A Report of a Patient and Public Involvement Consultation Event for a Study Proposal to Evaluate a Sleep Practitioner Intervention for Sleep Disorders in Children

Heather Elphick, Vicki Dawson, Jonathan Boote

April 2011
A Report of a Patient and Public Involvement Consultation Event for a Study Proposal to Evaluate a Sleep Practitioner Intervention for Sleep Disorders in Children

Heather Elphick, Vicki Dawson, Jonathan Boote

April 2011
Principal Investigator

Heather Elphick, Paediatric Respiratory and Sleep Medicine, Sheffield Children’s Hospital, Western Bank, Sheffield S10 2TH

Patient and Public Involvement Team

Vicki Dawson, Senior Sleep Practitioner, Sleep Solutions, Scope, 6 Market Road, London N7 9PW

Jonathan Boote, NIHR Research Design Service for Yorkshire and the Humber, School of Health and Related Research, University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA

Other Members of the Study Team

Daniel Hind, Assistant Director, Sheffield Clinical Trials Unit, School of Health and Related Research, University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA

Steven A. Julious, Medical Statistics Group, School of Health and Related Research, University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA
<table>
<thead>
<tr>
<th>1. Introduction</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Methods</td>
<td>2</td>
</tr>
<tr>
<td>3. Summary</td>
<td>2</td>
</tr>
<tr>
<td>4. Acknowledgement</td>
<td>3</td>
</tr>
<tr>
<td>5. References</td>
<td>3</td>
</tr>
<tr>
<td>6. Appendix</td>
<td>5</td>
</tr>
<tr>
<td>6.1. Draft Lay Summary Shown to Parents</td>
<td>5</td>
</tr>
<tr>
<td>6.2. Field Notes from the Public Patient Involvement Consultation</td>
<td>6</td>
</tr>
<tr>
<td>6.3. Application to the NIHR Research Design Service for Yorkshire and the Humber</td>
<td>10</td>
</tr>
</tbody>
</table>
1. Introduction

Sleep problems are common amongst children\textsuperscript{1-3}. The most commonly reported problems are difficulties in settling at bedtime, bedtime avoidance with related disruptive behaviour, episodes of night waking leading to disrupted sleep for parents and other members of the household and co-sleeping. Settling problems have been reported in 27% children aged 4-12 in mainstream schools and night waking in 13\%\textsuperscript{4}.

Sleep problems have a number of implications for the child and family. For parents, they are associated with high levels of stress and irritability\textsuperscript{5}. For the children they are associated with poor concentration and learning, as well as behaviour problems\textsuperscript{6}. In addition there is often significant sibling disturbance. The economic burden related to healthcare costs for these families may be significant\textsuperscript{7}. These findings emphasise the need to take sleep problems seriously. However, only a minority of families who have a child with a severe sleep problem appear to receive any help\textsuperscript{8}.

There is a growing awareness and input into the sleep problems of children with additional needs\textsuperscript{9} and behavioural interventions have been evaluated using randomised controlled trials\textsuperscript{10-12}. An evaluation of sleep practitioner support for children with additional needs showed improvement in both sleep disturbance index and general health of the parents\textsuperscript{13}. However, in the wider population, such as is seen in our sleep clinic and in general practice, there is very little input available for otherwise healthy, typically developing children with sleep problems. Health visitors are increasingly overburdened with safeguarding issues and there is no literature regarding sleep problems for parents in packs such as the Red book or School Health Services leaflets.

Cognitive behavioural therapy is often carried out by a psychologist. However, a fully trained sleep practitioner (A4C Band 5/6) has the capability of delivering a similar intervention which, in the current financial climate would be an attractive alternative to an expensive psychologist (Band 8b+). One aim of this study will be to assess whether the delivery of a relatively low-cost intervention will have cost-saving implications on the wider health service.

The evaluations that we will use will address the five Every Child Matters outcomes (‘Every Child Matters: change for children, December 2004) which will encompass health, relationships, money, employment and stress, as well as possible reduction in the need for support from other services. There is evidence to show that parents no longer require antidepressants, stress levels are reduced and there are improvements in family relationships directly because sleep problems have been resolved in children with additional needs, but there is no equivalent evidence for typically developing children.
To assist the team with the ongoing research we arranged a consultation event where we discussed the project with parents of children with severe sleep difficulties to get feedback on the intervention and to find out about their experiences with sleep problems.

2. Methods

The patient and public involvement consultation event was held on 21st April 2011 at The Clinical Research Facility of Sheffield Children’s Hospital. Heather Elphick led the discussions and Vicki Dawson described the intervention package. The field notes from these discussions are given in the Appendix.

3. Summary

Parents unanimously agreed that there is no current provision for effectively treating typically developing children with severe sleep disturbance.

The parents agreed that the questionnaires, sleep diaries and actiwatch were acceptable and useful outcome measures and recommended that each should be used at all timepoints. A 12 month follow-up period was recommended. Clarification of some points would need to be given by the research nurse. A consideration of involving the children’s teachers in assessing behavioural outcomes was suggested.

The parents decided that the most suitable location for completion of baseline questionnaires was at home with research nurse present unless stated otherwise by parents. Later questionnaires could be posted. Questionnaires to be completed by all adults caring for child during sleep (not just mums).

The lay summary was reviewed and recommendations were made for change. These were incorporated into the revised draft of the lay summary which is attached in the Appendix.

All the parents agreed to be contacted in the future with respect to this ongoing research project.
4. **Acknowledgement**

This event was funded through an award from the NIHR Research Design Service for Yorkshire and the Humber. The application for this funding is included as an appendix in Section 6.3.

5. **References**


9. Bartlet L, Ansell J, Hill CM. Training sleep practitioners for children with additional care needs – the development of the National Sleep Training Programme.


6. Appendix

6.1 Draft Lay Summary

Around 30% children have sleep problems. The most common problems are:

- difficulties in settling with disruptive behaviour at bedtime,

- waking during the night and disturbing other family members

- sharing a bed with the parents.

Sleep problems can have an effect on the whole family. Parents are often very tired and stressed and children have problems with concentration and learning, as well as behaviour. Brothers and sisters can be affected as well if their sleep is being disturbed. The lack of sleep can lead to physical and mental illness and time missed from work and school. We need to take sleep problems seriously.

Sleep practitioner programmes have been set up to help children with disabilities and have been shown to be effective. However, there is very little help available for children with sleep problems who are not disabled and have no other health problems. We want to show that a sleep practitioner programme will lead to better quality of life for the family, and reduce costs to society, for example by reducing visits to doctors and reducing the need to take time off work. The programme will consist of visits to the family, agreeing a plan to change the child’s sleep habits and support with regular phone calls.

We will be asking the parents of children with severe sleep problems to take part. To see if the programme works we will offer it to half of the children and the others will continue with their normal treatment. We will use questionnaires and sleep diaries to compare the two groups to see whether the programme is effective. The research team will include doctors who specialise in sleep problems, a sleep practitioner and academic experts in research.
6.2. Field Notes from the Public Patient Involvement Consultation

6.2.1. Qualitative discussion with Parents of Children with Severe Sleep Disturbance

Parents present: 5 mothers, 1 father and 1 grandfather of children with severe sleeping difficulties. Children were not invited to take part due to possible psychological factors associated with their sleep problems.

The agenda was as follows:
1. Description of study and purpose of PPI event (HE)

2. Description of sleep practitioner intervention package (VD)

3. Parent’s comments on outcome measures: questionnaires, sleep diary and actiwatch. The parents should complete the questionnaires for "face validity and acceptability". (HE)

4. Discussion with parents to include:
   - timepoints (before, after, 3 months, 6 months - is this acceptable?);
   - location (would they prefer to be consented/fill in questionnaires at hospital, at home with research nurse present, at home alone and send back later);
   - should we include Dads as well as Mums;
   - how best to measure impact on family;
   - any other important outcomes that we have not thought of?

5. Parents comments on the lay summary for the project

6. Further comments and recruitment to study advisory group.

The event took place as follows:

1. HE began by describing the study background and proposal. It was unanimously agreed that there is no current provision for effectively treating typically developing children with severe sleep disturbance.

2. VD then described the intervention package delivered by the sleep practitioners working for Sleep Solutions (organisation funded by Scope to provide sleep advice to families of children with additional needs).

There followed a brief discussion about the personal experiences of the families involved. On the whole, experiences with health professionals were negative and all of the parents involved had had considerable difficulty in finding help for their children. Comments included:
• “had to try different health visitors”
• “had to beg to see the health visitor”
• One parent had had safeguarding issues raised against her and had been referred to social workers making her reluctant to seek further help even though she desperately needed it
• “people don’t take sleep problems seriously”
• Health professionals always “know better” and had refused further help
• The stigma around having a child with sleep problems and the feeling that others think you are a bad parent
• One mother had been seeing her GP with other minor ailments as she was unable to think clearly enough to realise they were all related to the sleep problem because of her own sleep deprivation
• School nurses appear to have no knowledge/training on the subject of sleep and health visitors, GPs, teachers and even paediatricians have variable knowledge and/or interest
• Lack of consistent information and the damage that can be done by giving wrong/misinformed advice
• General lack of awareness of importance of sleep

3. Parent’s comments on outcome measures. All of the parents present completed each of the questionnaires presented:
• The Child’s Sleep Habits Questionnaire (CSHQ)
• The Pittsburgh Sleep Quality Index (PSQI) – assessment of parents’ sleep habits
• The Profile of Mood States (Parent)
• The Malaise Inventory (Parent)

The Children’s QOL questionnaire (Kathryn Stevens) was not available.

Completion of the questionnaires took approx 15-25 minutes (different for different individuals).

The CHSQ was felt to be self-explanatory. It was commented that the questionnaire gave “room for thought” and was useful to help the parents think about things differently. There was some discussion about the “Problem?” column being that a problem was being perceived by the parent at that point in time and it was agreed that some clarification would be needed in the explanation of the questionnaire to the parents by the research nurse for the study. A separation between night-time and daytime sleep would be useful.

The PSQI was found to be easy to use. There followed a discussion around the retraining of parents own sleep habits after resolution of the child’s sleep problems which can take many months to improve. The PSQI was thought to have some relevance to siblings and other family members and a suggestion was made to include
a paragraph for the siblings to complete if they wish. (This may be covered by the Children’s QOL questionnaire however). The PSQI was felt to be important to “make you aware of your own health problems”. It needs to be made clear by the research nurse that daytime parental sleep needs to be documented also.

The POMS was thought to be useful and important. It would be a good idea to have a research nurse present while this questionnaire was completed in case the parent’s emotions were released by completing this assessment and support was needed. There followed a discussion around the emotions that parents go through when dealing with a child with sleep problems and the ensuing sleep deprivation. Parent forums were suggested to share the problems with others as they found it a very isolating experience.

The malaise questionnaire included questions about physical symptoms. It was suggested that the research nurse asks the question “have you experienced any of these common problems in relation to the sleep problem” to highlight that sleep deprivation can lead the physical illness for the parents. Otherwise, the questionnaire was found to be self-explanatory and acceptable.

The parents were shown the actiwatch and HE explained its use. It was universally agreed that this would be an acceptable and useful measurement tool. It was agreed that all of the questionnaires presented were relevant, useful, acceptable easy to complete and should be included in the study.

Two sleep diaries were shown to the parents. HE’s sleep diary as used in the sleep clinic shows a clearer pattern of sleep vs wake and it was suggested that this diary should be used for data collection. VD’s sleep diary as used in the sleep practitioner’s intervention package includes more descriptive information about the behaviour patterns and should be used within the intervention package to guide treatment.

4. Discussion and comments on other specific questions:

Duration of study – all parents agreed that ideally the study follow up period should be at least 12 months because of changes over a 6-12 month period in a child’s life that can influence the sleep pattern, for example – holidays, change of school/teacher, daylight saving, environmental changes with the seasons (light/noise). The sleep habits of parents after an intervention to help the child’s sleep pattern can take much longer to change and this may require a longer study duration to capture fully.

Time points and outcome measures – all parents agreed unanimously that all questionnaires should be used at all time points. They felt this was entirely acceptable and even desirable/useful for the parents involved in the study to monitor their own progress.
Location – all agreed they would rather complete the questionnaire at home. Because of the possible emotional impact of the POMS it was felt that the expectation would be that the research nurse should be present while the questionnaires were completed unless the parents specifically wished her/him not to be present and preferred to return them by post or have them collected at a later date. It was thought that the follow up questionnaires could be completed by post.

Dads as well as Mums? – all parents agreed that dads and/or other family members involved in the child’s sleep routine eg grandparents should complete the questionnaires. One parent pointed out that behaviour patterns may differ in different environments (ie when parents separated or at grandparents house) or with different carers. Siblings should have the option to complete part of the PSQI or the children’s QOL questionnaire.

Other outcome measures and how to record impact on family –
- Behaviour at school - Interview teachers
- Learning - ? teachers KS level score for child – first and last time point only
- Survey to include:
  - Number of visits to GP/other health professionals eg health visitor for child/parents
  - Days off work
  - Financial impact in terms of reduction in working hours – open questions
  - Prescriptions for child/parents
- Impact on relationships and social life – open questions

5. Comments on the Lay Summary
One of the parents present was a Plain Language expert and suggested changes to the formatting including bullet points and simplifying long words using Word. Other suggestions have been incorporated into a revised version of the Lay Summary.

6. Other comments
Recruitment – it was agreed that recruitment via hospital/university email and/or parent forums (one of the parents could help with this) would attract enough families. If it were possible to offer the intervention to the control group at the end of the study this would dramatically reduce drop-outs from the study.

All parents expressed an enthusiasm to take part in future aspects of the study. Paula Barker and Joanne Seymour were named as two parents who would like to be on the study advisory panel.
Application to the NIHR Research Design Service for Yorkshire and the Humber

Application for the RDSYH Public Involvement in Grant Applications Funding Award

Email your completed application form to rds-yh@sheffield.ac.uk, stating ‘RDSYH Public Involvement Funding Award’ in the email subject window.

Send the signed, hard copy of your completed application form to: Clare Clarke, The NIHR Research Design Service for Yorkshire and the Humber, The University of Sheffield, School of Health and Related Research (ScHARR), Ground Floor, Room G045, Regent Court, 30 Regent Street, Sheffield S1 4DA.

Please complete the form as fully as possible. The boxes given below for you to provide your answers are expandable, allowing you to write as much as you feel is necessary. Refer to the guidance notes or contact your public involvement advisor if you have any difficulties with answering the questions on this form.

1. Name and details of lead applicant for RDSYH Public Involvement in Grant Applications Funding Award

<table>
<thead>
<tr>
<th>Full name</th>
<th>Dr Heather Elphick</th>
</tr>
</thead>
<tbody>
<tr>
<td>Job title</td>
<td>Consultant in Paediatric Respiratory Medicine</td>
</tr>
<tr>
<td>Organisation</td>
<td>Sheffield Children’s Hospital</td>
</tr>
<tr>
<td>Work address</td>
<td>Floor E, Stephenson Unit, Western Bank, Sheffield</td>
</tr>
<tr>
<td>Postcode</td>
<td>S10 2TH</td>
</tr>
<tr>
<td>Telephone number</td>
<td>0114 2717585</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:Heather.Elphick@sch.nhs.uk">Heather.Elphick@sch.nhs.uk</a></td>
</tr>
<tr>
<td>Self-employed?</td>
<td>No</td>
</tr>
</tbody>
</table>

2. Please give the details of co-applicants (if applicable). Copy and paste the table below as appropriate if there is more than one co-applicant

<table>
<thead>
<tr>
<th>Full name</th>
<th>Mrs Vicki Dawson</th>
</tr>
</thead>
<tbody>
<tr>
<td>Job title</td>
<td>Sleep Practitioner</td>
</tr>
<tr>
<td>Organisation</td>
<td>Rotherham District General Hospital</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Full name</th>
<th>Ms Tina Blanchard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Job title</td>
<td>Sleep Practitioner</td>
</tr>
<tr>
<td>Organisation</td>
<td>Scope and face2face</td>
</tr>
</tbody>
</table>
3. Please provide an outline of the grant application that is being developed, including:

- Which specific type(s) of members of the public will be involved in developing the grant (e.g. a specific patient/service user/carer group, older people, children etc)
- How you intend to gain access to, and approach, members of the public to invite them to become involved
- How members of the public will be actively involved in developing the grant application, including an indication of the duration, location, and degree of complexity of all involvement activities
- How the involvement of members of the public in the development of the grant application will be evaluated
- How you intend to continue to actively involve members of the public should you be successful in winning the grant

A grant application is being developed to investigate the efficacy of a Sleep Practitioner intervention in normally-developing children with behavioural problems relating to their sleep. The intervention will be carried out by a qualified sleep practitioner and will include a full assessment and behavioural intervention package that has been validated in children with learning difficulties. The patient group to be studied will be identified from children attending the sleep clinic at Sheffield Children’s Hospital.

One (or two) member(s) of the public will be involved as a member of the project advisory group for development of the grant application – a parent (s) of a child with a behavioural sleep problem. This person(s) will be involved in the wording of the application and in particular the lay summary for the ethics application and the parent/patient information sheets. If appropriate, they may be involved in dissemination of results amongst parent forums and in reading and commenting on preparation of final reports/papers. This member of the advisory group will be involved throughout the project from early development of the application and throughout the data collection and reporting period. If any problems arise during the course of the data collection period with regard to questionnaires or collection of outcome data, this member will be consulted to give comments and suggestions.

In addition, we will involve a focus group of 6 parents and children with relevant clinical experience to comment on the intervention package and in particular the duration of time required to carry out the package and the number of contacts we are intending to use in the study. The outcome measures for the study will be mainly questionnaire-based and opinions as to choice and appropriateness of questionnaires will be sought. The focus group will be convened prior to the submission of the grant application as a single event, duration approx 30-60 mins, by a member of the research team at the clinical research facility at Sheffield Children’s Hospital. A summary of the findings will be made and used to inform the development of the grant application.

Parents and children with present or past experience of sleep behaviour problems will be identified from the population of the sleep clinic at Sheffield Children’s Hospital, which is run by Dr Elphick. If insufficient volunteers are identified through this source, other patient/parent groups interested in research involvement may be
identified through the PALS manager for Sheffield Children’s Hospital (Mrs Linda Towers) or through the Trust Foundation office (Mrs Jacqueline Mann).

4. Please state to which NIHR funding scheme (or other scheme) the grant application is to be submitted. Please also include: (1) the submission deadline of the grant that you are developing (and for applications to the Research for Patient Benefit scheme, indicate to which Competition you are applying); (2) an estimate of the total amount of funding being sought

Research for Patient Benefit scheme, Competition 14, deadline 21st January 2011. Funding yet to be finalised, total grant available £250,000

5. Please provide a breakdown, together with costings, of how the RDSYH Public Involvement in Grant Applications Funding Award will be spent (for example, venue, travel, subsistence, payments to members of the public)

Payments to members of focus group –

<table>
<thead>
<tr>
<th>costs</th>
<th>£20 per family + travel</th>
</tr>
</thead>
</table>

Total £180

6. If applicable, please indicate other sources of contributory funding already obtained for the active involvement of members of the public in the development of the grant application. If more than one source of contributory funding has already been obtained, please copy and paste the table below as appropriate

<table>
<thead>
<tr>
<th>Funding source</th>
<th>Amount</th>
</tr>
</thead>
</table>

DECLARATION (to be signed by the lead applicant for this award)

I confirm that to the best of my knowledge the information given on this form is correct. I understand that my name will be held on a database in accordance with the Data Protection Act, and that I may be asked to participate in future evaluations of this award scheme.

Signature  Dr Heather Elphick

…………………………………………….