JOINT TRIAL MANAGEMENT MEETING
4.00pm – 5.30pm, 6th November 2007, UEA

Minutes

Present:-

Jeanette Blacklock  Local study co-ordinator  UEA
Nicola Crabtree  Medical Physicist  University of Birmingham
Tony Dyer  SCOOP database manager  UEA
Ric Fordham  Co-applicant / Health economics lead  University of Southampton
Nick Harvey  Rheumatologist  UEA
Ali Heawood  Joint PI  University of Bristol
Richard Holland  Co-applicant  UEA
Amanda Howe  Primary care lead  UEA
Katharine Knight  Local study co-ordinator  University of Sheffield
Liz Lenaghan  SCOOP study manager  UEA
Eugene McCloskey  PI / SCOOP clinical lead  University of Sheffield
Natasha Mitchell  Local study co-ordinator  University of York
Terence O’Neill  PI  University of Manchester
Jim Parle  Primary care  University of Birmingham
Gill Pearson  Rheumatologist  University of Sheffield
Niamh Redmond  Local study co-ordinator  University of Sheffield
Lee Shepstone  Chief investigator  UEA (Chair)
David Torgerson  PI  University of York

1. Welcome & introductions

Lee welcomed everyone to the first meeting of the SCOOP Joint Trial Management Group.

2. Overview of progress with study set-up & project milestones

Liz presented a summary of progress with study set-up*. The earliest randomisations are expected in March 2008. It was agreed that a date should be fixed for randomisation of the final participant – provisionally planned for 30/06/09.

3. Progress report from study centres

i)  **Norwich**  (Report by Liz Lenaghan)

*Local TMG* – continued from feasibility study. Members include immediate study team, co-applicants from UEA, a GP representative, radiologist and radiographer from DEXA service at Norfolk & Norwich University Hospital (NNUH), plus two lay members.

*  Documents available on study centre area of SCOOP study website www.scoopstudy.ac.uk
**Staff appointments** - Liz Lenaghan (study manager), Jeanette Blacklock (local study co-ordinator), Veronica Bion (project administrator) all continuing in post from feasibility study.

**NHS service support costs** – Primary care costs for 07/08 covered by R&D transitional funding from Norfolk PCT.

**R&D approval** – Submitted applications to Norfolk PCT and NNUH; due to hear outcome shortly. Further application will be submitted to 2nd DEXA provider (James Paget University Hospital, Great Yarmouth).

**DEXA provision** – Plan to use DEXA facilities at NNUH in Norwich and Northgate Hospital in Great Yarmouth. Still to confirm capacity of each service which will in turn inform the recruitment targets in each area.

**Identification of GP practices** – A total of 66 GP practices have been approached by ‘SPHERE’ / East of England PCRN by email (approx 50% of Norfolk practices). Feasibility study practices excluded at this stage, plus practices in West Norfolk where DEXA provision is currently poor. Have received responses from 28 practices so far, 18 are interested in taking part, 5 are undecided, 5 have declined. Six of the interested practices have been identified for the first recruitment phase and the study co-ordinator and CI will visit these in late November / early December to explain more about the study and agree a start date for eligibility searches and invitation mailings (mid Jan to mid Feb 08). The other interested practices will also be asked to formally sign up to the study at this stage and agree which of the later recruitment phases they will take part in (phase 2 planned to start June 08, phase 3 in October 08).

**Birmingham** (Report by Jim Parle)

**Local TMG** – chaired by Neil Gittoes (PI, endocrinologist); other members include study co-ordinator, Nicola Crabtree (Medical Physicist / DEXA lead), Jim Parle (primary care lead).

**Staff appointments** - Katie Jarand (local study co-ordinator) started in post early November (currently on annual leave), Helen Duffy (study secretary) also now in post.

**NHS service support costs** – Primary care costs for 07/08 covered by R&D transitional funding from South Birmingham PCT. PCRN facilitator has confirmed that no problems are envisaged with committing funding in the long term.

**R&D approval** – Application submitted to University Hospital Birmingham (UHB). Application to PCT planned shortly.

**DEXA provision** – Plan to use DEXA facilities at UHB.

**Identification of GP practices** – Primary care practices in Birmingham are not ‘over-researched’ and osteoporosis treatment rates are low, therefore would hope for a good response. Plan to employ a strategy to identify a set of practices that will provide good ethnic diversity. Will initially focus on a set of practices with a population of 60,000 between them. Based on a rough estimate of 6% eligible and 30% response rate, could expect up to 1,000 consenting participants (target: 1,650).

**Bristol** (Report by Ali Heawood)

**Local TMG** – members include Tim Peters and Ali Heawood (joint PIs), study co-ordinator, Shane Clarke (Rheumatologist), and Richard Darling (GP lead with interest in osteoporosis). Next meeting scheduled for 15th November 07.

* Documents available on study centre area of SCOOP study website www.scoopstudy.ac.uk
**Staff appointments** - Niamh Redmond (local study co-ordinator) and Sam Cross (study secretary) in post. Have also appointed Clare Emmett as RA for qualitative study of acceptability of screening (start date: 1st April 08).

**NHS service support costs** – Primary care costs for 07/08 covered by R&D transitional funding from North Somerset PCT.

**R&D approval** – Applications submitted to North Somerset PCT and Weston Area Health Trust (WAHT).

**DEXA provision** – Plan to use DEXA facilities at WAHT.

**Identification of GP practices** – Initially approaching practices in North Somerset PCT area due to proximity of DEXA facilities at Weston and high elderly population. GP contact is assisting with identification of suitable practices. May involve GP practices in Bristol at a later date – currently liaising with the organisers of another osteoporosis trial recruiting from the Bristol area to ensure that the two studies don’t overlap.

iv) **Manchester** (Report by Terence O’Neill)

 Local TMG – members include Terence O’Neill, study co-ordinator, Sue Knight (Rheumatologist), and Judy Adams (Radiology). Plan for Vicki Wilkinson or Lorraine Woods from North West PCRN to also join.

 Staff appointments - Local study co-ordinator has recently been appointed with a planned start date of 14th Jan 08. Project assistant also appointed and will start in post on 26th November.

**NHS service support costs** – Dept of Health ad hoc levy will cover primary care costs for 07/08 on behalf of Central & Eastern Cheshire PCT.

**R&D approval** – Applications submitted late October, Research Governance Committee will consider at meeting on 10th December.

**DEXA provision** – Plan to use a combination of a mobile scanner (University of Manchester) and referrals to the Regency Hospital (private) in Macclesfield. Estimated cost of private referrals are £65/scan (ie. below NHS service support cost of £79/scan identified for SCOOP).

**Identification of GP practices** – Liaising with NW PCRN co-ordinator to identify and approach suitable practices, initially in Central & East Cheshire PCT area.

v) **Sheffield** (Report by Eugene McCloskey)

 Local TMG – membership continued from feasibility study.

 Staff appointments - Katharine Knight (local study co-ordinator) and Matthew Fidler (study clerk) continuing in post from feasibility study.

**NHS service support costs** – Primary care costs for 07/08 approved by Sheffield Health & Social Research Consortium.

**R&D approval** – Application submitted research consortium, awaiting approval.

**DEXA provision** – Plan to use DEXA facilities within osteoporosis clinical trials unit (Northern General Hospital)

**Identification of GP practices** – Need to recruit new practices not involved in feasibility study. Plan to work with soon to be appointed South Yorkshire facilitator from East Midlands and South Yorkshire PCRN.

vi) **Southampton** (Report by Nick Harvey)

 Local TMG – members include Cyrus Cooper (PI), study co-ordinator, Nick Harvey & Gill Pearson (rheumatologists), Karen Collins (osteoporosis research nurse / admin support)

* Documents available on study centre area of SCOOP study website www.scoopstudy.ac.uk
Staff appointments – Janet Cushnaghan (local study co-ordinator) in post. IT support in place (main link: Jamie Green).

NHS service support costs – Dept of Health ad hoc levy will cover primary care costs for 07/08 on behalf of Southampton City PCT.

R&D approval – Application to be submitted shortly to Southampton City PCT and Southampton University Hospital Trust (SUHT).

DEXA provision – Plan to use DEXA facilities at SUHT.

Identification of GP practices – South West PCRN have adopted study and plan to advertise to local practices. Approx 5 additional practices from Hampshire PCT area may be required for later recruitment phases – will plan further R&D application in early 08/09.

vii) York (Report by David Torgerson)

Local TMG – members include David Torgerson (PI), study co-ordinator, Mike Green (Rheumatologist, York), Sue Steel (Bone Physicist, Hull), fracture prevention trial co-ordinator (York Trials Unit), Ian Watt (GP link, York Trials Unit).

Staff appointments – Natasha Mitchell (local study co-ordinator) in post. Shortlisting for study secretary w/b 13th Nov, interviews early Dec, aim to have in post by w/b 7th Jan 08.

NHS service support costs – Dept of Health ad hoc levy will cover primary care costs for 07/08 on behalf of North Yorkshire & York PCT.

R&D approval – Applications to be submitted shortly.

DEXA provision – Plan to use DEXA facilities at Nuffield Hospital (York) and Hull Royal Infirmary.

Identification of GP practices – Northern & Yorkshire PCRN are very supportive of the study and are in the process of contacting practices for expressions of interest.

4. Overview of economic evaluation

Ric Fordham presented a brief overview of the planned approach to economic evaluation*. It was agreed that this trial provides a good opportunity to collect realistic cost data in relation to screening in addition to evaluating the clinical effectiveness of the intervention. John Kanis stated that the trial will provide valuable data for economic modelling using different DEXA thresholds.

Nicola Crabtree pointed out that the duration of the scan would not be materially affected by only scanning one body site (hip joint) rather than the usual two (eg. hip and lumbar vertebrae). The majority of the scan appointment is taken up by clerking, height and weight measurement and general preparation for the scan.

David Torgerson queried whether it would be feasible to wait until the latter stages of the trial before collecting data on primary care resource use, as the data of those participants that die during follow-up may be difficult to obtain. Amanda Howe and Jim Parle thought that computerised data would still be available on practice systems and that only paper records are archived.

Ric agreed to contact John Kanis, Eugene McCloskey and David Torgerson to discuss the data requirements for the planned cost utility analysis in more depth. (Action: Ric Fordham)

* Documents available on study centre area of SCOOP study website www.scoopstudy.ac.uk
5. Recruitment of GP practices

Lee Shepstone emphasised the importance of trying to involve a range of GP practices with the aim of recruiting a study population as representative of the UK population as possible. This was agreed, although several members of the group pointed out that this is difficult to achieve due to the frequently observed tendency for a bias towards higher socio-economic status in consenting participants. LS reported that this was certainly observed in the feasibility study, based on responses regarding educational level (occupational coding not yet completed). Furthermore, some modelling from the feasibility study has shown that those practices with a higher deprivation index score are likely to have lower response rates overall. JK pointed out that there is currently no evidence of an association between SES and fracture rate.

6. Plans for research in addition to main SCOOP trial

i) **Qualitative study – Acceptability of screening**

Ali Heawood circulated a summary of the aims and methods for this study* which will be undertaken over 2 years, starting in April 2008. It will involve interviewing a small subset of the participants involved in the main trial (purposeful sample of 30 women). The aim is to investigate whether screening for risk of fracture raises anxiety and to explore the general impact of the intervention.

ii) **Qualitative study – Adherence with medication**

Amanda Howe outlined the intention to carry out a qualitative investigation of factors affecting adherence and persistence with osteoporosis medication. An application for funding to Dunhill Medical Trust is currently being prepared, due to be submitted in mid-December 07.

iii) **Studies requiring blood samples (bid to MRC)**

LS reported that a bid to the MRC is planned for April 2009 for funding to collect and store blood samples from SCOOP study participants. The funding being applied for will include costs of a prospective study to analyse the relationship between n-3 fatty acid (and vitamin D intake) and fracture rate. The MRC bid is being led by Aedin Cassidy and Sue Fairweather Tait from UEA. As the main funder of the SCOOP trial, the MRC have indicated that they would be receptive to allied studies of this type. However they have stipulated that participants should not be approached about consenting to a blood sample until the recruitment and screening phases are complete in order to ensure that the main study is not compromised.

The samples collected could be used for blood studies by other study centres, however funding for any additional analyses would need to be found separately. A protocol summary will be circulated to study centres shortly. PIs (& colleagues) will be asked to respond regarding a) whether they wish to collect blood samples, b) what resources they require to collect and store samples (these will vary dependent on existing facilities), and c) whether they wish to collect blood for other purposes and, if so, what fraction and volume would be required. *(Action: Lee Shepstone / Liz Lenaghan)*

* Documents available on study centre area of SCOOP study website www.scoopstudy.ac.uk
iv) **Proposal to randomise envelope colour to measure impact on response rate**
David Torgerson presented a protocol for the above study*. It was agreed that the methods would be trialled by York in recruitment phase 1 and extended to other willing study centres if it proved practicable.

7. Study centre visits – Nov / Dec 2007
Liz Lenaghan stated that study centre visits are scheduled for 5 of the study centres in late November / early December. A visit to Manchester will be arranged once their study co-ordinator comes into post in mid-January 08.

8. Any other business

i) **Quantitative measure of muscle function**
Nicola Crabtree proposed that Birmingham and other interested study centres take additional measurements at the DEXA appointment in order to investigate the correlation between muscle strength and fracture rates. Terence O’Neill confirmed that Manchester would be interested in collaborating (contact: Kate Ward). Additional funding would be required for the jumping plate equipment if not already in place at study centres. Liz pointed out that the PIS included brief information about additional measurements that may be taken at the DEXA appointment, however Lee stated that an ethics amendment is likely to be required due to patient safety issues.

ii) **Dates for future meetings**
Lee suggested that a joint trial management meeting should be held to mark the final randomisation (ie. summer 2009). There was some support for joint TMGs to be an annual event. Jim Parle suggested that teleconferencing could be useful for interim meetings.

* Documents available on study centre area of SCOOP study website www.scoopstudy.ac.uk