n=106) 94%
6-week Follow-up
(n=111) 93%
6-month Follow-up
(n=100) 88%
6-month Follow-up
(n=109) 96%
6-month Follow-up
(n=112) 93%

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.**

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