Low Back Pain Trial Repository Programme
Information Sheet for Investigators
Programme Summary and Investigator Involvement

Warwick CTU has been funded by UK National Institute of Health Research to do individual patient data meta-analysis of data from trials of low back pain treatments. We are inviting custodians of existing trial datasets to contribute data to this project. There are two stages to this; the first stage is for our currently funded project to explore sub-groups in low back pain (LBP) and the second stage is to maintain a data repository of individual patient data from trials of therapist delivered intervention in low back pain as a resource for the back pain community. The Chief investigator for this project is Martin Underwood.

Stage 1: Improving outcomes from the treatment of back pain

At a population level, we have useful data on the management of LBP. What is not clear is how we can use these data to maximise the treatment benefit for the individual patient i.e. which patients are most likely to benefit from which treatment choices. If we could predict which patients would be most likely to benefit from different treatments, overall effectiveness, and cost-effectiveness, of treatments for Low Back Pain would improve. Any randomised controlled trial (RCT) to directly address this problem would need to be very large.

We have received funding from the NIHR to undertake an individual patient data meta-analysis to identify moderators of treatment effect. From this programme of research, we aim to produce evidence to help patients, their clinical advisors and health service purchasers to select the 'right treatment for the right person at the right time'. We are interested in both clinical and cost-effectiveness.

We have obtained ethical approval for this project from both the University of Warwick's Biological Research Ethics Committee and also a UK National Health Service research ethics committee flagged to assess applications to establish a research database. We have of course considered ethical issues of secondary analysis of data carefully. We will only request and utilise anonymous data and will seek assurance from collaborators that nothing in the original consent process would preclude sharing anonymous data in this way.

In this first stage, once we have sufficient data, we will explore how the complex relationship between demographic factors, patient history and patient characteristics can be used to predict the response to different treatments. We will;

1. estimate within-trial indicators of clinical and economic outcomes at the individual patient level (e.g. health care costs and QALYs over the trial period),
2. statistically analyse the RCT dataset to identify moderators that could contribute to a practical Clinical Prediction Rule that can be used to inform LBP management.

We would like you to share data for this work. Ideally we want to include individual item responses to outcome measures rather than summary values in order that we can ensure consistency in how summary scores are calculated. However, we would like to stress that you

are under no obligation to send us any data you wouldn't wish to share. If you only have summary measures available we would still be delighted to have your data. We are particularly interested in any data that will inform our cost-effectiveness analyses.

We would like you to share the following data with us:

- Participant characteristics and baseline measurements
- Assigned intervention(s)
- Intervention(s) received
- Recorded outcomes at each time point (during the intervention and follow-up) including
    - Values of individual items from all the questionnaires
    - Health economic/utility measurements (e.g. EQ5D or SF6D items)
- Recorded use of health services and related expenditure for patients (during intervention and follow-up)
- Anonymised data allowing us to measure any clustering by therapist or site

If they are available and you are happy to share them with us then copies of the following documents:

- The final protocol
- Case report forms (CRF)
- Coding manual for the CRF codes

We are aware that these documents may not be available – for example we know of one large study that lost all its archived material in a flood. Whatever you have available would be very helpful to the team.

Upon receiving the dataset we will run a validity and quality check to ensure data integrity. A validity-quality report will be sent to you for comment and/or feedback. We aim to resolve any inconsistencies in the data before integrating the dataset with the rest of the dataset in the repository. Once the dataset has been integrated into the repository, the original dataset from you will be destroyed.

We have established secure methods to transfer anonymous data sets and will send you full details when appropriate. We are only too aware of how hard it was to collect these data in the first place; will handle them very carefully!

At present we are asking for data sharing agreements for this study only. We will produce a new data sharing agreement for stage two of the project.

All research teams who contribute to the project will be acknowledged in any publications. Where possible, we will do this by including one member of each trial team as a named member of the collaborative group who have supported this programme; you may choose whom is acknowledged. This may be a different person for each set of trial data you share with us. This will ensure your contribution will be recognised by PubMed and citation tracking. We will give you the opportunity to comment on any papers that have used your data prior to submission. You will not, however, be obliged to comment.

Stage 2: Future use of the repository

Once developed, we would like to maintain this pooled data set as a resource for the research community as we anticipate that there will be many future research questions to be asked from this data set. Therefore any shared data sets will need to be as complete as possible as we will only be able to put each study into the repository once; this is why we are asking for such a detailed dataset for stage one of the project.

We will establish a governance structure including an independent steering committee to oversee fair access to the data by ourselves and others in the future. As a collaborator we would welcome any application to utilise this data (subject to steering committee approval). I do not anticipate needing to charge for access to these data. We will be seeking additional funding to maintain and add to the pooled dataset as a resource for the back pain research community.

We will be looking for additional funding to continue supporting the database and adding further trial data sets in the future.

We will ask for separate and additional consent from you to include your data in phase 2. If you do not wish any of your data to be used in any subsequent analyses, you will be able to specify this at this point. Please be assured that we will not use your data for any other analyses than those stipulated by you and those which have received approval from the steering committee.

Thank you for taking the time to read this information and we hope that you will consider our request to share your data and contribute to this valuable programme.

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