A Study of
School Performance and
Well-Being
in Children with Narcolepsy

PARENT/LEGAL GUARDIAN INFORMATION SHEET

NARCOLEPSY GROUP

The Paediatric Narcolepsy Project

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Cognitive Function and Psychosocial Well-Being in Childhood Narcolepsy
Participant information sheet for parents/legal guardians of children with narcolepsy
Version 1. 17.06.15
A study of school performance and well-being in children with narcolepsy

We would like to invite you and your child to join The Paediatric Narcolepsy Project which has been set up by The University of Leeds. Before you decide, we would like you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully, and discuss it with others if you wish.

If anything is not clear, or if you would like more information, please contact the research team using the details above. Take time to decide whether or not you wish to take part.

Thank you for taking the time to consider taking part in The Paediatric Narcolepsy Project.

What is the purpose of the study?

The purpose of this study is to investigate the differences between school performance and well-being in children with narcolepsy and children without narcolepsy. We are investigating how children’s school performance and well-being is affected by having narcolepsy.

Narcolepsy is a neurological sleep disorder which can cause excessive daytime sleepiness, cataplexy (loss of muscle tone) and disturbed night time sleep. We want to understand whether children with narcolepsy have any additional difficulties (such as impairments in memory and attention) that might impact on their school performance and well-being.
The study will run until 2017/18 and the findings may inform the design of effective interventions that may help to reduce the impact of this condition on educational and psychological outcomes.

### Why have we been invited to take part?

The study is looking to recruit 30 children and their families meeting the following criteria: (1) children aged 8-16 years who (2) have a medically-validated diagnosis of narcolepsy (with or without cataplexy), (3) are fluent in English and (5) are currently living in the UK or Ireland.

### Do we have to take part?

No, it is completely up to you and your child (wherever possible) to decide to join the study. We will explain the study and go through this information sheet with you if you would like. If you agree to take part, we will then ask you to sign a consent form. If your child is able to understand the research and is happy to take part and can write their name, they will be asked to sign an assent form with you, if they want to.

If you do decide to take part, you will be given a copy of the information sheet and the signed consent/assent forms to keep for your records.
What does taking part in the study involve and what will we have to do?

Taking part in the study would involve you:

- Agreeing for a researcher (Jane Blackwell) to visit you and your child in your home. The care your child receives will be unaffected by your decision to enter or not enter the study.

- Agreeing to provide details of your child’s diagnosis of narcolepsy (for example showing the research team a personal copy of your child’s medical records or letters confirming diagnosis) and giving permission for the long term anonymised storage and use of this information for future ethically-approved research purposes only.

- Agreeing to complete parental questionnaires assessing your child’s sleep, behaviour, day time activity, strengths and difficulties. You will be asked to complete some of these questionnaires before the visit and during the visit.

- You will also be required to help your child set up an ‘actiwacth’ which records how active your child is in the day and how they sleep at night. Your child will asked to wear this for nine consecutive days and nights. This will be sent out to you in the post before the first visit.

- During the visit you will be asked if you are happy to participate in an interview about your how your child’s narcolepsy affects their school and home life. The interview length varies from one person to another but will last approximately 30 minutes. The questioning style will be semi-structured, meaning the researcher (Jane Blackwell) will be using open-ended questions to enable you to recount your experiences with as much or as little detail as you desire. With your permission, this will be audio recorded.
Agreeing that your child may complete some computerised tasks and assessments and that they can talk about their experiences at home and school. The interview with your child will also last approximately 30 minutes and an open-ended questioning style will be used so that your child can answer with as much or as little detail as they desire. With your and your child’s permission audio recording will be used during the interview. If your child does not feel comfortable with talking about narcolepsy they do not have to complete the interview.

Agreeing that your child takes part in a sleep study where their sleep will be recorded using specialist sleep equipment (polysomnography (PSG)) for one night at the visit to your home. Different monitors (14 tabs) will be attached to your child’s head to measure their sleep quality and duration and no video recording will be taken.

The total time for taking part in this study is:
One day, night and morning

What type of information will be sought from us as parents/legal guardians?

The interview questions will ask about your experience of being a parent of a child with narcolepsy and your child’s experience of narcolepsy. I will ask you to tell your story of how narcolepsy affects day-to-day life and your perspective on how your child manages with the condition. The interview may cover both the ups and downs of your experiences, your challenges and your triumphs, lessons learnt and the advice you would like to pass to other parents in a similar situation. We may therefore touch on painful memories, anxious moments and relationships with
important people in your life. You have control over what line of questioning you are comfortable engaging with, and the amount of detail you give.

We will also ask you a few questions about your background so that we have a few pertinent facts about your unique situation.

We will ask you to complete some parental questionnaires about your child and to complete a 9 day sleep diary on behalf of your child.

What type of information will be sought from child?

As our aim is to build a complete picture of how narcolepsy affects the lives of children, we are hoping to gather the following information on each child with narcolepsy:

- Information about their school performance: computerized and paper based tasks will be used to assess I.Q, memory, attention, learning and academic achievement.
- Information about their psychological well-being: questionnaires suitable for children will be used to assess their strengths and difficulties, well-being and quality of life.
- Information about their daytime activity: an actigraphy watch will be used to assess how active your child is in the day and how they sleep at night. Your child will be asked to wear this for 9 consecutive days and nights.
- Information about their sleep: Polysomnography (PSG) will be used to record sleep quality and stages over 1 night during the visit to your home. Sleep diaries and sleep questionnaires will also be used to collect information on their sleep patterns.

An interview with your child will allow them to address issues surrounding living with narcolepsy that are important to them.

Children will be given the opportunity to nap and take breaks and they can complete each task in their own time.
What are the possible disadvantages and risks of taking part?

Your child’s medical care will be unaffected by your decision to take part or not take part in the study. All equipment used in the study, including the sleep equipment (PSG), is completely harmless. Participation in the study will take approximately:

One day, one night (for the sleep recording) and one morning of your and your child’s time.

Some parents of children find talking about a disorder quite distressing. If at any time you or your child feels the actual or perceived distress is too great, please don’t hesitate to tell the researcher. We can let you know about services to support parents and children that you might find helpful.

Are there any benefits of me joining the study?

The information we collect may help us improve outcomes for children with narcolepsy in the future. Taking part in this study will not directly benefit you or your child now.

What will happen to the results of this study?

When the study has finished we will present our findings to parents, teachers and doctors and we will put the results in medical and psychology journals and on websites that professionals and those with a personal interest in narcolepsy read. All information will be anonymous, which means that you or your child will not be able to be identified from it.
A summary of the results will be made available online at http://sleepatleeds.net/ soon after the study is completed in 2017/2018.

**What happens if something goes wrong?**

If you have concerns about any aspect of this study, you should speak to the research team who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this through the normal university complaints procedure and contact the following person:

The registrar

University of Leeds

Leeds

LS2 9JT

**Will taking part in this study be kept confidential?**

Our procedures for handling, processing, storage and destruction of data are compliant with the Data Protection Act 1998.

All personal (identifiable) information which is collected about you or your child during the course of the research will be kept strictly confidential. Once the study is complete all information will be kept in your and your child’s confidential notes. This information will be retained for at least 2 years after the study is published.

Any data from the study will be anonymised (name and address removed) so that you or your child cannot be recognised from it. Results will be identified via code number only. You or your child will not be able to be identified in any reports or publications.

All data including the audio-recordings of the interviews will be transferred to a password protected drive on the University of Leeds server as soon as possible after
the visit to your home and deleted from any other device. Copies of this material will be held on a digital memory device in a locked filing cabinet at the University of Leeds to ensure against loss. Only anonymised data will be kept and used for analysis. Signed consent forms will be sealed in an envelope and placed in a locked cabinet in the researcher’s office at The University of Leeds (Jane Blackwell). Completed questionnaires and family interviews will be kept separately and in a locked filing cabinet so that only the research team will be able to link real participant names with anonymised data for the purposes of the research (e.g., rechecking if participant “Sarah” has “Narcolepsy with cataplexy” or “Narcolepsy without cataplexy”).

We will obtain permission from you via the consent form to record the interview via audio-recording. Recordings will be transcribed (typed up) to enable us to study what you and your child say in detail. We will ask your permission to use anonymised quotes from transcripts in reports of the research which will include my doctoral thesis, publications, and conference presentations. Your identity will be masked through the use of a pseudonym and through omitting or changing details which together might make you relatively identifiable. No other use will be made of the recordings without your written permission and no one outside the project will be allowed access to the original recordings.

We will also ask permission to inform your family GP that your child will be taking part in the study.

We are obliged to let you know that there are limits to confidentiality in research under some very unusual and specific circumstances: - if, during the interviews, you or your child reveals any intentions of harming yourself or others, or tell us about any serious criminal activity that you have been involved in, the researcher (Jane Blackwell) will have to consult with her supervisor to decide on what action to take. However, we assure you that this kind of information is not sought in the research and we do not at all expect that this will be an issue.
What will happen if we don’t want to carry on with the research?

You can withdraw yourself and your child from the study, without giving a reason and this will not affect the standards of care your child receives. Please see details below:

**Withdrawing before or after the visit:**

You can withdraw from the study at any point before data analysis begins (1\textsuperscript{st} June 2016) without giving a reason. This will not affect the standards of care your child receives. Yours and your child’s identifiable data forms and your anonymized data will be destroyed if you withdraw before this date.

If you withdraw from the study after 1\textsuperscript{st} June 2016 (when data analysis begins), we will destroy yours and your child’s identifiable data forms if you wish, but we will need to use the anonymised data collected up to your withdrawal.

Who is organising and funding the study?

The Paediatric Narcolepsy Project has been setup by researchers at The University of Leeds. Jane Blackwell is completing the project as part of her PhD. Jane is funded by a University of Leeds Anniversary Research Scholarship. The other researchers do not get any extra money for doing this research.

The Paediatric Narcolepsy Project has received additional funding from Sufferers of Unique Narcolepsy Disorder (S.O.U.N.D) Ireland, Narcolepsy UK, Child Brain Research and The Max Hamilton Fund at The University of Leeds.

Who has approved the study?

All research is reviewed by an independent group of people, called a Research Ethics Committee which is there to protect your safety, rights, wellbeing and dignity.
The ethical guidelines for this research have been set out by the British Psychological Society code of ethics. These guidelines include ethical principles such as making sure you know how your and your child’s data will be used and that you consent to take part in the research.

This research has received ethical approval, ref no: 15-0198, on 03.08.15. If, however, you have any comments or complaints regarding my conduct you may contact directly my (Jane Blackwell’s) supervisors, Dr. Hannah Nash and Dr Anna Weighall, who will be happy to discuss appropriate actions to undertake (contact details are at the start and the end of this booklet).

From this information sheet we hope you have had sufficient information about the study. Please feel free to contact us with your queries (contact details are at the start and the end of this booklet).

What should I do now?

If you have acquired this information sheet and the subsequent consent form through a website or a friend/acquaintance and wish to participate please contact the lead researcher (Jane Blackwell) using the details found on the first page of this booklet.

If Jane was the one to give you the form (in person, via email or via post) and already has your contact information, please let her when you have decided whether or not to take part. If you have been sent the information by post please return the signed consent/assent forms using the pre-paid envelop. If Jane does not hear from you, she will contact you within about a week to see whether or not you and your child would like to take part in the study.

If you and your child wish to take part, we will establish together a convenient date and time for me to come and visit you and your child in your home.
On the day of the visit, I will go over the information sheet and consent form with you and your child in detail to clarify any questions you might have. The purpose of the consent form is to provide you with as much and as detailed information about what will happen to the data gathered from this visit.

In order to reduce distractions from the study tasks and to allow for good quality audio recording, it would be ideal if a quiet downstairs space with a table was available in your home on the day of the visits. It is really important that your child is able to concentrate on the tasks/questionnaires and therefore it would be preferable (if possible) that other distractions (e.g. animals, siblings, friends) are asked to stay quietly in other rooms or go out for the day.

How can we find out more about the research?

You can contact Jane Blackwell, Dr Hannah Nash or Dr Anna Weighall who can tell you more about the study and answer any questions you have. You can contact them via the details on the front page and last page of this information booklet.

If you and your child decide to take part in this study, you will be given a copy of this information sheet and the signed consent and assent forms to keep.

Thank you for taking the time to read this information sheet.

Some resources

- NHS Choices – Narcolepsy

  http://www.nhs.uk/conditions/Narcolepsy/Pages/Introduction.aspx
Introduction, symptoms, causes and treatment for Narcolepsy, including links for further information.

- **Patient UK-Narcolepsy and Cataplexy**

  http://www.patient.co.uk/doctor/narcolepsy-and-cataplexy-pro

  Patient.co.uk is the UK’s leading independent health site, established for over 15 years. It is a trusted source of information for both patients and health professionals nationwide. It is accredited by The Information Standard, NHS England’s quality mark.

- **Narcolepsy UK**

  www.narcolepsy.org.uk

  Information and Support Line-Tel: 0845 450 0394

  Narcolepsy UK is an association of people with narcolepsy, their relatives and others interested in improving their lot. Its registered objects are the benefit, relief and aid of persons suffering from narcolepsy.

- **Sufferers of Unique Narcolepsy Disorder (S.O.U.N.D) Ireland**

  http://soundireland.ie/

  S.O.U.N.D. is a support group set up by parents of children and young people who developed Narcolepsy in Ireland following the vaccine Pandemrix.

- **Child line**
https://www.childline.org.uk/pages/home.aspx

UK Telephone: 0800 1111
Republic of Ireland: 1800 666666

ChildLine is a private and confidential service for children and young people up to the age of 19. You can contact a ChildLine counsellor about anything - no problem is too big or too small. Call free on 0800 1111.

- The Samaritans

http://www.samaritans.org/

UK Telephone: 08457 90 90 90
You can call for free in the Republic of Ireland on 116 123.
You can call for free in Northern Ireland on 08457 90 90 90

Available 24 hours a day to provide confidential emotional support for people who are experiencing feelings of distress, despair or suicidal thoughts.

Contact us

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