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Acupuncture, Counselling and Usual care for Depression (ACUDep trial):

findings for effectiveness and cost-effectiveness

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Research questions:

- Is acupuncture clinically effective / cost-effective for depression?
- Is counselling clinically effective / cost effective for depression?
- How do acupuncture and counselling compare? (adjusting for time and attention)

Methods

Design:

Three arm pragmatic RCT, using unequal (2:2:1) allocation ratio:

- 1. Acupuncture plus usual care (40%) – 12 sessions – TCM style.
- 2. Counselling plus usual care (40%) – 12 sessions - humanistic approach.
- 3. Usual care alone (20%)

Primary outcome / endpoint:

- Patient Health Questionnaire (PHQ-9) at 3 months

Data collection:

Postal questionnaires - sent at baseline, 3, 6, 9, and 12 months.

- SMS pre-notification / reminders
- Postal reminders x 2
- Telephone follow-up for non-response

SMS mood score (1 to 9) – first 15 weeks

In-depth interviews (sub sample)

Outcome measures:

- PHQ9
- SF36 Bodily Pain subscale
- BDI-II
- EQ5D

Analysis

- intention-to-treat
- analysis of covariance at 3 months
- 'area under the curve' at 12 months
- cost-effectiveness at 12 months

Population

Setting: UK Primary Care – 27 general practices

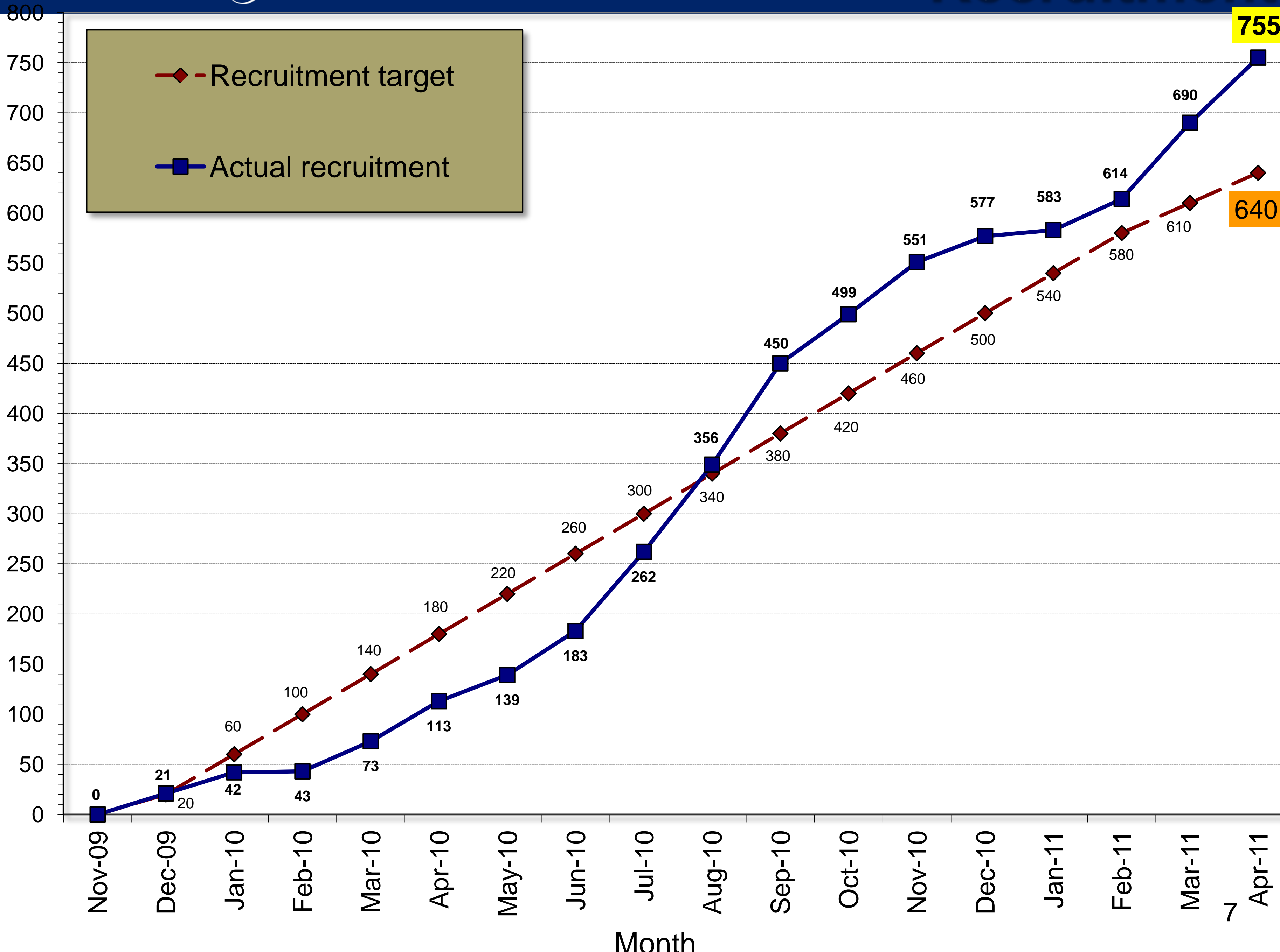
Eligibility criteria:

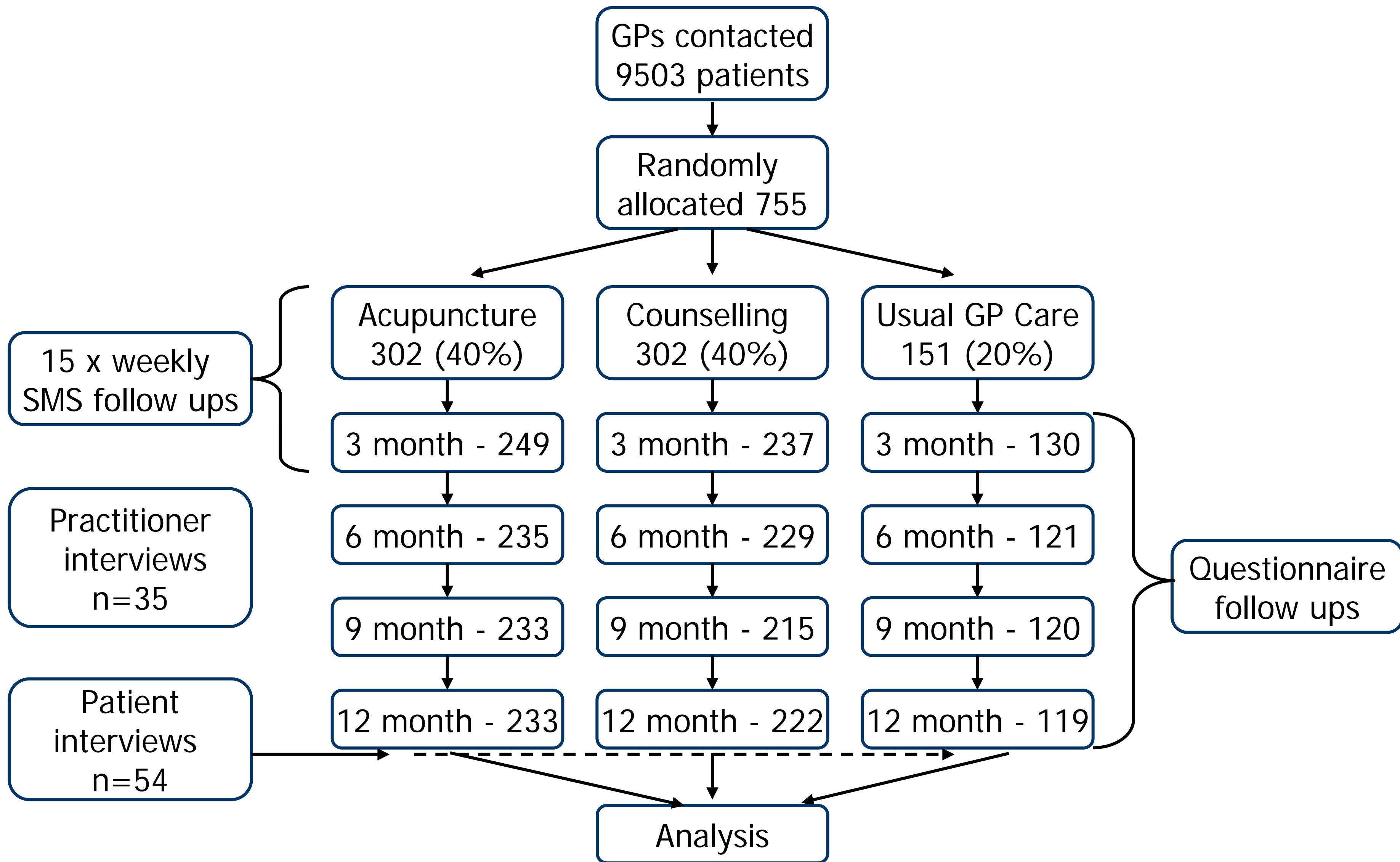
- 18 years of age or over
- Diagnosed with depression
- Baseline score 20 or above on BDI-II (moderate to severe depression)

Exclusion criteria:

- Already receiving acupuncture or counselling
- Terminal illness, transmissible blood disorder
- Pregnancy, recently bereaved

Recruitment




GPs contacted
9503 patients
Randomly allocated 755
Acupuncture
302 (40%)
Counselling
302 (40%)
Usual GP Care
151 (20%)
15 x weekly SMS follow ups
3 month - 249
3 month - 237
3 month - 130
Practitioner interviews n=35
6 month - 235
6 month - 229
6 month - 121
9 month - 233
9 month - 215
9 month - 120
Questionnaire follow ups
Patient interviews n=54
12 month - 233
12 month - 222
12 month - 119
Analysis

Participants

Baseline characteristics

- Predominantly female (73%)
- Mean age 43.5 yrs
- Age at first major depressive episode 25.2yrs
- Majority (62%) reporting “severe” depression - mean BDI-II score of 32.5
- 69% taking anti-depressant medication
- Treatment preferences:
  - 58% acupuncture
  - 22% counselling
  - 19% no preference
  - 1% usual care

Results

Attrition / adverse events

- Withdrew from trial: n = 41 (5.4%)
- Died: n = 3 (0.4%)
- SAE's n = 51 (6.8%); NSAE's n = 143 (18.9%) – no adverse events needed reporting to REC and there were no major differences between groups

Uptake of interventions

- 88% uptake of acupuncture – mean of 10 sessions
- 76% uptake of counselling – mean of 9 sessions

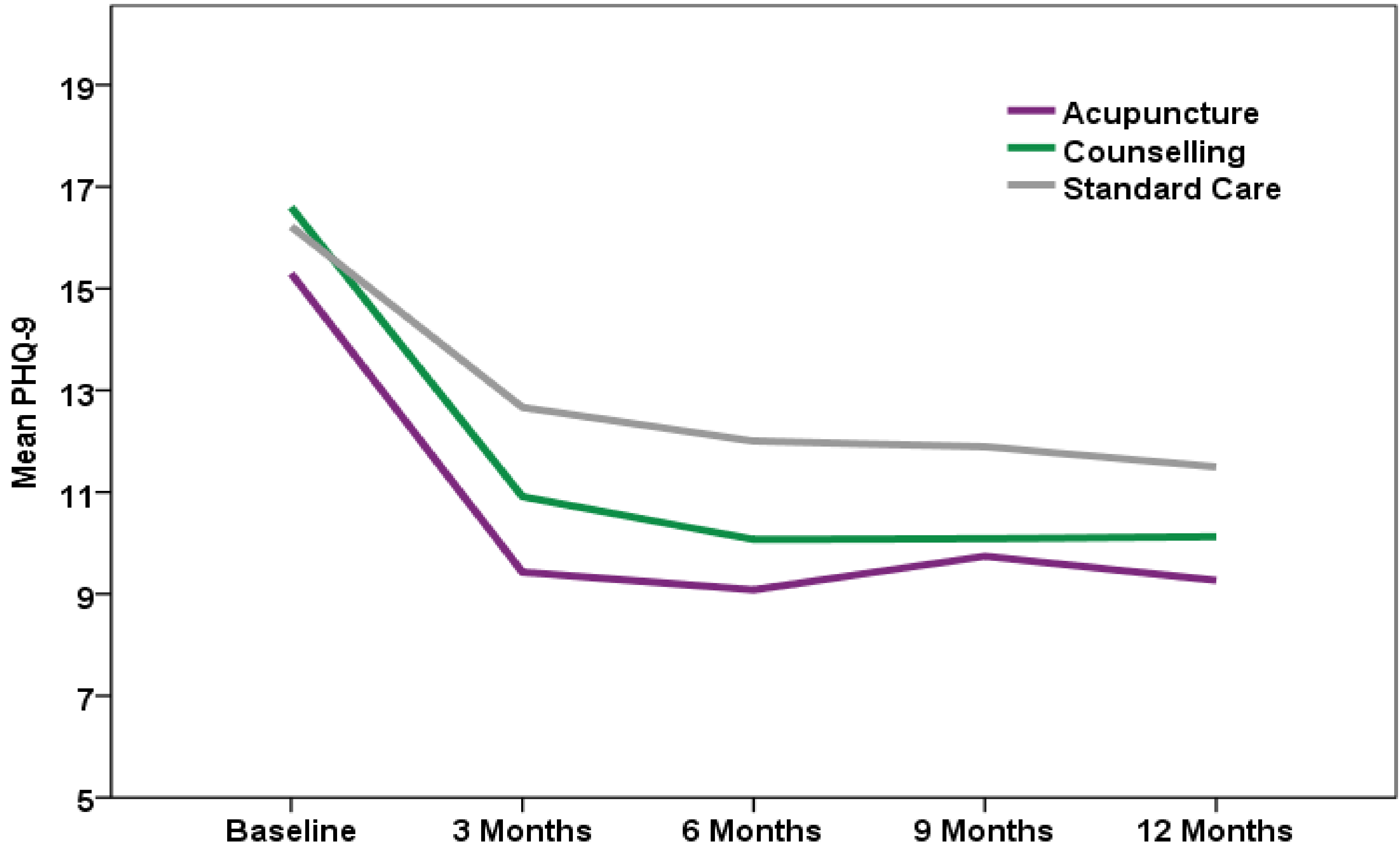
Results

Follow-up rates

Valid PHQ-9 data analysed / absolute no. recruited

- **81.3% at 3 month** (n=614, 20% greater than 511 specified in power calculation).
- 77.2% at 6 month (n=583).
- 75.4% at 9 month (n=569).
- 75.8% at 12 month (n=572) - £5 incentive

Unadjusted PHQ-9 scores from baseline to 12 months



Results

Clinical effectiveness

Difference at 3 months for PHQ-9, adjusting for expectation and preference using ANCOVA (95% CI)

- Acupuncture more effective than Usual Care

  -2.46 (-3.72 to -1.21) points, ES -0.39 (-0.58 to -0.19)

- Counselling more effective than Usual Care

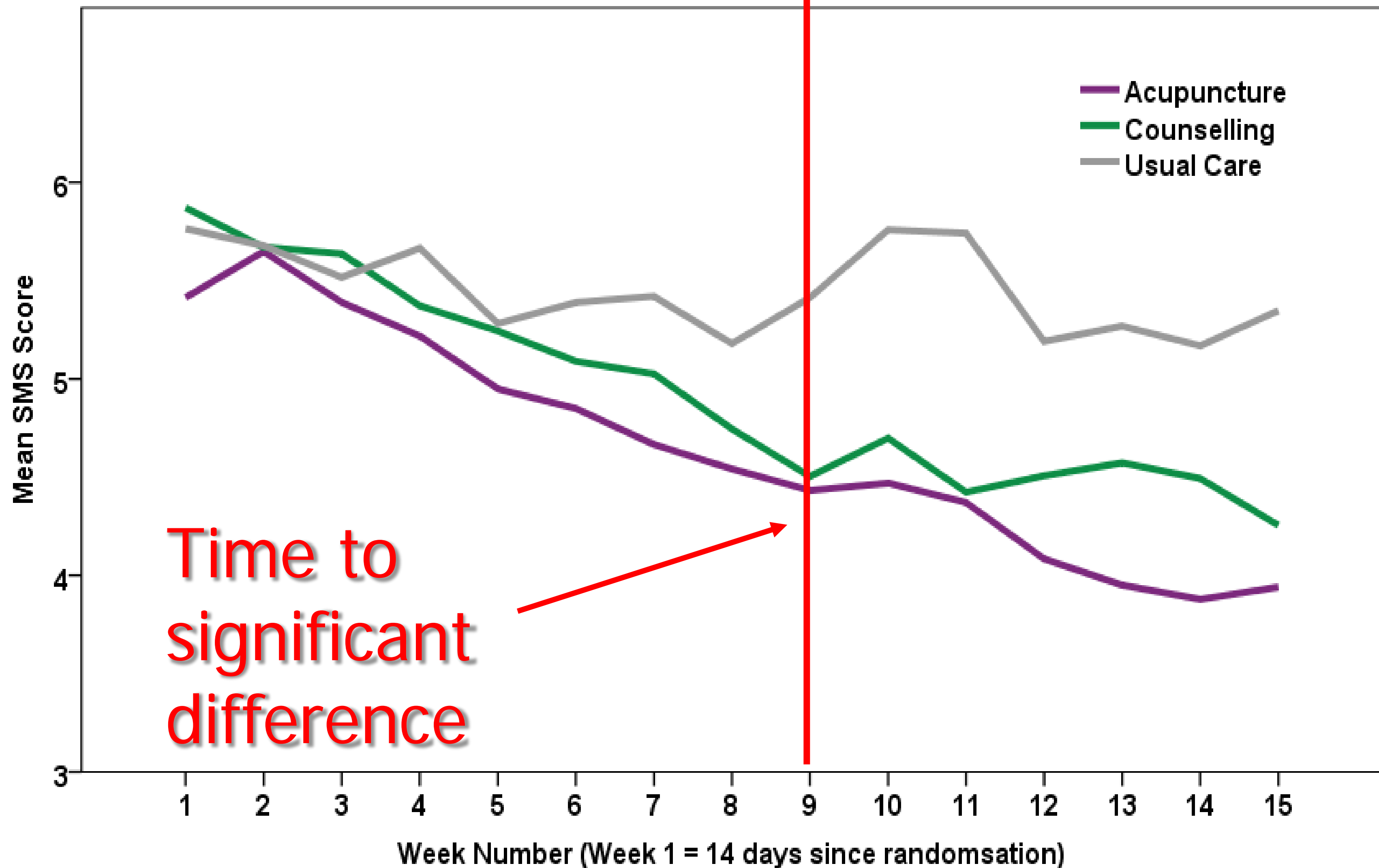
  -1.73 (-3.00 to -0.45) points, ES -0.27 (-0.47 to -0.07)

- Acupuncture vs. Counselling

  - 0.76 (-1.77 to 0.25), no significant difference (after adjusting for contact time and attention).

Mean SMS mood scores by trial arm

(1 = not at all depressed, 9 = extremely depressed)



Incremental cost-effectiveness ratio

- Counselling (vs usual care) = £5,412/QALY

  90% probability of cost-effectiveness (at a threshold of £20,000 per QALY) if acupuncture is not available

- Acupuncture (vs usual care) = £3,417/QALY

  95% probability of cost-effectivness (at a threshold of £20,000 per QALY if counselling is not available.

Conclusions

- Both acupuncture and counselling result in significantly reduced depression symptoms in the short to medium term (3 to 12 months).
- Acupuncture plus usual care is most cost-effective, followed by counselling plus usual care.
- Usual Care alone is least cost-effective.

Current sub-studies

- Feasibility/validity of texted depression scores
- Details of treatments provided
- Patient experiences of acupuncture and counselling
- Practitioner perspectives on provision of treatment

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